

Compliance and Alcohol Treatment: An Overview

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One of the few universal problems in the delivery of health care is treatment compliance. Across a wide variety of disorders and treatment regimens, research consistently indicates that a substantial minority, and sometimes a majority, of clients do not adhere to their prescribed regimen (see reviews¹⁻³). For example, rates of adherence to pharmacotherapy regimens in general medical practice have been estimated at only 50-55 percent.⁴

A recent meta-analysis of 164 studies evaluating methods of improving patient's keeping medical appointments indicated that the average rate of compliance was 58 percent.⁵ Most individuals referred for psychotherapy do not follow through on that recommendation.⁶ As many as 50 percent of hypertensive individuals in the United States drop out during the first year of treatment, and of those who remain in treatment, most do not comply adequately with their prescribed medication regimen.^{7,8}

Noncompliance raises profound problems from both clinical and research perspectives. Clinically, compliant clients generally have better outcomes than noncompliant clients,⁹⁻¹² although this relationship is not uniform and may be quite complex.¹³

Moreover, the strong relationship between compliance and outcome holds even when placebo treatments are being evaluated.¹⁰ This suggests that compliant behavior may tap important beneficial processes other than active ingredients of the treatment itself, such as the instillation of hope, self-efficacy, and enhanced health-promoting behaviors.

Noncompliance leads to need for additional services (clinic visits, hospital admissions, emergency room visits) and for increased provider time, thereby reducing access of other patients to needed

services, and increases health care costs and the risk of complications and even patient death.^{5,14,15}

From a research perspective, noncompliance is problematic because it reduces statistical power to detect treatment effects, leads to the need for larger sample sizes, increases sample bias, undermines the internal validity of a study, and is associated with a host of other methodological and statistical concerns.¹⁶⁻¹⁹ In clinical trials, differential compliance across treatments leads to compliance bias,²⁰ where differences in outcomes between treatments may be due to differences in the level of compliance across treatments rather than effects of the treatments themselves.

Noncompliance and the Treatment of Alcohol Use Disorders

Compliance is a prominent issue in the treatment of alcohol and substance abuse and dependence, where rates of treatment dropout range from 25 to 90 percent.^{21,22} That alcohol abuse poses special problems for compliance is illustrated by the frequency with which trials evaluating treatments for disorders other than substance abuse refuse to accept substance users into their protocols in order to improve compliance.²³ Similarly, substance abuse is often cited as a correlate of noncompliance in other populations.²⁴⁻²⁸

Like the broader field of compliance with medical recommendations, compliance with alcohol treatment recommendations usually results in improved outcome. Compliance with psychotherapy (treatment attendance) and pharmacotherapy (medication compliance) has been associated with improved outcome in several studies.²⁹⁻³²

Table 1.1 presents rates of one type of noncompliance in alcohol treatment—dropout—defined broadly (and oversimply) here as the proportion of clients who do not complete treatment. The table summarizes attrition rates across several recent uncontrolled studies and randomized clinical trials which include a range of client populations, settings, treatment types, and length of prescribed treatment.

Review of the attrition rates among the uncontrolled studies is for the most part similar to that reported in 1973 by Baekeland and colleagues,⁵⁶ where:

- 17.5 percent were immediate dropouts (i.e., failed to return after the first visit).
- 26 percent were rapid dropouts (after 1 to 4 weeks of treatment).

Table 1.1. Rates of dropout from alcohol treatment: Selected recent studies

<i>Study</i>	<i>Treatment studied</i>	<i>Sample size</i>	<i>Rates of dropout</i>
Single-site studies			
Allan 1987 ³³	Outpatient community	112	64% drop out by 4 weeks 93% by 6 months
Brizer et al. 1990 ³⁵	Outpatient	178	52% drop out before 9 visits
Castaneda et al. 1992 ³⁶	Inpatient & outpatient	109	54% don't follow through on referral
Fink et al. 1984 ³⁷	Extended inpatient	258	41% noncompleters
Huselid et al. 1991 ³⁸	Female halfway house	30	47% drop out
Jones 1985 ³⁹	Residential	34	71% drop out
Leigh et al. 1984 ⁴⁰	Outpatient	172	72% drop out (15% don't start)
Noel et al. 1987 ⁴¹	Outpatient couples	105	35% don't start 22% drop out
Pekarik & Zimmer 1992 ⁴²	5 settings	3240	52.7% average across programs
Rees 1985 ⁴³	Outpatient	117	77% drop out by 6 months
Verinis 1986 ⁴⁴	Outpatient	121	38% don't start 36% drop out
Randomized clinical trials			
Chick et al. 1988 ⁴⁵	Advice vs treatment	152	45% of treatment group drop out by 10 appts.
Fuller et al. 1983 ³⁰	Disulfiram	128	78% keep less than 85% of scheduled appointments
Ito et al. 1988 ⁴⁶	Aftercare psychotherapy	39	25% don't start, 20% drop out at 6 months
Kadden et al. 1989 ⁴⁷	Aftercare psychotherapy	96	19% drop out after 2 sessions
Kranzler et al. 1994 ⁴⁸	Outpatient, buspirone	61	18% don't start, 31% drop out by 3 months
Kranzler et al. 1995 ⁴⁹	Outpatient, fluoxetine	101	22% don't start, 6% drop out by 3 months
Mason et al. 1994 ⁵⁰	Outpatient, nalmefene	21	76% drop out by 3 months
Murphy et al. 1986 ⁵¹	Lifestyle modification	60	20% don't start, 35% drop out by 4 months
Monti et al. 1993 ⁵²	Cue exposure + coping	40	21% drop out by 3 months
Naranjo et al. 1995 ⁵³	Outpatient, citalopram	62	37% noncompleters
O'Farrell et al. 1993 ⁵⁴	Outpatient couples	59	19% drop out
O'Malley et al. 1992 ⁵⁵	Naltrexone/psychotherapy	97	26% don't start 35% drop out
Powell et al. 1986 ³¹	Outpatient	100	30% drop out by 6 months

- 30 percent were slow dropouts (leaving between 2 and 5 months of treatment).
- 26.6 percent persisted in treatment longer than 6 months.

Rates of dropout tend to be somewhat lower in the recent randomized trials than the uncontrolled studies, but this may in part reflect inclusion of more select samples in clinical trials, research procedures which may have enhanced retention, or the treatments evaluated. Similarly, rates of alcohol clients' compliance with aspects of treatment other than retention, such as medication compliance, have also been poor in many studies.⁵⁷

High rates of dropout and noncompliance suggest that no matter how effective a treatment is, its success will be constrained by its ability to retain clients. In other words, compliance may be a necessary, but not sufficient, component of treatment effectiveness. Furthermore, available treatments for substance abuse are often considered effective to the extent that they demonstrate the ability to retain clients.²³

For example, methadone maintenance, despite its drawbacks, is the most successful pharmacologic strategy for opioid dependence, in large part due to its power to retain clients over extended periods. On the other hand, naltrexone, which is an elegant, safe, long-acting, and theoretically perfect antagonist treatment for opioid dependence, is infrequently used and often perceived as ineffective largely because of its historically poor record of retention.⁵⁸ Similarly, the combined voucher and CRA approach described by Higgins and colleagues⁵⁹⁻⁶⁰ has generated a great deal of excitement because several trials evaluating this approach have shown unusually high retention and abstinence rates among cocaine abusers. In part, the failure of many alcohol and drug abuse treatments to retain clients beyond a few weeks has led to increased emphasis on developing and evaluating brief treatments, such as motivational approaches.⁶¹⁻⁶² These treatments, which typically involve only a session or two, have been found to have durable effects on alcohol use as well as low rates of attrition.⁶³⁻⁶⁴

Defining Compliance in Alcohol Treatment

The broad definition of compliance is "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice."⁶⁵ However, specific definitions of compliance vary with the treatment prescribed and research questions asked in particular studies.

In treatments involving the administration of medications, compliance is usually defined as the person's taking the prescribed dose of medication, at the prescribed schedule, for the prescribed duration of therapy, and also refraining from using other medications or substances that may interact negatively with the medication prescribed. Here, compliance can be measured by a variety of mechanisms, including monitoring medication plasma levels, pill counts, markers introduced into the medication, MEMS caps and other monitoring devices, client self-reports, and so on.^{14,57,86,87}

The bulk of alcohol treatment consists of psychosocial treatments, principally group, family, or individual counseling or therapy, with pharmacotherapies such as disulfiram or naltrexone typically delivered as adjuncts to a primarily psychosocial approach. Thus, compliance is defined and measured differently in psychosocial treatments for alcohol abuse, usually falling into one of two broad categories: retention-related and treatment-specific (table 1.2).

Table 1.2. Indicators of compliance in psychosocial treatments

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| <p>Table 1.2. Indicators of compliance in psychosocial treatments</p> <hr/> <p><input type="checkbox"/> Retention-related indicators</p> <ul style="list-style-type: none"> — Number of prescribed sessions attended — Number of sessions missed — Lateness to sessions — Repeated rescheduling of sessions — Failure to call to cancel sessions — Attending sessions while intoxicated — Use of other psychoactive substances <p><input type="checkbox"/> Treatment-specific indicators</p> <ul style="list-style-type: none"> — Failure to complete homework assignments — Incomplete homework assignments — Failure to attend AA meetings — Involvement in non-study treatments — Failure or refusal to bring in spouse or family for family therapy — Overt resistance (e.g., silence, hostility) — Failure to provide breath/urine/blood samples |
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Retention-Related Indicators

In psychosocial treatments, the most important indicator of compliance is treatment attendance; that is, whether or not the client attends the sessions prescribed. Retention is particularly important

ant because it is often closely related to outcome in alcohol treatment.⁶⁷ In addition, a variety of secondary indicators are related to retention, including lateness to sessions, missed sessions, and rescheduling of sessions.

Treatment-Specific Indicators

Psychosocial treatments for alcohol abuse typically include a number of specific recommendations or tasks for clients, and the degree to which clients adhere to these prescribed activities is another indicator of compliance. Depending on the specific treatment, these might include completion of homework assignments (e.g., practicing a skill taught during therapy), attending self-help meetings or getting a sponsor, practicing skills learned during therapy, or bringing in one's spouse or family members for recommended family meetings.

It is important to note that different indicators of compliance may not converge; for example, high attendance does not always imply that clients have fully complied with treatment. Thus, multiple indicators of compliance may be needed to fully assess compliance and its effects on process and outcome in a clinical trial. Some aspects of treatment compliance, particularly treatment attendance, are frequently monitored and reported on in clinical trials and reports on treatment outcome. However, other aspects of compliance are less frequently evaluated. For example, client compliance with key aspects of therapy, such as homework completion, is rarely monitored.⁶⁸

Client Characteristics Associated With Noncompliance

Traditionally and persistently, the causes of noncompliance and attrition have been conceived as client driven. That is, investigators have focused their efforts on searching for client characteristics associated with poor compliance, such as demographic characteristics, social instability, and low motivation.^{33,34,36,39,41,44,56,69-71}

The search for universal client characteristics associated with compliance has met with mixed success, in large part because findings of client characteristics associated with dropout in one treatment setting are frequently not replicated in other settings with differing treatment approaches.⁴²

Although there is little consistency across studies and treatment settings in terms of characteristics of clients who comply with or drop out of treatment, there is a good deal of consistency across studies suggesting that the bulk of attrition occurs early, with the majority of dropouts usually occurring during the first month of treatment.^{21,72}

Furthermore, in both clinical and research settings, client heterogeneity has often been met with treatment homogeneity. That is, regardless of clients' backgrounds and preferences, the nature or severity of their alcohol abuse and related problems, or the factors that precipitated treatment-seeking, many treatment programs offer only a single type of treatment. With this "one size fits all" model, variations in compliance and outcome have traditionally been ascribed to client factors and characteristics.⁷³ Thus, clients who are a good "fit" for a given approach are more likely to remain in treatment, and those who are less well suited to the treatment may be more likely to drop out.

Again, in treatment settings that offer only a single approach, it may not make sense to ask clients what they need, desire, or expect out of treatment. If clients want something other than the services the center provides, very often staff can do little to accommodate them. In addition, clients often have only an uncertain idea of what treatment will entail until it begins. Thus, early attrition may reflect self-selection, where clients may find themselves in the wrong treatment setting, wrong group, with the wrong therapist, or participating in a treatment geared to a stage other than the one they are in. It is thus not surprising that dropouts usually seek treatment again elsewhere.⁷⁴

Treatment as a Partnership

The emphasis on identifying client correlates of noncompliance is shifting, and current efforts to reduce attrition and enhance compliance reflect increasing awareness that compliance is related to a combination of conditions and efforts contributed by therapists, investigators, and research staff, as well as clients.^{25,52,75-77} Thus, in this manual, compliance is conceived as a partnership relationship among client, therapist, treatment, and setting. In other words, compliance may have more to do with what investigators and treatment providers do than who their clients are.

Furthermore, the implications of seeking client characteristics associated with noncompliance or dropout are quite different, depending upon whether one sees noncompliance as solely client driven or as the product of a partnership. If seen as client driven, identification of client characteristics associated with dropout or noncompliance could be used to identify a profile of clients who are less likely to continue or have good outcomes in the treatment program. This strategy could be used to direct costly treatment resources primarily to those clients who are most likely to benefit from the program and not 'waste' resources on those who will derive little benefit. However, characteristics usually associated with dropout and noncompliance are frequently those associated with the greatest need for treatment (e.g., low socioeconomic

status, more psychiatric impairment, and fewer social supports). Treatment programs using this strategy might thus be faced with the unpleasant prospect of refusing treatment to those who need it most. Moreover, given the inconsistent findings linking client characteristics to outcome and the heterogeneity in alcohol outcomes, some clients, who might in fact do well in the treatment program, could be turned away merely because they have the wrong "profile".

Conversely, if one sees compliance and retention as the product of a partnership, information about client characteristics associated with noncompliance or dropout can, and should, be used to make treatment programs more responsive to the special needs of these clients, broaden the scope of services offered to meet heterogeneous needs of clients, and identify treatment practices or therapists which discourage compliance.

This manual is organized to reflect this latter strategy, which recognizes multiple determinants of compliance and emphasizes methods of enhancing treatment programs to meet the needs of heterogeneous clients, thereby improving compliance.