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Estimating the efficacy of Alcoholics Anonymous without self-selection bias: An instrumental variables re-analysis of randomized clinical trials

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Abstract

Background—Observational studies of Alcoholics Anonymous' (AA) effectiveness are vulnerable to self-selection bias because individuals choose whether or not to attend AA. The present study therefore employed an innovative statistical technique to derive a selection bias-free estimate of AA's impact.

Methods—Six datasets from 5 National Institutes of Health-funded randomized trials (one with two independent parallel arms) of AA facilitation interventions were analyzed using instrumental variables models. Alcohol dependent individuals in one of the datasets (n = 774) were analyzed separately from the rest of sample (n = 1582 individuals pooled from 5 datasets) because of heterogeneity in sample parameters. Randomization itself was used as the instrumental variable.

Results—Randomization was a good instrument in both samples, effectively predicting increased AA attendance that could not be attributed to self-selection. In five of the six data sets, which were pooled for analysis, increased AA attendance that was attributable to randomization (i.e., free of self-selection bias) was effective at increasing days of abstinence at 3-month (B = .38, p = .001) and 15-month (B = 0.42, p = .04) follow-up. However, in the remaining dataset, in which pre-existing AA attendance was much higher, further increases in AA involvement caused by the randomly assigned facilitation intervention did not affect drinking outcome.

Conclusions—For most individuals seeking help for alcohol problems, increasing AA attendance leads to short and long term decreases in alcohol consumption that cannot be attributed to self-selection. However, for populations with high pre-existing AA involvement, further increases in AA attendance may have little impact.

Keywords

Alcoholics Anonymous; self-help; mutual help groups; research methods; treatment outcome

Observational research long ago established that Alcoholics Anonymous (AA) involvement is associated with better outcomes on alcohol-related, psychological and social measures (Emrick et al., 1993; Humphreys, 2004; Tonigan et al., 1996). Researchers and clinicians

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hotly debated for many years whether this correlation reflected AA's effectiveness or was merely an artifact of self-selection (e.g., those who attend AA are more motivated to change). In the past decade, the former explanation received a major boost as a series of scientific teams conducted randomized clinical trials in which professionally-provided AA-involvement facilitation interventions were shown to improve patient outcomes (e.g., Walitzer et al., 2009). Although consistent with the hypothesis that AA is genuinely effective, these trials still cannot rule out the possibility that self-selection bias inflates estimates of AA participation; intent to treat analyses provide information on the effectiveness of AA facilitation not AA per se. However these randomized trials do provide the empirical basis to generate a self-selection free estimate of AA's effectiveness. Specifically, their data can be analyzed using instrumental variables to generate a self-selection bias free estimate of AA's impact. The present paper is we believe the first effort to take advantage of this scientific opportunity.

Instrumental variables methods have been extensively used in other fields, but because they have rarely been employed in the addiction field, we begin with some explanation of these techniques and what they can offer to AA research. In everyday discussion we usually describe a clinical trial of treatment A versus treatment B as a rigorous assessment of which treatment is more effective. But such studies are in fact a test of whether being *assigned* to treatment A versus treatment B is more effective (Sussman and Hayward, 2010). This is a particular challenge in studies of Alcoholics Anonymous facilitation interventions, in which some subjects randomized to the intervention do not attend AA while other subjects not so assigned seek out AA on their own. After the trial is completed, the investigator can of course restrict the analysis only to those who followed through on the assigned AA facilitation intervention condition's requirements. But this generates a biased estimate of outcome because the subsample of perfectly adherent research participants is a self-selected group in both conditions (Food and Drug Administration, 1998).

To elaborate the evaluation challenge here, consider a hypothetical study in which Condition 1 comprises an intervention that facilitates AA involvement and Condition 2 offers no such intervention. In a perfect world, the AA attendance rate in Condition 1 would be 100% and the AA attendance rate in Condition 2 would be 0%. In the far messier world in which we live, trials show that we can expect results to look more like those in Figure 1. Only about two thirds of the individuals in the AA facilitation condition followed through, whereas 20% of the subjects not encouraged to attend AA nonetheless sought it out on their own. An intent-to-treat analysis of this trial would *not* generate a selection bias-free estimate of the impact of AA participation itself, but a selection bias-free estimate of the effectiveness of being assigned to an intervention that facilitated AA attendance. A post-hoc regression analysis of the relationship between research subjects' actual level of AA attendance and outcome would be biased by selection because actual level of AA attendance was not randomly assigned. For example, people who went to AA in both conditions might have been unusually motivated to change, particularly well-organized, or unusually low in co-occurring psychiatric problems – variables that produce bias because they are all likely to affect outcome independent of any potential effect of AA.

Note, however, that the results in Figure 1 do imply something important: at least some of the actual AA attendance in Condition 1 was entirely due to randomization to treatment and is thus free of self-selection bias. This is reflected in the bottom bar, the difference between 65% and 20%. Recall that the individuals in Condition 1 and Condition 2 are randomly assigned and thus theoretically equivalent, except of course for the condition to which they were randomly assigned. And it is that difference which explains not their actual AA attendance but the difference in actual AA attendance between the two conditions. The AA attendance of people in both conditions is influenced by self-selection factors, but only people in Condition 1 are also influenced by an exogenously assigned condition (the AA facilitation intervention). That group's "extra" AA attendance is thus due to an exogenous factor (i.e., the condition to which they were randomized). If one could mathematically isolate the proportion of their AA attendance that was attributable to their randomization, and use that proportion of AA attendance to predict outcome, one would have the "holy grail" long sought by AA researchers: an estimate of AA's impact that was free of selection bias. Instrumental variables are the statistical method that makes such estimates possible.

Only two prior studies have used instrumental variables to assess the influence of AA. Humphreys and colleagues (1996) found that use of instrumental variables increased estimates of AA's effectiveness over results obtained in traditional regression models, suggesting that selection bias was negative (i.e., people with worse prognosis were more likely to go to AA). Fortney and colleagues (1998), who had conceptually superior instrumental variables to Humphreys et al., found the reverse: the effectiveness of AA at promoting abstinence shrank from an odds ratio of 3.7 to 1.7, suggesting that conventional covariate control techniques *overstate* AA's effectiveness. Both studies were limited because the predictive power of the available instruments was weak, which can lead to biased estimates (Staiger and Stock, 1997). Now that AA facilitation has been examined in multiple randomized clinical trials, a new powerful instrumental variable has become available: Being randomized to a condition that actively facilitates AA involvement. Using data from previously conducted randomized clinical trials, we employ instrumental variables modelling to estimate whether AA participation itself improves outcome, or, whether its association with better outcomes is an artifact of self-selection.

Materials and Methods

Study Selection

The NIH RePORTER interface (formerly CRISP) was searched using the term "Alcoholics Anonymous," to identify all treatment comparison trials in which (1) alcohol use disorder patients were randomized to at least one treatment that aimed to increase participation in AA and (2) included a comparison condition that did not aim to facilitate AA involvement and (3) had published peer-reviewed outcome results no later than 2010. The deadline for publication was set a few years prior to this project's start date as researchers understandably wish to publish their own papers before releasing data for secondary analysis. A total of 5 randomized trials met the criteria, one of which (Project MATCH) was actually two parallel trials. This present project thus has 6 datasets available for analysis. The details of these trials are presented in Table 1.

Participant Selection

All individuals enrolled in the clinical trials were included, with one exception. The NIDA Cocaine Collaborative Treatment Study (CCTS; Crits-Christoph et al., 1999) required only that participants had a cocaine use disorder. Given our focus on AA's impact on drinking, we limited our analysis of that dataset to those participants who also had an alcohol use disorder (219 of 487).

Study Coding

Participant Demographic information—Each study included age (coded into the categories: <35 years, 35 to <55 years, and >=55 years), gender, race/ethnicity (coded as: Non-Hispanic white, black, Hispanic, or other), whether each participant had at least 12 years of education, marital status (coded as: married, formerly married, or single and never married), and employment status (coded as: full-time, part-time, or other).

AA facilitation condition—Each randomized intervention was coded as being an AA Facilitation Intervention (AAFI) or not an AAFI. The most common form of AAFI was Twelve Step Facilitation (TSF) developed as part of Project MATCH. In Project MATCH, TSF included 12 manual-guided sessions that focused on introducing participants to 12-step concepts, with an emphasis on working the first several steps, and encouraging participants to affiliate with and begin active involvement in AA (Nowinski et al., 1995). Two of the other trials included in our analysis used a treatment based on MATCH TSF (Litt et al., 2007; Walitzer et al., 2009). In McCrady et al. (1999) study of behavioral couples therapy, the AAFI incorporated discussions of AA concepts and included explicit encouragement to attend meetings and work the first several steps. Finally, Crits-Christoph et al. (1999) used a treatment based on the 12-step philosophy that incorporated specific 12-step related tasks, including attending mutual help group meetings. All of the trials compared the AAFI to another active treatment. Further details may be found in the respective publications.

Alcoholics Anonymous and Alcohol Use Variables—The main outcome variable was percent days abstinent from alcohol (PDA), which was measured in all 6 trial datasets. AA attendance was measured as percent days attending a meeting (PDMT), which also was measured in every trial. We focused on change of PDA and PDMT from baseline (before the start of treatment) to short-term follow-up at three months after the start of treatment, and to longer-term follow-up at 15 months after the start of treatment. The window for assessing PDA and PDMT at baseline varied across trials. Specifically, PDA was assessed for one month (Crits-Christoph et al., 1999), for three months (Litt et al., 2007; McCrady et al., 1999; Project MATCH Research Group, 1993), or six months (Walitzer et al., 2009) prior to study participation. Baseline PDMT was assessed for three months (Project MATCH Research Group, 1993), six months (Walitzer et al., 2009), or one year (Litt et al., 2007) prior to study participation, and was not available for two of the studies (Crits-Christoph et al., 1999; McCrady et al., 1999). At the three and 15 month follow-up points, wherever possible, we created variables that measured PDA and PDMT for the entire follow-up period, from the start of treatment. However, at the 15 month follow-up point, there were two studies for which this was not possible for PDMT (Litt et al., 2007; McCrady et al.,

1999), so we instead used the available measure of PDMT, which was only the three months prior to the 15 month follow-up.

Results

Pooling Datasets

The five trials differed in sample size and inclusion/exclusion criteria and it could therefore not be assumed that they could be pooled for analysis. To examine the appropriateness of pooling the six datasets we regressed PDA on baseline demographics (i.e., age, education, gender, marital status, employment status, and race) for each trial. We compared the coefficients across the datasets to determine whether the estimated coefficients in one trial were similar to the coefficients estimated from another (this procedure is sometimes referred to as a "Chow test").

The results of the Chow test showed that the estimated coefficients predicting PDA at 3 and 15 months in the MATCH aftercare sample significantly differed from three of the other datasets (F statistics < .01 in the three comparisons). Therefore, we analyzed the MATCH aftercare dataset separately from the remaining five datasets (including that of the MATCH outpatient trial), which were pooled.

Demographic information for the pooled and MATCH aftercare samples is presented in Table 2. Most of the participants were white men aged between 35 and 55. Most had at least a high school education and a majority was employed full-time. Marital status of participants was fairly evenly distributed across married, formerly married (i.e., divorced or widowed), and single (never married).

As expected from the Chow test, the Project MATCH aftercare sample (which was the only sample to be drawn from an inpatient setting) differed in numerous respects from the subjects in the pooled datasets. Relative to the pooled sample, the MATCH aftercare participants were older, more likely to be male, more likely to be Black or Hispanic and more likely to be formerly married. At baseline, they had higher prior AA involvement and a lower percentage of days abstinent.

Test of Predictive Power of Instrument

The logic behind the instrumental variables model is to estimate two regression models to account for the fact that PDMT is chosen by the person (and subject to selection bias). In the first model, PDMT is regressed on demographic variables and the instrumental variable (randomization to AA facilitation), yielding the predicted value of PDMT. This prediction represents the change in PDMT as a function of being randomized to AA facilitation or not, and thus excludes any inherent selection bias. In the second regression equation, PDA is regressed on predicted PDMT to provide an unbiased estimate on the link between AA attendance, as influenced by randomization, and abstinence.

An important assumption of instrumental variables is that the instrument is a strong predictor of the first stage outcome. A common rule of thumb requires a partial F statistic greater than 10 (Stock et al., 2002). We tested this assumption by regressing randomization

on PDMT with the demographic variables and randomization. In all cases, randomization proved to be a strong predictor of PDMT at three months (F = 139.24 for the pooled sample and 23.24 for MATCH aftercare) and at 15 months (F = 20.24 for the pooled sample and 12.47 for MATCH aftercare).

Instrumental Variables Models

An instrumental variables model assesses the impact of additional AA (i.e., beyond what the person would have chosen to seek out in the absence of intervention) attributable directly to the randomly assigned condition. Our first step therefore was to calculate the differences between the two conditions. As shown in Figure 2, in the pooled model, the comparison is between individuals with little or no AA attendance versus moderate, experimentally induced attendance, whereas for the MATCH aftercare sample, the comparison is between moderate attendance and extremely high attendance.

In the instrumental variables model, an increase in PDMT was significantly associated with increased PDA at both 3 and 15 months in the pooled sample (see Table 3). The 3 month model showed that an increase in attendance of 1% (i.e., one absolute percentage point, not 1% of prior attendance) predicted an increase in PDA of about a third of a percentage point (B = 0.38, p = .001).[1] To put these results in context, consider that the average PDA in the pooled sample was 77% at 3 months and 74% at 15 months, which places some limits on potential amount of benefit. That said, the results imply that an increase in PDMT of 28.6 absolute percentage points (i.e., going to an additional 2 AA meetings each week), would be associated with an increase in PDA of 10.9 percentage points, or an additional 3.3 days of abstinence per month. Surprisingly, for the 15 month follow-up point, the effect of PDMT on PDA was not attenuated and indeed was modestly higher (B = 0.42, p = .04).

In contrast, for the Project MATCH Aftercare sample, there was no evidence that the additional AA meetings prompted by the AA facilitation intervention were beneficial. The weight for the relationship of PDMT to PDA was not significantly different than zero at 3 months (B = −0.122, p = .43) or 15 months (B = −0.076, p = .79).

Discussion

As any introductory research methods book will teach, correlation does not equal causation. The long-established positive association between AA involvement and better outcomes was therefore consistent with, but did not prove, causation. Determining whether this association truly reflected AA's effectiveness or was merely an artifact of the most motivated, less troubled or most socially stable alcohol dependent individuals attending the organization has been a goal of researchers for decades. Using multiple regression techniques (Morgenstern et al., 1997), structural equation models (McKellar et al., 2003; Pisani et al., 1993), quasi-experiments (Humphreys and Moos, 2001; 2007), and propensity scoring methods (e.g., Magura et al., 2013; Ye and Kaskutas, 2009) evaluators mounted progressively more

[1]In order to see if these results were sensitive to the inclusion of the 218 CCTS participants, all of whom were both alcohol and cocaine dependent, we recalculated the 3-month model without them. The result was virtually identical (B = .36, p =.002). We did not repeat this sensitivity analysis at 15 months because we did not have data from the CCTS at that wave.

sophisticated efforts to separate self-selection bias from outcome estimates and thereby obtain an accurate estimate of AA's effectiveness (or lack thereof). We believe the present study is a qualitative step forward in this direction that became possible only recently in light of developments in statistics (Nobel Prize Winner James Heckman's work on instrumental variables) and alcohol research (the emergence of randomized clinical trials of AA facilitation interventions).

That said, there are still possibilities for estimation errors in the results. Instrumental variables analysis does not resolve the problem of some individuals not being followed up, and follow-up rates being different across studies and conditions within studies. Neither can the approach used here correct for the fact that counts of AA meetings (they only variable in all the datasets analyzed here) tend to have weaker relationships to outcomes than do multi-component AA involvement measures (Humphreys, 2004). Despite those weaknesses, it is encouraging that the results here are broadly consistent with what prior research has found: AA appears to actually benefit people with drinking problems rather than simply cobbling together individuals who would have improved without it.

In the Crits-Christoph, Litt, McCrady, Walitzer, and Project MATCH outpatient datasets, AA involvement was effective at increasing days of abstinence. These benefits were in addition to those of the core AA facilitation intervention itself. Even more impressively in a field where intervention effects are often evanescent, the benefits persisted to 15 month follow-up. These findings should be carefully considered in ongoing efforts to re-orient the addiction treatment system away from acute care services and into long-term chronic care (Kelly and White, 2011).

The exception to the main findings was the Project MATCH aftercare sample, in which increases in AA involvement caused by the AA facilitation condition did not lead to any significant increase in days of abstinence. We cannot directly test for why there was no benefit evident, but suspect it had to do with a ceiling effect. The instrumental variables method estimated the impact of the AA participation that was added by the exogenous mechanism (random assignment to 12-step facilitation). Even prior to entering inpatient treatment (which is when prior AA involvement was measured), the Project MATCH aftercare sample had extensive AA involvement. They then participated in 12-step oriented inpatient or day treatment programs with regular 12-step meetings on site (Babor and Del Boca, 2010) followed by sessions of 12-step facilitation counselling. At that high level of pre-existing AA involvement, the addition of still further AA may have had no value. That is, those who were abstinent due to AA could not became any more abstinent with yet more meetings, and those who were not benefiting from AA after such extensive exposure were not likely to start doing so given the addition of even more exposure.

We can only speculate regarding this explanation because there was not enough variance in prior AA attendance to have power to run a reliable interaction model, and because the measurement of prior AA in the Project MATCH aftercare study was at a different time point than all the other datasets (i.e., prior to an AA-heavy inpatient or day treatment episode rather than being made at the start of a new outpatient treatment episode). That said, it seems logical to propose that, as with other health promoting behaviors (e.g., exercise), the

greatest gains of AA attendance may occur when someone moves from non-attendance to some attendance, or from light attendance to steady attendance, rather than from heavy attendance to even more heavy attendance.

In any event, the major result of this study is that in 5 of 6 randomized trial datasets, AA participation had a genuine benefit that was not attributable to self-selection bias. This is believable given that AA meetings are characterized by many processes generally found to be therapeutic, including social support for health behavior change, dry friendship networks, opportunities for altruism, the availability role models, instillation of hope and practical skill teaching (Moos, 2007; 2008).

For some long-term members of AA, this study may have seemed unnecessary because their own experience convinces them of the organization's effectiveness. But part of protecting and promoting public health involves subjecting all interventions that serve vulnerable people to careful evaluation. In this case, using what we believe is the most rigorous assessment yet of a 70 year old mutual help organization, the evaluation yielded positive results that will resonate with the experience of people who have become sober in AA. Our findings should also increase the confidence of clinicians, researchers, families and people with current drinking problems of the therapeutic value of Alcoholics Anonymous, even for those individuals who are not initially inclined to attend.

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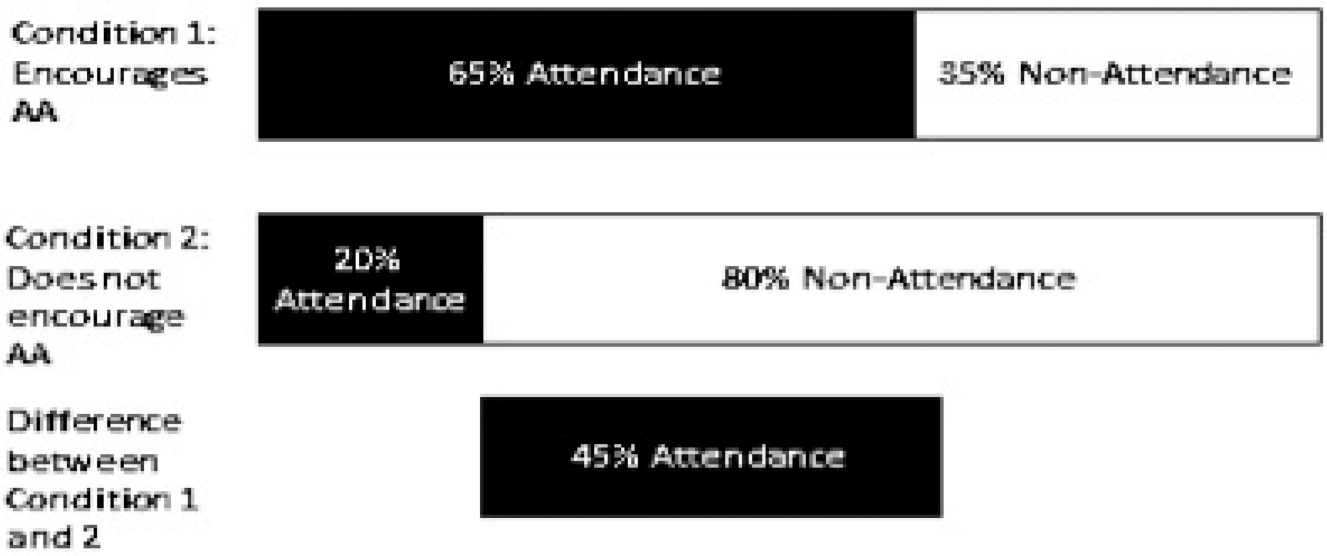

Figure 1.
Conceptual Model of the Proportions of AA Attendance that is Explained by a Randomly Assigned Intervention Which Encourages Attendance.

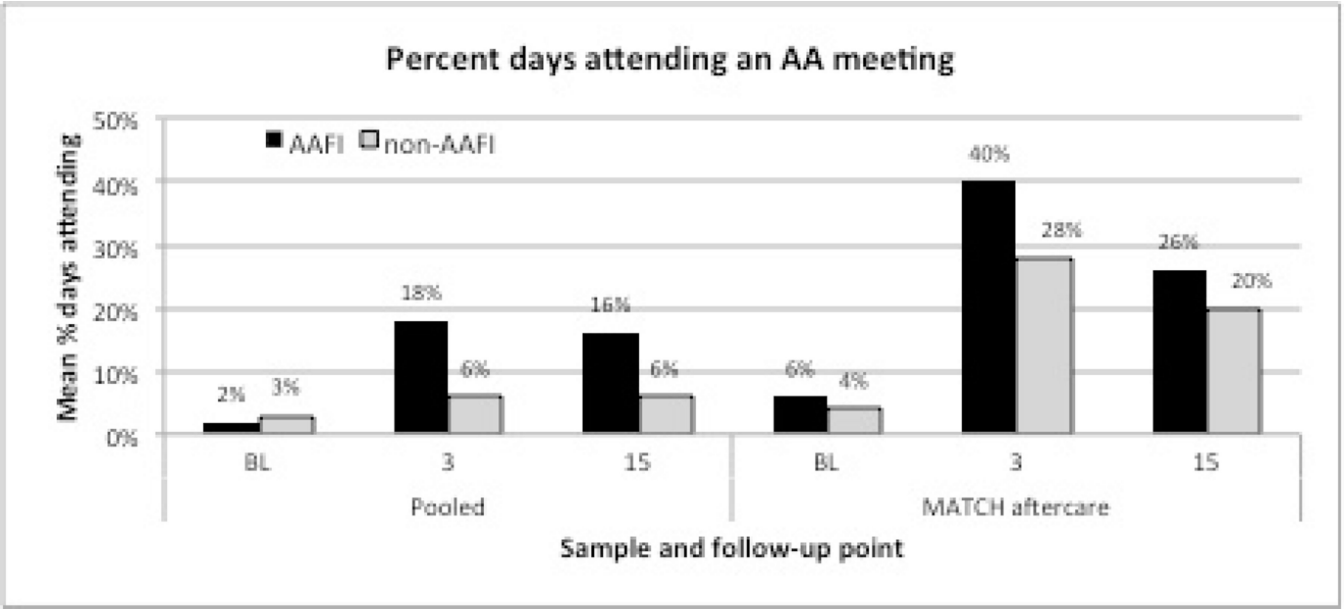

Figure 2.

Percent Days Attending an Alcoholics Anonymous Meeting, Based on Randomization to an AAFI.

Notes. AAFI=Alcoholics Anonymous Facilitation Intervention; BL=baseline.

Pooled sample includes MATCH outpatient, Walitzer, McCrady (15 months only), Crits-Christoph (3 months only), and Litt. At baseline, meeting attendance was assessed for 3 months (MATCH), 6 months (Walitzer), or 1 year (Litt) prior to study participation. At 15 month follow up, meeting attendance was measured for the 15 months since the start of treatment, except “last 3 months” in Litt and McCrady.

Table 1

Description of 6 datasets from 5 randomized clinical trials with an AA facilitation condition

Study name	Common treatment elements[1]	non-AAFI treatment groups	AAFI treatment groups
Project MATCH Research Group (1993) – outpatient sample	None.	• **Motivational Enhancement Therapy**: 4 sessions over 12 weeks. • **Cognitive Behavioral Therapy**: 12 weekly sessions.	• **TSF**: 12 weekly sessions.
Project MATCH Research Group (1993) – aftercare sample	None (prior to study participation, all participants had completed at least 7 days of inpatient or intensive day alcohol use disorder treatment).	• **Motivational Enhancement Therapy**: 4 sessions over 12 weeks. • **Cognitive Behavioral Therapy**: 12 weekly sessions.	• **TSF**: 12 weekly sessions.
Walitzer et al. (2009)	12 sessions of cognitive behavioral therapy skills training.	• **Treatment as usual**: told generally to attend a couple of AA meetings a week.	• **Directive**: TSF. • **Motivational**: Motivational Interviewing to encourage AA attendance[2].
Crits-Christoph et al. (1997)[3]	Weekly group drug counseling for 6 months (included strong encouragement to attend 12-step meetings).	• **Cognitive therapy**: twice a week for 3 months, weekly for 3 months, and monthly for 3 months. • **Supportive-expressive therapy**: twice a week for 3 months, weekly for 3 months, and monthly for 3 months. • **Common treatment only**.	• **Individual drug counseling**: twice a week for 3 months, weekly for 3 months, and monthly for 3 months.
Litt et al. (2007)	None.	• **Case management**: 12 weekly sessions exploring problems/goals and identifying appropriate available services.	• **Network support**: TSF with a focus on changing the social support network. • **Network support + contingency management**: As above, plus contingency management for 12-step activities and nondrinking social activities.
McCrady et al. (1996)[4]	15 sessions of alcohol-focused behavioral marital therapy.	• **Common treatment only**. • **Relapse Prevention**: added elements of relapse prevention.	• **AA/Alanon**: added an introduction to and encouragement to attend AA.

Note. AA=Alcoholics Anonymous. AAFI=AA Facilitation Intervention(s). TSF=Twelve-Step Facilitation treatment.

[1] Treatment elements that were provided to all participants during the study period.

[2] Motivational treatment was not associated with an increase in AA attendance or participation compared with treatment as usual (as reported in Walitzer publication), so we excluded this group from all of our analyses (comparing instead treatment as usual versus directive only).

[3] All participants had a cocaine use disorder. We limited our analyses to those who also had an AUD.

[4] All participants were men who had a female partner who was willing to participate in the treatment.

Table 2

Baseline demographic information, alcohol use and Alcoholics Anonymous attendance

Variable	Pooled sample (n = 1582)	MATCH aftercare (n = 774)	*p*-value
Age			<.001
% under 35	38%	28%	
% 35 to under 55	51%	57%	
% 55 or older	11%	15%	
% At least 12 years of education	91%	88%	.06
% Male	72%	80%	<.001
Race			<.001
% Non-Hispanic White	79%	80%	
% Black	10%	15%	
% Hispanic	8%	4%	
% Other	2%	1%	
Marital status			<.001
% Married	37%	31%	
% Formerly married	27%	44%	
% Single	35%	25%	
Employment status			ns
% Full-time	66%	71%	
% Part-time	11%	10%	
% Other	23%	19%	
PDA	38% (31%)	27% (30%)	<.001
PDMT	3% (9%)	4% (12%)	<.001

Notes. PDA=Percent days abstinent from alcohol; PDMT=Percent days attending an Alcoholics Anonymous meeting. For categorical measures, table shows the proportion of participants and *p*-value for Pearson Chi^2 test. For continuous measures, table shows mean (standard deviation) and *p*-value for t-test.

Table 3

Instrumental variable regression estimates for PDA in the pooled sample of 1,582 alcohol use disordered individuals participating in clinical trials.

	3 months *B* (SE)	15 months *B* (SE)
Percent days attending AA	0.382 (0.112)*	0.415 (0.207)*
Baseline PDA	0.327 (0.025)*	0.340 (0.027)*
Age (ref: <35 years)		
Age 35 to <55	−0.008 (0.018)	−0.020 (0.019)
Age 55+	−0.012 (0.028)	−0.020 (0.028)
Male	0.023 (0.017)	0.017 (0.017)
Race (ref: White)		
Black	0.052 (0.028)	0.120 (0.032)*
Hispanic	0.022 (0.027)	0.033 (0.027)
Other race	−0.002 (0.049)	0.022 (0.047)
At least high school	−0.009 (0.026)	−0.007 (0.026)
Marital status (ref: Married)		
Formerly married	−0.049 (0.019)*	−0.031 (0.019)
Single, never married	−0.077 (0.019)*	−0.044 (0.019)*
Employment status (ref: Full-time)		
Part-time	−0.005 (0.024)	0.004 (0.024)
Other employment	−0.043 (0.020)*	−0.002 (0.018)
Constant	0.686 (0.035)*	0.617 (0.035)*
Number of observations	1,291	1,178

Notes.

* $p < .05$.

PDA = Percent days abstinent from alcohol; AA = Alcoholics Anonymous.

The models also included dummy variables for each study (including MATCH outpatient, Walitzer, McCrady [15 month model only], Crits-Christoph [3 month model only], and Litt).