# Critical Review Form
## Therapy

Brief Intervention for Medical Inpatients with Unhealthy Alcohol Use: A Randomized, Controlled Trial, *Ann Intern Med* 2007; 146:167-176

**Objective:** **"To examine whether screening followed by brief intervention should inprove alcohol-related outcomes in 'typical' medical inpatients." (p. 168)**

**Methods:** **Trained research associates recruited eligible medical inpatients from Boston University Medical Center during an unspecified period. Eligibility criteria included age ≥ 18 years, English or Spanish speaking, drinking risky amounts currently (defined as > 14 drinks/week or ≥ 5 drinks/occasion and >11 drinks a week in men or ≥ 4 drinks/occasion in woman, and persons older than 66 years of age), two contacts to assist with follow-up, no plans to move from the area for one-year, and a Mini Mental Status Exam score ≥ 21. Research associates collected demographic data and administered the Alcohol Use Disorders Identification Test (AUDIT) and Composite International Diagnostic Interview (CIDI) to define alcohol dependence using Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV).**

**Eligible patients were randomized by an off-site data management group in blocks of eight stratified by AUDIT score (<12 or ≥ 12). In the control group patients received usual care (told of screening test results and provided opportunity to discuss drinking with their physician). The intervention group had a 30-minute session of brief motivational counseling by trained and supervised clinical psychology doctoral students. Counseling sessions were audiotaped and included two-way feedback with construction of a "change plan".**

**The primary outcome was self-reported alcohol assistance in the 3-month follow-up by patients with CIDI-defined alcohol dependence. The other primary outcome was the change in number of mean drinks per day using the Timeline Follow-back method. Secondary outcome measures included 12-month changes in the number of heavy drinking episodes, days abstinent, proportions of patients who were drinking risky amounts, having one or more heavy drinking episodes or abstaining for 30-days. Research associates also asked patients with risky drinking amounts to assess change readiness on a visual analog scale from 1 to 10. At 12-**

**months they assessed differences in readiness to change (SOCRATES 1996), alcohol problems (Miller 1995), physical and mental health related QOL (SF-12), ED visits, and days of hospitalization. Follow-up occurred in person at 3- and 12-months (10% and 12% respectively were by telephone) and included alcohol breath tests.**

**Logistic and linear regression analysis were used to analyze the outcomes. Investigators planned *a priori* to assess the following confounding variables: sex, alcohol assistance prior to enrollment, family history of alcoholism, any drug use, alcohol problem score, alcohol-attributable medical diagnoses and mean number of drinks per day. *Post-hoc* they also tested the interaction of patient-interventionist gender concordance. Patients were not excluded for missing data at a single point in time so investigators also analyzed the data with a longitudinal mixed effects model. The initial power calculation was revised because expected outcome rates and withdrawal rates were lower than anticipated. The final power calculation was based on 175 patients per group, and an absolute increase in ETOH assistance of 19%, decrease in drinking of 2.9 drinks a day with 80% power.**

| Guide | Comments |
|---|---|

| I. | Are the results valid? | |
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| **A.** | **Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?** | |
| 1. | Were patients randomized? | Yes. "An off-site data management group generated assignments to control and intervention groups by using permuted block (size 8) randomization procedure stratified by AUDIT score (<12 or ≥12) and provided us the assignment in sealed opaque envelops." (p. 168) |
| 2. | Was randomization concealed (blinded)? | No. "After each baseline assessment, research associates opened an envelope and informed the patient of his or her assignment." (p. 168) |
| 3. | Were patients analyzed in the groups to which they were randomized? | Yes. "We concealed randomization (to outcome assessors) and analyzed patients in the groups to which they were randomized regardless of receipt of intervention." (p. 174) |

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| 4. | Were patients in the treatment and control groups similar with respect to known prognostic factors? | No. "The randomized groups had similar characteristics at enrollment, except for sex, alcohol-attributable medical diagnosis, receipt of alcohol assistance and drug use." (p. 171)<br><br>% Control Intervention<br>Women 35 23<br>ETOH diag. 12 18<br>EtOH assist 20 30<br>Drug use 63 52 |
| **B.** | **Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?** | |
| 1. | Were patients aware of group allocation? | Yes. "Research associates and patients could not be blinded." However, "during follow-up, patients often could not correctly remember the group to which they had been randomized." (p. 174) |
| 2. | Were clinicians aware of group allocation? | Not clearly stated, but based upon I-B-1 clinicians probably were aware of group allocation. |
| 3. | Were outcome assessors aware of group allocation? | No. "64% of patients at 3-month follow-up and 85% of patients at 12-month follow-up were interviewed by a different research associate than at baseline." (p. 169) |
| 4. | Was follow-up complete? | Yes. "Over 12 months, 11 patients died and 90% (n=308) of all enrolled persons completed at least 1 follow-up visit." (p. 171) |
| **II.** | **What are the results (answer the questions posed below)?** | |

<table>
<tr><td>1.</td><td>How large was the treatment effect?</td><td>
<ul>
<li>7824 persons were approached, 5813 screened, and 986 (17%) reported drinking risky amounts of alcohol in the past month. After excluding 645 (183 declined, 94 refused completion of screening, 52 were moving within 12 months, 230 lacked two contacts and 86 had MMSE <21) 341 were enrolled with 172 randomized to intervention and 169 to usual care.</li>
<li>As noted in Table 1, the patients were predominantly middle age (mean age 45) males (under 30% females), often unemployed, homeless (25%) and 50% had used the ED in the preceding 3-months.</li>
<li>77% of subjectswere ETOH dependent.</li>
<li>The following treatment effects were noted:</li>
</ul>
<table>
<tr><th>Outcome at 12-months</th><th>Control</th><th>Intervention</th><th>Adjusted OR (95% CI)</th></tr>
<tr><td>Alcohol assistance①</td><td>44%</td><td>49%</td><td>1.2 (0.6-2.5)</td></tr>
<tr><td>Alcohol assistance① AUDIT >12</td><td>43%</td><td>48%</td><td>1.3 (0.6-2.7)</td></tr>
<tr><td>Number drinks/day</td><td>2.6</td><td>1.8</td><td>----</td></tr>
<tr><td>Increase days abstinent</td><td>4.2</td><td>2.5</td><td>----</td></tr>
<tr><td>Drinking risky amounts %</td><td>64</td><td>62</td><td>1.1 (0.7-1.9)</td></tr>
<tr><td>Heavy drinking episodes %</td><td>62</td><td>62</td><td>1.2 (0.7-2.0)</td></tr>
<tr><td>Abstinence %</td><td>27</td><td>30</td><td>0.9 (0.5-1.6)</td></tr>
</table>
①ETOH dependent subset only.
<ul>
<li>Sex concordance did not significantly affect results</li>
<li>Intervention did not significantly affect readiness to change, alcohol problems, physical or mental health related QOL, ED visits, or days hospitalized.</li>
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</td></tr>
<tr><td>2.</td><td>How precise was the estimate of the treatment effect?</td><td>See 95% CI above, all cross 1 (no effect).</td></tr>
<tr><td>III.</td><td>How can I apply the results to patient care (answer the questions posed below)?</td><td></td></tr>
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| 1. | Were the study patients similar to my patient? | Yes. Although these are inpatients, they are urban academic medical center patients with ETOH-related diagnoses, ETOH dependence and socioeconomically deprived with high rates of substance abuse, homelessness, and unemployment. |
| 2. | Were all clinically important outcomes considered? | Yes, although longitudinal follow-up is limited to 12 months and family morbidity related to ETOH use disorders is not evaluated. |
| 3. | Are the likely treatment benefits worth the potential harm and costs? | No not based on the current data which demonstrate no benefit to a brief ETOH intervention for medical inpatients. |

## Limitations

1) **Lack of blinding of research associates and patients so multiple forms of bias possible.**

2) **Large academic medical center in urban America so limited external validity.**

3) **Potential assessment-effect bias since patients in the control group received slightly more than standard care.**

4) **Reliance upon self-report even though the authors contend that "biological measures are not better than self-report." (p. 174)**

## Bottom Line

**Although recommended by the Institute of Medicine and US Preventive Services Task Force, in this study evaluating brief interventions for medical inpatients with unhealthy alcohol use (75% of who were alcohol dependent), brief interventions are inadequate to link patients with assistance for dependence or to reduce alcohol consumption or alcohol-related health problems. Future trials are needed to identify pragmatic ED- and inpatient-based strategies while delineating the optimal intensities and duration that effectively reduce alcohol-related morbidity.**