Critical Review Form
Therapy

Brief alcohol intervention for general hospital inpatients: a randomized controlled trial, *Drug Alcohol Dep* 2008; 93: 233-243

Objective: **"To test the effectiveness of a MI (motivational interviewing) based brief intervention among inpatient non-dependent problem drinkers in general hospitals…We also aimed to investigate whether the effectiveness of a MI based intervention differs by whom it is delivered." (p. 234)**

Methods: **This was a randomized controlled trial conducted from April 2002 – June 2004 and recruited adult patients from four hospitals in northeastern Germany including 29 wards (which were internal medicine, surgery, orthopedics, or ENT wards). Inclusion criteria included ages 18- to 64-years with a minimum 24-hour hospital length of stay. Exclusion criteria included cognitive or physical incapability to participate as determined by the clinical staff, language barriers, previous enrollment, or patients employed at the hospital. Pre-consent, pre-randomization self-administered screening with the German adaptation of the AUDIT (Saunders 1993) and LAST (Rumpf 1997) was performed in order to identify patients with an alcohol problem. A positive screen on either test prompted further diagnostic testing with the German M-CIDI (Lachner 1988) which provided the DSM-IVR diagnoses. Investigators used the 1995 British Medical Association Guidelines on sensible drinking to quantity and qualify the frequency of alcohol use. The investigators used the following definitions:**

Alcohol dependence – as per the M-CIDI
Alcohol Abuse – as per the M-CIDI
At-risk drinking – as per the British Medical Association, > 20 grams of pure alcohol for women or > 30 grams for men daily.
Heavy episodic drinking – >5 (women) or >8 (men) drinks on one occasion twice monthly.

The diagnostic testing and standardized questionnaires were conducted by one of three psychologists, two social workers, or two research nurses. Informed consent was obtained after diagnostic testing. The diagnostic interview lasted 22-minutes and the questionnaire 31-minutes, on average.

Randomization was organized by the date upon which patients presented and occurred after the questionnaire on the date of admission. The investigators planned for each block of time (for randomization) to last for 4-month intervals. In the first block of time, (range 16-40 weeks) control patients were enrolled. In the second block of time, (range 11-30 weeks) intervention group liaison group patients were enrolled. This group received a brochure called "Alcohol and Health" with counseling by the same person who conducted the assessment using Motivational Interviewing (MI, Miller and Rollnick 2002) and the Trans Theoretical Model of behavior change (TTM, Prochaska and Velicer 1997; Prochaska and DiClemente 1984) lasting a mean of 25-minutes. The intervention was adapted to the participants, situation and aimed to increase motivation to the alcohol problem behavior. Each counselor received 24-hours of advanced training by the principal investigator, a member of the Motivational Interviewing Network (MINT). Prior counseling experience was heterogeneous and supervision was maintained every 2- to 3-weeks via audio recordings. In the third time block which was an intervention group of physicians and which ranged in duration from 12- to 57-weeks, all physicians of participating wards were invited to receive MI training to become the counselors. Ultimately 80/110 (73%) did receive at least one form of MI training, but any evaluation of physician-led counseling was not possible due to substantial missing data.

Outcomes included average daily alcohol intake, total alcohol intake in the past week, heavy episodic drinking, at-risk drinking, alcohol abuse, or having any alcohol problem at follow-up. Alcohol intake was assessed using the Timeline-Follow back method. Motivation to change was assessed with the Readiness to Change Questionnaire which assesses readiness to change drinking and the Treatment Readiness Tool which assesses readiness to seek formal help for alcohol problems. Investigators also assessed patients' satisfaction with life, mental health, and self-rated health using the FEG Health Behavior Questionnaire (Dlugosch and Krieger, 1995).

Linear and logistic regression analyses were conducted, along with generalized estimating equation to assess associations between outcome measures and treatment group.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No, this is a pseudo-randomized design with allocation determined by the date of enrollment. As noted by the authors, this is a source of potential bias since "as the control group was recruited first, it probably included more patients who were hospitalized repeatedly and who were excluded as re-admissions later on when the intervention groups were recruited. This suggests that the control group included more patients with severe illnesses, explaining the lower health satisfaction scores at baseline. Thus, randomization by time-frame does not seem well suited for studies lasting this long." (p. 241)
2.	Was randomization concealed (blinded)?	No. "The staff was not blind to the study group to which participants had been assigned." (p. 234)
3.	Were patients analyzed in the groups to which they were randomized?	Probably. No cross over is depicted but there is no clear intention-to-treat statement.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. "No significant differences ($p < 0.05$) were found for gender, age, intimate partner, employment status, AUDIT score, LAST score, type of alcohol problem and health satisfaction." However, "between group differences were found for satisfaction with health, age, and having an intimate partner" with liaison group older (42 vs. 39), more likely to have intimate partner (70% vs. 55%) than the physician group. (p. 237-238) However, "the three groups did not differ significantly regarding alcohol

		variables."
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. "The baseline differences regarding motivational aspects and satisfaction with health are most likely attributable to the fact that the control group was recruited first…it probably included more patients who were hospitalized repeatedly and who were excluded as re-admissions later on when the intervention groups were recruited." (p. 241)
2.	Were clinicians aware of group allocation?	Yes. "An associated disadvantage was that the staff that conducted the assessments knew what group the participants were in." (p. 241)
3.	Were outcome assessors aware of group allocation?	Sometimes. "Sixty-two percent of the participants had different interviewers at baseline and at follow-up." (p. 235) However, based on the time of follow-up outcome assessors could have easily deduced group allocation.
4.	Was follow-up complete?	No. "One year later 70% (N=415) of the participants were followed up, 4% (N=25) had died, and the rest was lost due to refusal of further study participation (n=98) or other reasons (n=57)." (p. 236)
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• 14332 patients were screened with 20% (2924) demonstrating a positive screening result with either the AUDIT or the LAST (or both) and 2337 (80%) agreed to participate in the subsequent diagnostic interview. After 1281 (55%) met criteria for AD, AA, AR, or HE, 599 (47%) with alcohol dependence were excluded. Of the remaining 682 non alcohol dependent patients with AA, AR , or HE 595 (87%) consented to study. • Demographics of study participants included a mean age of 41-years, 94% male, 65% had an intimate partner, 48% had 11-years of schooling and 45% were employed. 57% were at risk drinkers, 25% alcohol abusers and 18% heavy episodic drinkers. • Alcohol consumption and alcohol abuse decreased over time while readiness to seek help and life satisfaction increased over time. There was a more profound drop of readiness to seek help among controls (OR 2.90, 95% CI 1.06-7.95) and stronger increase of readiness to change drinking in the intervention group (OR 2.11, 95% CI 1.03-4.33). However, baseline differences were found for readiness to seek help that probably explain this statistical observation. • Alcohol consumption outcomes diminished in each group but none of the group comparisons were statistically significant at 12-month follow-up (see left). However, there did seem to be a trend favoring the physician intervention.

	Control % (n=155)	Intervention Liaison (n=184)	Intervention Physician (n=76)
Alcohol Abuse	9	8	11
At-risk drinking	68	71	34
Heavy episodic	50	69	22

2.	How precise was the estimate of the treatment effect?	See the 95% CIs above
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Not really – medical inpatients in Germany. The length of the intervention alone (not to mention the training and supervision of requisite personnel) is not pragmatic for most busy ED's.
2.	Were all clinically important outcomes considered?	Not really. The investigators report collecting data on patient-centric outcomes like satisfaction with life, mental health, and self-rated health, but they provide very little details about these outcomes. Additionally, they do not assess any societal impacts of alcohol-use disorders like motor vehicle citations, unemployment or costs.
3.	Are the likely treatment benefits worth the potential harm and costs?	No, not based upon the current data.

Limitations

1) **Pseudo-randomization via time-of-enrollment without the ability to mask allocation of treatment received to patients, caregivers, or outcome assessors. There was significant potential for bias including enrolling sicker more dependent patients in the first group (the control group).**

2) **Significant (30%) lost to follow-up without any sensitivity analysis.**

3) **Limited external validity for emergency medicine with time-consuming intervention and generally more heterogeneous (mix of inpatient and outpatient) subjects with alcohol-use disorders.**

4) Self-reported data about alcohol use/abuse is of uncertain accuracy.

Bottom Line

Among middle-aged male German patients admitted to the hospital for a medical illness, 20% will screen positive for unhealthy alcohol use and half of those will meet criteria for alcohol abuse, alcohol dependence, risky drinking, or heavy episodic alcohol use. Providing an information brochure and Motivational Interviewing counseling by psychologists or physicians will not reduce alcohol consumption at 12 months any better than routine care. Future studies are needed using valid randomization schemes and pragmatic ED screen/treat or refer models to more accurately evaluate the effectiveness on heterogeneous ED populations.