Critical Review Form
Therapy

Effectiveness of Brief Interventions After Alcohol-Related Vehicular Injury: A Randomized Controlled Trial, *J Trauma* 2006; 61: 523-533

Objective: "To determine whether 12 months after serious injury resulting from an MVC, brief intervention strategies were effective in reducing alcohol consumption and adverse events in non-alcohol dependent, harmful drinking hospitalized young adults." (p. 524)

Methods: Drivers or passengers between ages 18 to 45 years who were hospitalized with a motor vehicle accident-related injury at one of two Level I Trauma Centers in Southwestern Ohio were evaluated. Inclusion criteria also included blood alcohol level $\geq$ 10 mg/dL, hospital admission within 24 hours of the injury, English-speaking, intact cognition, and potential for discharge within 4 weeks of study entry. Exclusion criteria included attendance at alcohol treatment program in the last one-year, signs/symptoms of alcohol withdrawal, healthcare provider advice to reduce alcohol consumption in the preceding 3 months, consumption of >150 grams (12 drinks) per day, or score of $\geq$ 2 on the Alcohol Use Disorders Identification Test. (AUDIT) Eligible patients were identified through a daily review of the ED or trauma service admitting logs.

Eligible patients were randomized (by whom and using what methods is not detailed) to one of three groups. A control group received a 20-minute health interview with no intervention. The simple advice group received the same health interview and an additional 5-minutes of advice about the importance of sensible drinking or abstinence. The brief counseling group received the health interview, 5-minutes of advice, and an additional 15-minutes of patient-centered counseling on personal problem-solving strategies. (p. 524) The interviews were conducted by a study nurse who were not part of the clinical care team. These nurses used an interview protocol adapted from the trial of Early Alcohol Treatment (Fleming 1997) and the brief counseling intervention arm added components of Miller's Feedback, Responsibility, Advice to Change, Menu of Alternative Choices, Empathy, Self-Efficacy (FRAMES) model with reflective listening techniques. The important component of the simple advice arm was discussing low-risk drinking. The simple advice group had a "booster" session via telephone at one-month after discharge. The brief counseling group had brief counseling group also had a one-month

telephone "booster , but it was a patient-centered counseling using the FRAMES model. These study nurses were trained by an experienced social psychologist and were videotaped delivering the information every six months with re-training performed as needed.

The primary outcome was change in alcohol consumption as measured by drinks per month and binges per month. Binges were defined as drinking days when females consumed $\geq$ 4 standard drinks or males consumed $\geq$ 5 standard drinks. Other variables included traffic crashes, driving citations (suspensions, DUI), or health status changes (number of ED visits, number of times physical activity was limited because of injury/illness over 12 months). Driving events 12 months before or after the study intervention were included as outcomes. Outcomes were ascertained by self-report via telephone interview at 3-, 6-, and 12-months after study entry.

Generalized linear mixed modeling was used to analyze the primary outcome of alcohol consumption change. Time was partitioned into two segments: 0 to 3 months and 3-12 months. Using an *a priori* power calculation based upon an effect size of "moderate effect for alcohol consumption" (which is neither quantified nor referenced) and with no statement of Type I error rate (α=?), the between-group power was 84% and within-group over time power was 99% if 40 participants per group were enrolled.

	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?	Yes. "Participants were randomly assigned to the Control (C) Simple Advice (SA) or Brief Counseling (BC) condition." (p. 524) But how were they randomized (date, time, envelope, number generator) and by whom (study personnel, central registry)?
2.	Was randomization concealed (blinded)?	Uncertain. There is no clear statement of blinding.
3.	Were patients analyzed in the groups to which they were randomized?	Uncertain. There is no clear statement of intention to treat but Figure 1 (CONSORT diagram) notes no cross over.

4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. As noted in Table 1 (p. 527) "participant sex, race/ethnic identity, age, BAC, or ISS did not vary significantly across treatment conditions. However, at the time of the MVC, significantly fewer participants assigned to the SA condition were drivers (71%), as compared with BC (85%) or C (81%) conditions (p=0.04)."
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, there is no mention of blinding.
2.	Were clinicians aware of group allocation?	Yes, there is no mention of blinding.
3.	Were outcome assessors aware of group allocation?	Yes, there is no mention of blinding.
4.	Was follow-up complete?	Yes, contrary to the authors' statement that "the attrition rate did not vary significantly among treatment conditions" (p. 527) Figure 1 displays a lost to follow-up rate of 39% in the control group versus 41% in the brief counseling group and 57% in the simple advice group with no sensitivity analysis.
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• Mean age of participants was 29 with 77% male and 89% Caucasian. • 80% were drivers and the mean blood alcohol level was 165 mg/dL with an injury severity score of 10. • 187 participants were enrolled: 63 BC, 68 SA, and 56 C. • Baseline alcohol consumption across groups was similar for drivers but varied for passengers. • Driver alcohol consumption (and binges) at 3-months decreased more than in passengers (46.3 drinks vs. 23.8 drink decreases). • African-Americans increased alcohol consumption at 12-months more than Caucasians. • Driving records one-year before and after enrollment were available for 96% with the event rates as noted at left.
		• No significant changes were found for any of the driving events when stratified by treatment group. • Only 44/124 (35%) of drivers received a DUI for the index event. • The only significant change in health status was the frequency of illness/injury limiting physical activities $\geq$ 1 day decreasing from 37% at baseline to 20% at 1-year with a significant improvement in the BC group (46% to 12%).

Event	1 year before	1 year after
$\geq$ 1 suspension	19%	26%
$\geq$ 1 Citation	35%	24%
$\geq$ 1 DUI	6%	8%

2.	How precise was the estimate of the treatment effect?	Uncertain since no confidence intervals were provided.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Uncertain. These were predominantly white males. How many were ED patients? Could this intervention occur in ED settings? What proportion had a primary care physician or insurance? What was the prevalence of co-addiction and psychiatric co-mortality? During what time period did this study occur? Based upon these unanswered questions, the study's external validity is uncertain.
2.	Were all clinically important outcomes considered?	No. The study does not evaluate the detrimental effect of ETOH on work, socioeconomic strata, or family. Furthermore, ETOH-related MVA's often involve a second vehicle driven by a non-intoxicated individual. The impact of ETOH on these crossfire victims should also be evaluated.
3.	Are the likely treatment benefits worth the potential harm and costs?	No, not based on the current evidence which only demonstrates a temporary 3 month reprieve from ETOH consumption.

Limitations

1) **Insufficient detail of methods**
   a. **Which ED's recruited these patients?**
   b. **When (during what time period) were patient enrolled?**
   c. **What socioeconomic strata of subjects were enrolled (including the proportion employed with health insurance)?**

2) **No reference of CONSORT methods for RCT**

3) No details are provided about the method of randomization or blinding so **subverting randomization** was possible.

4) No details about **power calculation**. What is "moderate effect"?

5) No clear statement of **intention-to-treat** analysis.

6) Significant lost to follow-up rate with no sensitivity analysis.

7) Very confusing presentation of results via the statistical modeling without clear interpretation (NNT, CI's) for clinicians.

8) An initial refusal rate of 61% thereby limiting the external validity of these results to a select subset of trauma patients (i.e. those willing to contemplate change).

<u>Bottom Line</u>

Significant upfront participation refusals, unequal and exceedingly large attrition rates, and insufficient methodological details limit reader's ability to deduce confident effects of either brief counseling or simple advice following alcohol-related motor vehicle accidents involving drivers or passengers admitted to Level I Trauma Center. Most alcohol-related motor vehicle accident drivers do not receive citations when admitted as victims of their accident.