# Brief Physician and Nurse Practitioner-delivered Counseling for High-risk Drinking

# Results at 12-Month Follow-up

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**BACKGROUND:** The objective of this study was to determine the effects of a brief primary care provider-delivered counseling intervention on the reduction of alcohol consumption by high-risk drinkers. The intervention was implemented as part of routine primary care medical practice.

**METHODS:** We performed a controlled clinical trial with 6- and 12month follow-up. Three primary care practices affiliated with an academic medical center were randomly assigned to special intervention (SI) or usual care (UC). A total of 9,772 primary care patients were screened for high-risk drinking. A fourth site was added later. From the group that was screened, 530 high-risk drinkers entered into the study, with 447 providing follow-up at 12 months. The intervention consisted of brief (5–10 minute) patient-centered counseling plus an office system that cued providers to intervene and provided patient educational materials.

**RESULTS:** At 12-month follow-up, after controlling for baseline differences in alcohol consumption, SI participants had significantly larger changes (P=.03) in weekly alcohol intake compared to UC (SI = -5.7 drinks per week; UC = -3.1 drinks per week), and of those who changed to safe drinking at 6 months more SI participants maintained that change at 12 months than UC.

**CONCLUSIONS:** Project Health provides evidence that screening and very brief (5–10 minute) advice and counseling delivered by a patient's personal physician or nurse practitioner as a routine part of a primary care visit can reduce alcohol consumption by high-risk drinkers.

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H igh-risk drinking is a major and costly health care and public health problem<sup>1-3</sup> which contributes to hypertension, trauma, stroke, and gastrointestinal cancers,<sup>4,5</sup> accidents,<sup>6</sup> and psychosocial problems such as depression, domestic violence, difficulty in social and occupational functioning, and alcoholism.<sup>6.7</sup> Approximately 10% of patients seen in primary care settings meet criteria for high-risk drinking.<sup>8.9</sup>

At least 80% of adults in the United States see their primary care provider at least one time per year,<sup>10</sup> making the primary care visit an important opportunity to intervene with high-risk drinkers. This intervention opportunity, coupled with past research demonstrating the effectiveness of brief interventions delivered by a health care provider in helping reduce high-risk alcohol consumption,<sup>11–17</sup> highlights the importance of developing and testing appropriate brief intervention strategies that can be used in a general medical visit to address high-risk drinking.

Our past research has demonstrated that screening, brief provider-delivered patient-centered counseling, and prompting providers to intervene has a significant effect on change in health-related behaviors<sup>18,19</sup> when used in the primary care setting during regular primary care visits. This method has been associated with significantly more change in dietary behavior,<sup>18</sup> smoking behavior,<sup>19</sup> and reduced high-risk drinking at 6-month follow-up when compared to usual primary care.<sup>20</sup>

Project Health is a controlled clinical trial that compares a special intervention (SI) consisting of patient-centered counseling for high-risk drinkers to usual care (UC) in the primary care setting. To our knowledge, it is the first such trial that has been conducted in internal medicine offices and in the context of a regularly scheduled office visit (one not scheduled specifically for alcohol intervention purposes). As noted above, at the 6-month follow-up, the SI was found to be significantly more effective in reducing weekly alcohol consumption when compared to UC in the primary setting.<sup>20</sup> This article reports the 12-month follow-up results and the pattern of changes from high-risk drinking to safe drinking from 6-month to 12-month follow-up, allowing us to determine the durability of the intervention effects from 6 to 12 months.

#### METHODS

## **Health Care Providers**

This controlled clinical trial took place at University of Massachusetts Memorial Healthcare, Incorporated (UMMH). Three primary care internal medicine practices were the initial study sites. We randomized the sites to the SI or UC after combining two adjacent practice sites and randomizing them as a single unit to prevent contamination during the trial. Randomization was accomplished by means of the random number generator in SAS statistical software (SAS Institute, Cary, NC). The sites had separate nursing staff, patient assignments, and coverage

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arrangements. A fourth site was added 22 months into the study to boost recruitment for UC participants because the UC site had fewer participants than did the SI site. The added site is located in a community practice and is part of the UMMH system.

Of the 47 attending physicians and nurse practitioners, all but one agreed to participate. Provider characteristics have been presented elsewhere.<sup>20</sup> When compared on age, years since receiving degree, gender, and provider type, the only significant difference between providers in the SI and UC conditions was that a greater percentage of the UC providers reported having had prior training in alcohol counseling. The attending physicians were all board-certified internists. All providers were academically affiliated. There were no significant differences between groups in the types of providers seeing patients. In the SI there were 11 attending physicians, 5 residents, and 3 nurse practitioners. In the UC there were 15 attending physicians, 7 residents, and 5 nurse practitioners.

# **Study Population**

The study population has been described in detail elsewhere<sup>20</sup> but is reviewed here. Participants between 21 and 70 years old who were scheduled to be seen by study primary care providers between April 1994 and April 1997 were screened for high-risk drinking. For men, high-risk drinking is defined as more than 12 standard drinks per week (12.8 grams of alcohol per drink: e.g., 5 ounces of wine, 12 ounces of beer, or 1.5 ounces of 80-proof liquor) or binging on one or more occasions in the previous month. For women, high-risk drinking is defined as more than 9 standard drinks per week or binging on one or more occasions in the previous month. Binge drinking is defined as 5 or more drinks on one occasion for men and 4 or more drinks on one occasion for women. Only 2% of our sample reported symptoms or signs of alcohol dependency such as symptoms of physical withdrawal or reported unsuccessful attempts at cutting down on drinking. Patients were not excluded because of excessive drinking. However, they were excluded from the study if they were pregnant, did not speak English, planned to move out of the area within the year, did not have a telephone, were already participating in an alcohol intervention program, had an Axis I psychiatric disorder<sup>21</sup> other than substance abuse problem that in the judgment of the provider or research assistant prevented them from participating, or were unable to complete the informed consent.

### Assessment

The assessment procedures have been described in detail elsewhere.<sup>20</sup> Briefly, patients were first screened using the Health Habits Survey.<sup>22</sup> This survey is a brief standardized health habits screening questionnaire that presents questions about alcohol along with questions on exercise, diet, depression, anxiety, and smoking. The alcohol questions are presented in this manner to increase the acceptance of the questionnaire as a general health screening and to minimize focus on the assessment of alcohol intake. Of the 9,772 patients screened (65% of patients enrolled in the practice panels at 4 sites), 1,760 screened positive for high-risk drinking and were asked to complete a standardized Lifestyle Interview lasting 20–35 minutes which was conducted in person or over the phone depending on availability of both patient and interviewer. The Lifestyle Interview has alcohol questions embedded with questions about other health behaviors. Of the 1,760 potentially eligible patients, 1,500 were reached by phone and 99% agreed to complete the Lifestyle interview.

There were 703 (47%) patients eligible for the study based on the alcohol assessment from the Lifestyle Interview. They were asked to participate in a study of "health habits" and if they were interested, informed consent was obtained. Participants were also asked to provide a name of a close contact who could be called to respond to questions about the participant's health habits and they were told that they might be called for more interviews in the future. Patients were paid for each interview. Patients who saw their primary care provider within 6 months of the baseline Lifestyle Interview were included in the study (545, 88%). A random subset of 65% of the total patient group was contacted after their enrollment visit and asked questions to assess the content of the provider's intervention. This procedure is called a patient exit interview (PEI) and is described in detail elsewhere.<sup>6</sup> PEIs were conducted in person or over the phone and contained questions determining whether the provider had administered alcohol counseling and which of 15 possible counseling steps where implemented. PEI questions regarding alcohol counseling were embedded in parallel questions regarding dietary, smoking, and exercise counseling as with other study assessment tools.

Follow-up interviews were conducted at 6 and 12 months after the initial visit to assess change in alcohol use. As was done at baseline, questions on alcohol use were embedded in a questionnaire about other health behaviors.

#### Intervention

After the assessment was completed UC participants received a health booklet, which included advice on general health issues, and they were told to address any health questions to their providers. Usual care providers were encouraged to identify and intervene with patients with alcohol-related issues to whatever extent they thought appropriate. All providers were encouraged to attend the weekly conference series in which the approach to the patient with alcohol problems was presented biannually as part of a 2-year curriculum.

After baseline assessment was completed, SI participants were told that at their next regularly scheduled appointment their providers probably would discuss one of the health issues that was asked about in their Lifestyle Interview. They were given the same health booklet as UC participants.

Special intervention providers received 2.5 hours of training in patient-centered alcohol counseling. This training and intervention has been described in detail elsewhere.<sup>20,23</sup> The SI providers were asked to carry out the brief 5- to 10-minute patient-centered alcohol counseling sequence at the time of a regular visit with patients identified by Project Health as highrisk drinkers. Patient-centered counseling elicits active patient involvement in behavior change through initially nondirective, open-ended questions (e.g., "How do you feel about your drinking?" or "How might you go about cutting down?"). This approach contrasts with the traditional provider-centered model in which the provider assumes a greater degree of control, advises the patient what to do, or questions the patient in a directive fashion without eliciting the patient's thoughts or feelings (e.g., "You have a drinking problem" or "You need to stop drinking"). The intervention algorithm for the initial visit includes 6 steps that focus on cognitions and behaviors. Providers focused their counseling efforts either on the number of drinks per week, binge drinking, or both, depending on the participant's problem area(s). Special intervention providers were instructed in the use of goal setting and requesting that the patient set a follow-up visit to review progress.

Special intervention office sites also had a limited office support system designed to assist the busy primary care provider in carrying out the intervention. Although implemented by Project Health research assistants, the system was designed to be easily incorporated into usual office procedures. The office support system includes the research assistant attaching the following to the chart of the high-risk drinker: 1) Lifestyle Interview summary, which reports the participant's alcohol history (drinks per week, history of binge drinking, family history of alcohol abuse); 2) intervention algorithm, to remind the physician of the counseling sequence taught in the training sessions; and 3) patient educational materials, in the form of Tip Sheets for the provider's use with patients.

## **Statistical Analysis**

The primary end points used to assess the effectiveness of the intervention are alcohol consumption measured as the total number of drinks consumed per week and the number of episodes of high-risk (binge) drinking per month. A change score was calculated for both outcome measures by subtracting the baseline value from the 12-month value. Additionally, subjects were categorized as drinking at safe or unsafe levels based on gender-specific cut points for weekly drinking and monthly binge drinking as described above. Comparisons between treatment conditions or practice sites for patient characteristics were made using the Fisher's exact test of independence and ANOVA for categorical and continuous measures, respectively.

The provider group (practice site) is the unit of randomization and intervention, within which provider is nested. The patient is the unit of measurement (i.e., patient drinking behaviors), and therefore analysis. We expected that patients with the same provider would be more similar to each other in behavior and response to the intervention than to patients of other providers. The analysis takes into consideration the variation at each level by use of a hierarchical modeling approach for continuously measured drinks per week and episodes of high-risk drinking (binges per month) using GLLAMM (generalized linear latent and mixed models), a Stata function (StataCorp, College Station, TX).<sup>24</sup> This analytic approach allowed us to account for the nested nature of the study design (patients are nested within physicians nested within practice site). The dependent variable in this analysis was change in drinking/binging calculated as a 12-month measure minus the baseline measure, and treatment condition was fit as a fixed effect. In this model we controlled for patient age, gender, smoking status, and baseline level of weekly drinking or monthly binging as appropriate. We examined the interaction between these factors and treatment condition, as well as the effects of other potentially important covariates such as patient educational level, marital status, family history of alcohol dependence, and provider gender and type (attending, resident, nurse practitioner). We also repeated similar analyses but using a hierarchical logistic regression model for probability of safe drinking.

Preliminary analyses were performed on all variables to determine whether the assumptions of linear regression (i.e., normality, linearity, and independence) were met. Diagnostic statistics were used to examine model fit and identify outliers. One subject who consumed high levels of alcohol throughout the study was identified as an outlier. Models were fit with and without this observation and we determined that the results were not materially changed by its inclusion. Thus, the final model includes all subjects for whom we had complete data (n = 445).

Sixteen percent of the 530 eligible subjects did not have 12-month data. We carried out a multiple imputation estimation to consider the effect of the missing data on our results.<sup>25,26</sup> We used two simple imputation models. The first assumed missing subjects were similar to the population in general (disregarding condition) and the second assumed a mean change from baseline of zero for drinking behavior measurements (drinks per week and binges per month) and variation similar to the population variability in response. The number of imputations used was 10 which, given a missing rate of 16%, results in an efficiency of 98.5%. The results, not reported here, remained statistically significant and were similar to the estimates from the analysis in the cohort of 445, with estimated differences slightly smaller and confidence intervals slightly wider.

# RESULTS

### Intervention Implementation

Seventy-six percent of the patients had attending-level physicians as their providers, 5% had resident physicians, and 19% had nurse practitioners. Patient exit interviews demonstrated that all except 1 SI participant were counseled about alcohol use and that there were no significant differences between provider type and PEI scores. As described elsewhere,<sup>23</sup> the mean score on the PEI for SI participants was 9.8, and 1.7 for UC participants. Of the total study population, 59% had more than 1 additional visit with their provider between the baseline and 6-month assessments. Providers were not cued to administer alcohol counseling between the 6- and 12-month assessment interviews.

### **Follow-up Rates**

Of the original 530 participants, 83 did not complete the 12month interview, yielding a sample of 447. There was no significant difference between groups in the number of participants who did not complete the 12-month interview, with 44 (17.2%) of UC and 39 (14.2%) of SI not completing the 12month interview. There were no differences at baseline on age, number of drinks per week, family history of alcohol abuse, gender, proportion of white and nonwhite respondents, and use of sleep medication between participants who completed the 12-month interview and those who did not. However, the group who did not complete the 12-month interview compared to those who did complete it had a lower proportion with a college degree or more (21% vs 44%) and a higher proportion of smokers (54% vs 33%). In addition, for the cohort of 445, there were no significant differences between the UC and SI groups

Table 1.	<b>Baseline</b> Pa	atient Characteristic	s by Treatment	Condition and	Randomization	Status (N=445)	*
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Characteristic	Usua	Care	Special Intervention		
	Added	Randomized	Randomized	P Value	
Mean age, y ( $\pm$ SD)	$45.7 \pm 14.7$	$44.4 \pm 14.1$	$43.8 \pm 13.8$	$.70^{\dagger}$	
Gender, n (%)				$.19^{\ddagger}$	
Male	26 (60)	98 (59)	158 (67)		
Female	17 (40)	64 (41)	77 (33)		
Educational level, n (%)				$.49^{\ddagger}$	
Less than high school graduate	1 (3)	12 (8)	20 (9)		
High school graduate; some college	24 (60)	75 (48)	100 (46)		
College graduate or more	15 (37)	70 (45)	97 (45)		
Ethnicity, n (%)				$.18^{\ddagger}$	
White	36 (90)	146 (97)	193 (95)		
Nonwhite	4 (10)	5 (3)	9 (5)		
Family history of alcohol abuse, n (%)				$.67^{\ddagger}$	
No	20 (50)	82 (52)	103 (47)		
Yes	20 (50)	75 (48)	114 (53)		
Current smoker				$.79^{\ddagger}$	
No	28 (70)	109 (68)	143 (65)		
Yes	12 (30)	51 (32)	76 (35)		

\*Usual care (n = 210); special intervention (n =235).

<sup>†</sup>An ANOVA was used to compare practice sites.

<sup>‡</sup>The Fisher's exact test was used to assess the independence of proportions.

SD, standard deviation.

at baseline. Please see Table 1 for baseline patient characteristics by condition and randomization status.

### **Alcohol Outcome Measures**

Table 2 describes the alcohol intake by treatment condition from baseline to 12 months for the 445 participants who completed both the baseline and 12-month interviews. Compared to the UC, SI participants reported nonstatistically significantly higher levels of both drinks per week and binge drinking at baseline. Means and standard errors for baseline, 6 months, and 12 months for weekly and binge drinking by condition for the 422 participants with respective measurements are presented in Table 3.

Table 4 presents the mixed-model results for change in weekly drinking levels and change in the number of monthly binge drinking episodes from baseline to 12 months (n=445) that adjusts for baseline drinking levels. At 12 months, SI

Table 2. Baseline and 12-Month Measures of Weekly Alcohol				
Intake and Monthly Binge Drinking by Treatment Condition and				
Gender (N=445)*				

Characteristic	Usual Care	Special Intervention		
	Mean ( $\pm$ SD)	Mean ( $\pm$ SD)		
Drinks per week <sup>†</sup>				
Baseline <sup>‡</sup>	16.3 (12.1)	18.3 (12.2)		
Twelve months	13.3 (13.1)	12.6 (14.9)		
Binge drinking episod	es			
per month $^{\dagger}$				
Baseline <sup>‡</sup>	3.8 (5.8)	4.8 (6.2)		
Twelve months	2.4 (5.3)	2.6 (5.4)		

\*Usual care (n =210); special intervention (n =235).

<sup>†</sup>Alcohol intake is assessed as the average number of drinks per week. Binge drinking is defined as drinking on one occasion more than 4 drinks for females or more than 5 drinks for males.

 $^{\dagger}Not$  statistically significantly different, P=.08 for drinks per week; P=.07 for binge drinking.

SD, standard deviation.

participants significantly reduced their alcohol intake by 2.5 drinks per week more than UC (P=.03). Relative to the UC, the SI experienced a reduction of 0.4 binges per month. For every 100 treated there was an increase of 13 safe drinkers in the SI condition versus the UC condition. This means that approximately 8 high-risk drinkers needed to be treated for every 1 extra safe drinker. Although the absolute reduction within the SI group was 2 binges per month, the difference between SI and UC was not statistically significant.

Entry into the study was based on either an excessive intake of drinks per week, binge drinking, or both. Patients were categorized into safe or unsafe drinking at both baseline and 12 months for both outcome measures. We then examined the progression from unsafe patterns of intake at baseline to safe levels at 12 months. Table 5 presents the prevalence of change to safe drinking at 12 months by treatment condition for drinks per week, binge drinking, and both behaviors combined.

When we combined information on weekly drinking and binge drinking into safe/unsafe drinking categories (n=445),

Table 3. Unadjusted Mean Drinks per Week or Mean Binges over Time for Participants with Complete Data (All Three Time Points, *N*=422)

Variable	Baseline Mean (SE)	Six Months Mean (SE)	Twelve Months Mean (SE)
Drinks per week <sup>†</sup>			
Special intervention	18.2 (0.83)	12.4 (0.86)	12.8 (1.01)
Usual care	16.1 (0.82)	13.1 (0.93)	13.1 (0.87)
Binge drinking episodes per month <sup><math>\dagger</math></sup>			
Special intervention	4.9 (0.40)	2.8 (0.39)	2.7 (0.35)
Usual care	3.7 (0.43)	2.8 (0.41)	2.3 (0.37)

\*Usual care (n = 202); special intervention (n = 220).

<sup>†</sup>Alcohol intake is assessed as the average number of drinks per week. Binge drinking is defined as drinking on one occasion more than 4 drinks for females or more than 5 drinks for males. SE, standard error.

Table 4. Change in Weekly Drinking Levels and in the Number of
Monthly Binge Drinking Episodes from Baseline to 12 Months by
Treatment Condition $(N = 445)^*$

Variable	Mean Change <sup>‡</sup>	(SE) <sup>‡</sup>	P Value <sup>§</sup> 95% Cl
Change in the average			.03 <sup>§</sup>
Special intervention	- 5.7	(0.74)	(-7.19  to  -4.29)
Usual care	- 3.2	(0.79)	(-4.72  to  -1.73)
Difference	-2.6	(1.08)	(-4.53 to -0.27)
Change in the average			$.36^{\$}$
number of binge drinking			
episodes per month <sup>†</sup>			
Special intervention	-2.0	(0.31)	(-2.58 to -1.37)
Usual care	-1.6	(0.33)	(-2.19 to -0.89)
Difference	-0.4	(0.45)	(-1.33 to -0.45)

\*Usual care (n =210); special intervention (n =235).

<sup>†</sup>Alcohol intake is assessed as the average number of drinks per week. Binge drinking is defined as drinking on one occasion more than 4 drinks for females or more than 5 drinks for males. The change value is calculated as the 12-month value minus the baseline value.

<sup>‡</sup>The mean change in drinks per week and binges per month is the least square mean change (LSMEANS) derived from the mixed-model analysis after adjustment for age, gender, and baseline level of drinking or binging.

 $^{\$}P$  value from the t test for the difference in the least square mean scores between treatment conditions.

SE, standard error; CI, confidence interval.

we found that 42% of SI subjects were drinking at safe levels compared to 29% of UC. Overall, the odds ratio for SI subjects to progress to safe drinking compared to UC was 1.58 (95% confidence interval [CI], 0.99 to 2.52). When we considered drinks per week (n=343) and binges per month (n=339) separately, the odds ratio was 1.60 comparing SI to UC in likelihood of decreasing alcohol intake to safe levels for drinks per week (95% CI, 1.00 to 2.54) and 1.37 for binges per month (95% CI, 0.86 to 2.12); however, only the improvement for drinks per week attained statistical significance.

### Change in Prevalence of Excessive Drinking

As described above, we categorized participants to reflect how their drinking status changed from safe to non–safe drinking over the duration of the study (i.e., from baseline to 6 months and from 6 months to 12 months). Three sets of analyses were done, one for high-risk weekly drinkers, one for high-risk binge drinkers, and one for participants who met either criterion. Conditional on a change to a healthy drinking status at 6 months, we estimated the proportion that relapsed from 6 to 12 months using the mixed-model analysis described above. As seen when both weekly and binge drinking criteria are used, the SI group was significantly less likely to relapse to unsafe drinking from 6 to 12 months, with an odds ratio of relapse of 0.32 favoring the SI group. We also examined the odds that those participants who had not changed to safe drinking at 6 months would change to safe drinking at 12 months. There were no significant differences between the conditions in the proportion of participants changing to safe levels from 6 to 12 months, with approximately 24% of UC and SI participants changing to safe drinking from 6 to 12 months.

### Comment

Project Health demonstrated that brief (5–10 minute) providerdelivered alcohol counseling conducted in the primary care setting during a regular clinic visit can significantly reduce drinking at 12 months in high-risk drinkers and help them to maintain reductions previously achieved. This was evidenced by a significantly greater reduction in number of drinks per week in SI participants, a significantly larger group of SI participants who progressed to safe drinking at 12-month follow-up when compared to UC, and significantly fewer SI participants who had changed to safe drinking at 6 months relapsing to high-risk drinking when compared to UC.

The reduction in alcohol consumption in the UC is consistent with our 6-month results<sup>20</sup> and those of other investigators.<sup>12,14,17,27</sup> Regression to the mean was adjusted for by controlling for baseline values in analyses. The measurement techniques were the same for both groups; therefore, we would not expect regression to the mean to affect each group differentially, given that we have adjusted for baseline drinking. Changes in UC alcohol consumption may represent a true improvement in drinking habits over time, the effect of repeated assessment of drinking behaviors over the course of the study, or some combination of both factors. Additionally, although we controlled for the effect of provider, due to the need to add a site to increase enrollment, 1 site was not randomly assigned. Though the UC and SI groups did not differ on variables related to alcohol history, smoking, and demographics (other than gender), there is a possibility that

 Table 5. The Change in Prevalence of Safe Drinking at 12 Months for Excessive Weekly Drinking, Binge Drinking, and Both Drinking Behaviors

 Combined by Treatment Condition (N = 445)\*

	Usual Care N (%)	Special Intervention N (%)	Odds Ratio (95% CI) $^{\dagger}$	P Value
Safe drinking at baseline	55 (26)	48 (20)		
Safe drinking at 12 months	103 (49)	128 (54)	1.60 (1.00 to 2.54)	.05
No binge drinking at baseline	57 (27)	51 (22)		
No binge drinking at 12 months <sup>‡</sup>	103 (49)	130 (55)	1.37 (0.86 to 2.12)	.18
Safe weekly drinking and non-binge drinking at 12 months	61 (29)	98 (42)	1.58 (0.99 to 2.52)	.06

\*High-risk drinkers were eligible by either excessive weekly drinking using gender-specific cut points (male >12 and female >9 drinks per week); or by binge drinking, measured using gender-specific binge cut points (male >5 and female >4 standard drinks) on one or more occasions in the previous month.

<sup>†</sup>The odds ratio and 95% confidence interval were derived using the Stata GLLAMM. The odds ratio is "risk" of safe drinking at 12 months comparing intervention to usual care adjusted for baseline safe drinking, patient gender, and physician gender.

<sup>‡</sup>Non–binge drinking was defined as no binges per month.

The referent group for the comparison is usual care.

CI, confidence interval.

there is some difference between the treatment and control groups that we did not examine that might have differentially affected treatment outcomes.

Because this is a randomized trial with only 2 sites randomized, we also estimated effect size. With 20 physicians per group (13 patients per physician) and an intraclass correlation of 0.025, we would have 85% power for a mean difference of 3.5 drinks per week. At 12 months, the estimated difference between UC and SI was -2.4 drinks per week, with a 95% confidence interval of -4.7 to -0.5.

Strengths of this study include a high rate of follow-up with our participants (91% at 6 months and 84% at 12 months). This high follow-up rate helps to ensure generalizability to primary care settings that have patient demographics similar to our study population. Additionally, our study was a randomized trial using a "regular" primary care visit during which counseling was done. This sets our study apart from others that have used treatment models which include scheduling of "special" visits for alcohol counseling and helps to confirm the generalizability of brief intervention for high-risk drinkers to the primary care setting where providers are often pressed for time to address many health issues. Our results provide evidence that providers in a primary care setting can effectively help their patients reduce high-risk drinking while briefly addressing these issues within a visit that may have been scheduled to focus on another health issue.

In addition, our physician training program, screening, and office system are adaptable to other primary care practices. Our clinician training was implemented in 2.5 hours and has been shown to be effective in helping clinicians to develop counseling skills.<sup>23</sup> The screening methods used in the current study were labor intensive because brief screening tools for high-risk drinkers had not been well validated at the time of the onset of the study. Since that time, the 10-item Alcohol Use Disorders Test has shown promise as an easily used screening tool for the identification of high-risk drinkers.<sup>28</sup> Office systems that prompt physicians to intervene on other health behaviors (such as smoking) can be modified to include prompting for screening and intervention with high-risk drinkers.

Limitations of this study include the self-report nature of the data. Unfortunately, to date there is not a biological measurement that reliably detects reduction in drinking at moderate levels of alcohol intake, and research indicates that using self-report alcohol consumption is more reliable than other methods of measuring alcohol consumption. We used methods reported in the literature<sup>29-31</sup> to help reduce selfreport bias in the assessment of alcohol intake by telling the patient that this is a research project, that the results will not be entered into his/her medical chart (interview results were put into separate research charts given to providers prior to appointments and retrieved immediately after appointments), and by masking alcohol questions by embedding them in a questionnaire along with questions about other health habits (eating, physical activity, and smoking). Additionally, we used standardized alcohol report methodology for collecting multiple measurements of alcohol use, and collateral calls were made to facilitate high-quality reporting by participants.

Our sample was primarily white and thus is limited in its generalizability to primary care settings without minority populations.

Taken together, the above results confirm the growing literature that demonstrates that screening and brief interven-

tion is effective in reducing high-risk alcohol consumption to safe levels. It also provides support for the durability of changes in alcohol consumption with brief intervention. Additionally, this study shows that screening and brief intervention for high-risk drinking can be done in a regular primary care visit without involving visits set up specifically to focus on alcohol intervention or additional providers. However, even with screening and brief intervention, a substantial proportion (58%) of alcohol users remained in the unsafe drinking category. Therefore, an important question is whether additional interventions, such as telephone counseling by health counselors, would increase the proportion who become safe drinkers and who remain safe drinkers after initial intervention. Incorporation of provider-delivered brief interventions into the regular patient visit requires reminder and training resources. The provision of such resources is both a public health and clinical challenge.

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#### REFERENCES

- Bradley KA, Donovan DM, Larson EB. How much is too much? Advising patients about safe levels of alcohol consumption. Arch Intern Med. 1993;153:2734–40.
- Institute of Medicine. Broadening the Base of Treatment for Alcohol Problems. Washington, DC: National Academy Press; 1990.
- National Institute on Alcohol Abuse and Alcoholism. The Physician's Guide to Helping Patients with Alcohol Problems. USDHHS, PHS, NIH; 1995. Report No. 95-3769.
- Criqui MH. Alcohol consumption, blood pressure, lipids, and cardiovascular mortality. Alcohol Clin Exp Res. 1986;10:564–9.
- Klatsky AL, Friedman GD, Siegelaub AB, Gerard MJ. Alcohol consumption and blood pressure: Kaiser-Permanente Multiphasic Health Examination data. N Engl J Med. 1977;296:1194–200.
- Anda RF, Williamson DF, Remington PL. Alcohol and fatal injuries among US adults. Findings from the NHANES I Epidemiologic Follow-up Study. JAMA. 1988;260:2529–32.
- Rice D. The Economic Cost of Alcohol Abuse and Alcohol Dependence: 1990. Washington, DC: National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health; 1993.
- Fleming MF. Screening and brief intervention for alcohol disorders. J Fam Pract. 1993;37:231–4.
- Oleckno WA, Blacconiere MJ. A multiple discriminant analysis of smoking status and health-related attitudes and behaviors. Am J Prev Med. 1990;6:323–9.
- U.S. Department of Health and Human Services. Current Estimates from the National Health Interview Survey, 1993 (Series 10: Data from the National Health Survey No. 190). Hyattsville, MD: Public Health Service, Centers for Disease Control, National Center for Health Statistics; 1994. Report No. 95-1518.
- Bien TH, Miller WR, Tonigan JS. Brief interventions for alcohol problems: a review. Addiction. 1993;88:315–35.
- Fleming MF, Barry KL, Manwell LB, Johnson K, London R. Brief physician advice for problem alcohol drinkers. A randomized controlled trial in community-based primary care practices. JAMA. 1997; 277:1039–45.
- Kristenson H, Ohlin H, Hulten-Nosslin MB, Trelle E, Hood B. Identification and intervention of heavy drinking in middle-aged men: results and follow-up of 24–60 months of long-term study with randomized controls. Alcohol Clin Exp Res. 1983;7:203–9.
- Wallace P, Cutler S, Haines A. Randomized controlled trial of general practitioner intervention in patients with excessive alcohol consumption. BMJ. 1988;297:663–8.
- Wilk AI, Jensen NM, Havighurst TC. Meta-analysis of randomized control trials addressing brief interventions in heavy alcohol drinkers. J Gen Intern Med. 1997;12:274–83.

- Fleming MF, Manwell LB, Barry KL, Adams W, Stauffacher EA. Brief physician advice for alcohol problems in older adults: a randomized community-based trial. J Fam Pract. 1999;48:378–84.
- Fleming MF, Mundt MP, French MT, Manwell LB, Stauffacher EA, Barry KL. Benefit-cost analysis of brief physician advice with problem drinkers in primary care settings. Med Care. 2000;38:7–18.
- Ockene IS, Hebert JR, Ockene JK, Merriam P, Hurley TG, Saperia GM. Effect of training and a structured office practice on physiciandelivered nutrition counseling: the Worcester-area Trial for Counseling in Hyperlipidemia (WATCH). Am J Prev Med. 1996;12:252–8.
- Ockene JK, Kristeller J, Goldberg R, et al. Increasing the efficacy of physician-delivered smoking intervention: a randomized clinical trial. J Gen Intern Med. 1991;6:1–8.
- Ockene JK, Adams A, Hurley TG, Wheeler EV, Hebert JR. Brief physician- and nurse practitioner-delivered counseling for high- risk drinkers: does it work? Arch Intern Med. 1999;159:2198–205.
- American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 3rd ed. Washington, DC: American Psychiatric Association; 1987.
- Fleming MF, Barry KL. A three-sample test of a masked alcohol screening questionnaire. Alcohol Alcohol. 1991;26:81–91.

- Adams A, Ockene JK, Wheeler EV, Hurley TG. Alcohol counseling: physicians will do it. J Gen Intern Med. 1998;13:692–8.
- Rabe-Hesketh S, Skrondal A, Pickles A. Reliable estimation of generalized linear mixed models using adaptive quadrature. Stata Tech J. 2002; 2:1–21.
- Rubin DB. Multiple Imputation for Nonresponse in Surveys. New York, NY: John Wiley & Sons; 1987.
- Rubin DB. Multiple imputation after 18+ years. J Am Stat Assoc. 1996; 91:473–89.
- Group WHOBIS. Across national trial of brief interventions with heavy drinkers. Am J Public Health. 1996;86:948–55.
- Allen JP, Litten RZ, Fertig JB, Babor T. A review of research on the Alcohol Use Disorders Identification Test (AUDIT). Alcohol Clin Exp Res. 1997;21:613–9.
- Babor TF, Steinberg K, Anton R, Del Boca F. Talk is cheap: measuring drinking outcomes in clinical trials. J Stud Alcohol. 2000;61:55–63.
- Babor T, Stephens R, Marlatt G. Verbal reports methods in clinical research in alcoholism: response bias and its minimization. J Stud Alcohol. 1987;48:410–24.
- Babor T, Brown J, Del Boca F. Validity of self-reports in applied research on addictive behaviors: fact or fiction? Behav Assess. 1990;12:5–31.