Brief Physician- and Nurse Practitioner–Delivered Counseling for High-Risk Drinkers

Does It Work?

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Background: There is a need for primary care providers to have brief effective methods to intervene with high-risk drinkers during a regular outpatient visit.

Objective: To determine whether brief physician- and nurse practitioner–delivered counseling intervention is efficacious as part of routine primary care in reducing alcohol consumption by high-risk drinkers.

Methods: Academic medical center–affiliated primary care practice sites were randomized to special intervention or to usual care. From a screened population of 9772 patients seeking routine medical care with their primary care providers, 530 high-risk drinkers were entered into the study. Special intervention included training providers in a brief (5- to 10-minute) patient-centered counseling intervention, and an office support system that screened patients, cued providers to intervene, and made patient education materials available. The primary outcome measures were change in alcohol use from baseline to 6 months as measured by weekly alcohol consumption and frequency of binge drinking episodes.

Results: Participants in the special intervention and usual care groups were similar on important background variables and potential confounders except that special intervention participants had significantly higher baseline levels of alcohol usage ($P = .01$). At 6-month follow-up, in the 91% of the cohort who provided follow-up information, alcohol consumption was significantly reduced when adjusted for age, sex, and baseline alcohol usage (special intervention, $-5.8$ drinks per week; usual care, $-3.4$ drinks per week; $P = .001$).

Conclusions: This study provides evidence that screening and very brief (5- to 10-minute) advice and counseling delivered by a physician or nurse practitioner as part of routine primary care significantly reduces alcohol consumption by high-risk drinkers.

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Physicians have contact with at least 80% of Americans each year, including the 20% to 25% of patients who identify themselves on outpatient screening tests as drinking alcohol at high-risk levels. Thus, several million adult high-risk drinkers could be reached annually by physicians during the course of ongoing medical care. This high contact rate, coupled with even a small absolute effect on moderation or cessation of alcohol overuse, could have substantial benefits to the health of a primary care (PC) population and to the health of the public.

High-risk drinking refers to a drinking pattern that has a high probability of causing harm (eg, frequent intoxication) and is an important public health problem; one in every 10 deaths in the United States is related to alcohol, and 20% of the total national hospital costs are attributable to alcohol-related illnesses. Therefore, the development of brief efficacious alcohol counseling interventions that can be used in an outpatient setting is of national importance.

Previous research, carried out predominantly in Europe, has suggested that socially stable, heavily drinking patients seen in general practitioners’ offices respond to intervention strategies consisting of 30 minutes of alcohol-related advice. Meta-analyses of randomized clinical trials conducted in health care settings found a similar effect size (20%-30% reduction). A recent randomized clinical trial set in family practitioners’ offices demonstrated a similar reduction in alcohol consumption found after receipt of two 15-minute sessions of physician advice, education, and contracting occurring as special visits for alcohol intervention, with follow-up telephone calls made by study nurses 2 weeks after each of the physician visits.
SUBJECTS AND METHODS

HEALTH CARE PROVIDERS

Four PC internal medicine practice sites (as defined by separate nursing staff, patient assignments, and coverage arrangements) at the University of Massachusetts Memorial Healthcare, Inc, Worcester, were randomized to special intervention (SI) or usual care (UC) conditions. Studies involving delivery of behavioral interventions by providers at specific practice sites require randomization at the level of practice site.11 Two adjacent practice sites were randomized as a single unit to prevent contamination. Randomization was accomplished by means of the random number generator in SAS statistical software.13

All except 1 of the 47 attending physicians and nurse practitioners agreed to participate. The attending physicians were board-certified internists, and other provider characteristics were similar across conditions (Table 1) with the exception that a greater percentage of UC providers reported having had previous training in alcohol counseling.

STUDY POPULATION

Patients between 21 and 70 years of age scheduled to be seen by study PC providers between April 1, 1994, and April 1, 1997, were screened for high-risk drinking. Patients eligible for the study were high-risk drinkers, defined as men who drank more than 12 standard drinks per week (12.8 g of alcohol per drink, eg, 5 fl oz [150 mL] of wine, 12 fl oz [360 mL] of beer, 1.5 fl oz [45 mL] of 80-proof liquor) or who binged (consumed 4 or more standard drinks) on 1 or more occasions in the previous month. Women were included in the study sample if they drank more than 9 standard drinks per week or binged (consumed 4 or more standard drinks) on 1 or more occasions in the previous month. Only 2% of our sample reported symptoms or signs of alcohol dependency (ie, symptoms of physical withdrawal or reported unsuccessful attempts at cutting down on drinking); no patient was excluded because of excessive drinking. Patients were excluded from the study if they were pregnant; 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 other than substance abuse that, in the judgment of the provider or research assistant (RA), prevented them from participating; or were unable to complete the informed consent.

ASSESSMENT

The RAs screened patients by telephone, by mail, or at a visit in the Primary Care Center by means of a brief standardized screening instrument of health habits, the Health Habits Survey.17 This validated instrument contains questions on alcohol that are embedded in questions on general health habits. This information would help determine whether there was differential misreporting between SI and UC participants. Participants also were told that they might be called for more interviews in the future.

Patients were entered into the study if they saw their PC provider within 6 months of the baseline assessment. Immediately after the enrollment visit, a random subset (65%) of participants in both conditions completed a standardized Patient Exit Interview. This interview, conducted in person or by telephone if the patient was missed at the clinic, assessed the content of the provider’s intervention.21 It contained questions to determine whether the provider had implemented alcohol counseling steps and which steps, of a possible 15 (corresponding to the intervention steps taught), were implemented. As with the other surveys and interviews, these questions were embedded among parallel questions on diet, smoking, and exercise.

Follow-up interviews were conducted by blinded RAs at 6 months after the initial visit. The primary objective of the 6-month interview was to assess change in alcohol use, and questions on alcohol were embedded in questions on the previously noted multiple health habits.

INTERVENTIONS

After the assessment was completed, UC participants received a health booklet that included advice on general health issues and were told to address any health questions with their providers. The UC 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 assessments were 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.

Continued on next page
The SI providers received 2½ hours of training in the patient-centered alcohol intervention program. The training included 2 group sessions, an individual tutorial, and feedback on their taped role-play counseling sessions. The change in orientation required to work with high-risk drinkers (where the goal may be reduction in drinking) vs alcohol-dependent patients (where the goal is abstinence) was emphasized. 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 as high-risk drinkers. Counseling focused on the number of drinks per week, binge drinking, or both, depending on the participant’s problem area(s). The training and intervention are described in more detail elsewhere.26 The SI providers were instructed to request that the patient set a follow-up visit to review progress.

The SI office sites also had a limited office support system designed to assist the busy PC provider in carrying out the intervention. Although implemented by Project Health RAs, the system was designed to be incorporated easily into usual office procedures and includes the RA affixing the following to the chart of the high-risk drinker:

- The Lifestyle Interview summary sheet, which reports the participant’s alcohol history (drinks per week, history of binge drinking, family history of alcohol abuse)
- The intervention algorithm (Figure) to remind the physician of the counseling sequence taught in the training sessions
- Patient education materials in the form of tip sheets for the provider’s use with patients.

STATISTICAL ANALYSIS

The primary end point used to assess the effectiveness of the intervention was change in alcohol consumption measured at 6 months, ie, change in the total number of drinks consumed per week, and the number of episodes of binge drinking per month (a change score was calculated for both as the 6-month minus the baseline measure). Subjects also were categorized as drinking at safe (ie, both safe weekly alcohol consumption and nonbinge drinking) or unsafe levels based on sex-specific cutoff points, as described above. The necessary sample size was determined to permit detection of a clinically significant decrease in alcohol consumption (a difference of at least 2 drinks per week between conditions).

Treatment conditions were compared for patient and physician characteristics for the categorical variables by means of the χ² test of homogeneity, or Fisher exact test when warranted by small cell sizes. For continuous variables we used a 2-sample t test. Continuous measures of alcohol intake were assessed for skewness and kurtosis. We found that these measures were slightly skewed, and subsequently a nonparametric test (Wilcoxon 2-sample test) was used for the between-treatment condition comparison. All analyses were conducted in SAS.13

The practice site was the unit of randomization and intervention, and the patient was the unit of measurement. Despite the fact that the number of patients far exceeded the number of providers (530 vs 46), it is likely 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, thus reducing the total available degrees of freedom for analysis to fewer than 530. The analyses take into consideration the within-provider group correlation of patient characteristics. For continuous measures, such as drinks per week and episodes of high-risk drinking (binges per month), a mixed-model analysis of covariance was used. This analytic approach allowed us to account for the nested nature of the study design (randomization occurred at the level of the practice, within which provider and patient were nested). Provider was included as a random effect, while treatment condition was fit as a fixed effect. In this model, we controlled for patient age and sex and baseline level of consumption. We examined the interaction between these factors and treatment condition, as well as the effects of other potentially important covariates, such as number of provider visits during the first 6 months (ie, 1 or more than 1), patient level of education, provider type, and previous training in alcohol counseling (which differed between the treatment conditions).

Preliminary analyses were performed on all variables to assess the adequacy of the assumptions of linear regression (ie, normality, linearity, and independence). Diagnostic statistics were used to examine model fit and to identify outliers. We identified several potentially problematic outliers. Subsequently, we fit the model with and without these observations and found that the results were not materially changed. Therefore, the final model includes all subjects for whom we had complete data (n = 481).

Study participants qualified for entry into the study on the basis of either consumption of an excessive number of drinks per week or the occurrence of episodes of binge drinking (67% of study subjects exhibited both behaviors). Since the intervention was not designed to treat these groups differently, the main outcome analyses focus on the entire group of subjects with 6-month outcome data (n = 481), regardless of why they entered the study. The effect of this analytic approach is to reduce the ability to see an intervention effect, because subjects with low baseline levels of alcohol consumption (they qualified on the basis of binge drinking) are included in the analysis. Additionally, we examined the study outcomes separately in the subset of subjects defined by each of these 2 criteria (ie, excessive weekly drinking at baseline, n = 360; and binge drinking at baseline, n = 360). Among drinkers classified as consuming unsafe levels of alcohol at baseline, we assessed the crude rate of progression to safe levels of drinking at 6-month follow-up by using contingency table methods. Odds ratios and their 95% confidence intervals were calculated as measures of the likelihood of drinking behavior change in the SI relative to the UC condition.

For each 6-month end-point analysis, we assessed the data with the use of the 481 participants for whom 6-month data were available. To evaluate the impact of missing outcome data, we also examined the data from the full cohort of 530 participants. In this analysis, we assigned the baseline value for the missing follow-up value, taking the conservative approach and assuming that those individuals unavailable for follow-up were unlikely to have made any changes in their drinking patterns. Because the follow-up rate was equal for both conditions, this approach would bias the result toward the null hypothesis of no effect.
On the basis of the results of our previous research in other health-related behaviors (ie, smoking and diet) demonstrating that very brief patient-centered behavioral counseling is an effective intervention modality when delivered by PC physicians, we decided to test its effect with high-risk drinkers. Patient-centered counseling, a collaboration between the physician and the patient, requires that the physician use skills such as questioning and feedback to help the patient develop a positive self-efficacy regarding his or her ability to make a behavioral change, to collaborate on the development of a plan for action, and to negotiate change goals. This approach differs from traditional physician-patient interactions in which the physician “advises” the patient about what to do. To date, the patient-centered counseling approach has not been adapted for use with high-risk drinkers. The use of such an approach, although not generally familiar to physicians, is consistent with recent developments in the training of physicians in communication skills. Brief (5- to 10-minute) patient-centered counseling can be an effective means of involving the less-motivated high-risk drinker, whereas initial confrontation with traditional physician-centered advice can result in a patient who does not return for follow-up.

Herein are presented the findings from Project Health, a large randomized clinical trial designed to test the efficacy of a very brief, provider-delivered, patient-centered alcohol counseling intervention on reduction of alcohol usage by high-risk drinkers. It is the first such trial, to our knowledge, conducted in the United States of alcohol usage by high-risk drinkers. It is the first such trial, to our knowledge, conducted in the United States in internal medicine offices and in the context of a regularly scheduled visit.

RESULTS

STUDY RECRUITMENT, INTERVENTION IMPLEMENTATION, AND FOLLOW-UP

There were 9772 patients from 4 PC practice sites (comprising 65% of patients enrolled in the practice panels) screened with the Health Habits Survey. Of those, 1760 patients (18%) screened positive for high-risk drinking. A total of 1500 (85%) of the 1760 potentially eligible patients were reached by telephone, and 99% agreed to complete the interview, 16 refused and 33 were unavailable at the 6-month follow-up interview (91% of the SI group and 87% of the UC group). Among the 49 who did not complete the interview, 16 refused and 33 were unavailable for follow-up (ie, they moved or could not be located).

PATIENT CHARACTERISTICS

Patient demographics did not differ between study conditions (Table 2). Significantly more women reported a family history of alcohol abuse (54%) than did men (44%) (P = .05), with no difference seen by treatment condition. Thirty-three percent were smokers and 18% had ever used prescription sleep medications. Baseline mean alcohol consumption was significantly higher among participants in the SI condition (18.7 drinks per week) than those in the UC condition (16.4 drinks per week) (Table 2).

ALCOHOL OUTCOME MEASURES

Comparison of the unadjusted changes from baseline to 6 months in the primary outcome measure, weekly alcohol consumption, showed a significant difference (P = .003) between the 2 conditions for the 481 participants who provided 6-month follow-up (Table 3).

Table 1. Provider Characteristics by Treatment Condition (n = 46)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care</th>
<th>Special Intervention</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y</td>
<td>33.8 ± 5.3</td>
<td>36.4 ± 6.7</td>
<td>.16†</td>
</tr>
<tr>
<td>Years since received degree, mean ± SD</td>
<td>7.2 ± 4.6</td>
<td>9.5 ± 6.1</td>
<td>.18†</td>
</tr>
<tr>
<td>Sex, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>10 (53)</td>
<td>11 (41)</td>
<td>.43‡</td>
</tr>
<tr>
<td>F</td>
<td>9 (47)</td>
<td>16 (59)</td>
<td></td>
</tr>
<tr>
<td>Provider type, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending physician</td>
<td>11 (58)</td>
<td>15 (56)</td>
<td>1.00§</td>
</tr>
<tr>
<td>Resident physician</td>
<td>5 (26)</td>
<td>7 (26)</td>
<td></td>
</tr>
<tr>
<td>Nurse practitioner</td>
<td>3 (16)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Prior training in alcohol counseling, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6 (32)</td>
<td>17 (68)</td>
<td>.02†</td>
</tr>
<tr>
<td>Yes</td>
<td>13 (68)</td>
<td>8 (32)</td>
<td></td>
</tr>
</tbody>
</table>

*Some providers did not answer the question about prior training.
†A 2-sample t test was used to compare treatment conditions. The P value is for the test of equality in group mean values.
‡The test of homogeneity of proportions was assessed by the x² statistic.
§Fisher exact text. The P value is for the test of equality in proportions in the 2 groups.
The data also were analyzed by adjusting for baseline alcohol consumption, age, and sex (Table 4). Significant reduction in weekly alcohol consumption was seen in the SI condition (adjusted mean reduction, 5.8 drinks per week) as compared with the UC condition (adjusted mean reduction, 3.4 drinks per week). However, there was only a suggestion of a significant decrease in the number of binge drinking episodes per month for SI (adjusted mean reduction, 1.8 episodes per month) compared with UC (adjusted mean reduction, 1.0 episode per month) participants (P = .09; Table 4).

In the mixed-model analysis, we controlled for age, sex, and baseline level of drinking. Age was not associated with a reduction in alcohol consumption; however, sex was observed to be a strong independent predictor (P = .002). Although men in both study conditions drank more heavily than the women at baseline and at 6 months, women demonstrated a nearly 2-fold greater relative reduction in alcohol consumption than did men. To explore this association more completely, we fit a treatment condition–by-sex term in the mixed model and found that there was not a significant interaction effect. Thus, although women reduced their alcohol consumption to a greater extent than men, this difference was unrelated to the intervention.

Among high-risk drinkers who were excessive weekly drinkers (for men, >12 drinks per week; for women, >9 drinks per week) at baseline, a significantly greater percentage in the SI condition (54%) achieved safe weekly drinking levels at 6 months than in the UC condition (39%) (P = .01; Table 5). Participants in the SI condition were 1.8 times more likely than the UC participants to have reduced their drinking to safe levels at 6 months. Among binge drinkers there was no signifi-
Table 3. Baseline and 6-Month Measures of Weekly Alcohol Intake by Treatment Condition and Sex (n = 481)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care (n = 233)</th>
<th>Special Intervention (n = 248)</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (overall)</td>
<td>16.4 ± 12.1</td>
<td>18.7 ± 14.6</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>19.4 ± 14.4</td>
<td>20.8 ± 16.4</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>12.2 ± 5.6</td>
<td>14.4 ± 8.6</td>
<td></td>
</tr>
<tr>
<td>6-mo (overall)</td>
<td>13.3 ± 12.7</td>
<td>12.6 ± 14.2</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>16.6 ± 14.8</td>
<td>15.1 ± 16.2</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>8.7 ± 6.6</td>
<td>7.6 ± 6.7</td>
<td></td>
</tr>
<tr>
<td>Change (overall)</td>
<td>-3.1 ± 10.2</td>
<td>-6.0 ± 11.2</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>-2.9 ± 11.9</td>
<td>-5.6 ± 12.5</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>-3.5 ± 7.0</td>
<td>-6.8 ± 8.0†</td>
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</tbody>
</table>

*Alcohol intake was assessed as the average number of drinks per week.
†Change in drinking level calculated as the 6-month value minus the baseline value.
‡Two-sample t test comparing treatment conditions: overall (P = .003), men (P = .05), and women (P = .003).

Table 4. Multivariable Model Results for Change in Weekly Drinking Levels and Change in the Number of Monthly Binge Drinking Episodes From Baseline to 6 Months (n = 481)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SE)</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in average number of drinks per week</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention (n = 248)</td>
<td>-5.8 (0.63)</td>
<td>-7.03 to -4.57</td>
<td>.001</td>
</tr>
<tr>
<td>Usual care (n = 233)</td>
<td>-3.4 (0.86)</td>
<td>-4.69 to -2.11</td>
<td></td>
</tr>
<tr>
<td>Difference</td>
<td>-2.4 (0.92)</td>
<td>-4.20 to -0.60</td>
<td></td>
</tr>
<tr>
<td>Change in average number of binge drinking episodes per month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention (n = 248)</td>
<td>-1.8 (0.31)</td>
<td>-2.41 to -1.19</td>
<td>.09</td>
</tr>
<tr>
<td>Usual care (n = 233)</td>
<td>-1.0 (0.32)</td>
<td>-1.63 to -0.37</td>
<td></td>
</tr>
<tr>
<td>Difference</td>
<td>-0.8 (0.45)</td>
<td>-1.68 to 0.08</td>
<td></td>
</tr>
</tbody>
</table>

*Alcohol intake was assessed as the average number of drinks per week. Binge drinking was defined as drinking on 1 occasion more than 4 drinks for women or more than 5 drinks for men. The change value is calculated as the 6-month value minus the baseline value.
†The mean change in drinks per week or binges per month is the least-squares mean change after adjustment for age, sex, and baseline level of drinking or bingeing.
‡P value for the t test for the difference of the least-squares mean scores between treatment conditions. CI indicates confidence interval.

Significant difference in the percentage of SI and UC participants who reduced the number of binge drinking episodes to zero. In the combined category, excessive weekly or binge drinking or both (n = 481), significantly more SI participants (39%) than UC participants (28%) became safe drinkers (P = .02; Table 5).

Significant SI-UC differences (P = .004) remained when the entire study cohort of 530 participants was included in the analysis, with the use of baseline levels of drinking for the 49 participants not available for 6-month follow-up. That is, mean alcohol reduction for the SI condition (adjusted mean reduction, 4.3 drinks per week) was significantly greater (P = .01) than for the UC condition (adjusted mean reduction, 3.1 drinks per week).

Table 5. Change in Prevalence and Odds Ratio of Excessive Weekly Drinking and Binge Drinking by Treatment Condition*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care, No. (%)</th>
<th>Special Intervention, No. (%)</th>
<th>Odds Ratio (95% CI)‡ P‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive weekly drinking at baseline (n = 360)</td>
<td>170 (100)</td>
<td>190 (100)</td>
<td>1.83 (1.20 to 2.78) .01</td>
</tr>
<tr>
<td>Safe drinking at 6 mo§</td>
<td>66 (39)</td>
<td>102 (54)</td>
<td></td>
</tr>
<tr>
<td>Binge drinking at baseline (n = 366)</td>
<td>174 (100)</td>
<td>192 (100)</td>
<td>1.24 (0.81 to 1.90) .32</td>
</tr>
<tr>
<td>Nonbinge drinking at 6 mo§</td>
<td>61 (35)</td>
<td>77 (40)</td>
<td></td>
</tr>
<tr>
<td>Excessive weekly drinking or binge drinking at baseline (n = 481)</td>
<td>233 (100)</td>
<td>248 (100)</td>
<td></td>
</tr>
<tr>
<td>Safe weekly drinking and nonbinge drinking at 6 mo§</td>
<td>66 (28)</td>
<td>96 (39)</td>
<td></td>
</tr>
</tbody>
</table>

*High-risk drinkers were eligible either by excessive weekly drinking with sex-specific cutoff points (men, >12 drinks per week; women, >9 drinks per week) or by binge drinking, measured with sex-specific binge cutoff points (men drank >5 standard drinks and women drank >4 standard drinks) on 1 or more occasions in the previous month.
†The unadjusted odds ratio for change to safe drinking where the referent group is the usual care. CI indicates confidence interval.
‡The test of homogeneity of proportions was assessed with the x² statistic.
§Nonbinge drinking was defined as no binges per month.

COLLATERAL REPORTS

Collateral contacts for 10% of the sample were interviewed by means of a standardized telephone interview. No significant differences in reporting discrepancies were seen between collaterals and participants in the 2 study conditions.

COMMENT

Project Health demonstrated that significant reductions in alcohol consumption can be achieved for male and female high-risk drinkers with screening and brief (5- to 10-minute) physician- or nurse practitioner–delivered alcohol counseling. At 6 months there was almost a 2-fold adjusted mean reduction in weekly consumption for participants in the SI as compared with the UC condition. This is even more impressive when one considers that 41% of the participants received only one 5- to 10-minute counseling intervention with their PC provider.

The reduction in alcohol consumption seen in the UC condition for men and women parallels the findings of previous studies.6,9,27 This may result from regression to the mean; a true change in drinking habits; the intervention effect of the research assessment protocol, which asked questions about alcohol usage on 3 occasions for both SI and UC participants; or a combination of all 3 factors. Of note, however, the matter of regression to the mean was addressed statistically by accounting for baseline level of drinking in all regression analyses.
The greater reductions in weekly alcohol use seen among the women in both conditions are consistent with the results from previous studies. The reasons for these greater reductions are not clear.

In our assessment of the study outcomes, we examined the association of change in patient drinking behavior with a number of potential confounders: previous training of providers, number of visits to providers, and educational level of participants. A significantly greater number of UC providers had received training in some form of alcohol counseling before the present study (Table 1). We fit this variable in our mixed-model (previous training, yes or no) and found that it was not significantly associated with participants’ change in alcohol use. Regarding the number of visits to providers, 59% of the study participants saw their providers for 1 or more additional visits after the initial visit and before the 6-month follow-up. When we fit a variable for extra visits (none vs 1 or more), we found that there was a trend toward a larger reduction in alcohol consumption (P = .12) in participants having multiple provider visits. One potential explanation for the lack of a stronger observed effect of additional contacts could be that little intervention actually took place at follow-up visits. We do not have measures to indicate how much intervention occurred. The effect of “dosage” of provider intervention on reduction of alcohol usage for high-risk drinkers is an area for future investigation. The educational level of individuals has been demonstrated to be related to behavior change outcomes (eg, smoking\(^29\)), making this an important variable to examine for alcohol use change. In the current study, education was weakly associated with change in alcohol consumption (P = .12). Individuals with less than a high school education experienced a smaller reduction in their drinking compared with those with more education. Tailoring treatment strategies to educational level is an area worthy of future investigation. To date, no major trial investigating brief intervention for alcohol use has reported on this.\(^8,9,27\)

Project Health has a number of unique strengths. It is the only randomized trial, to our knowledge, looking at the effect of a very brief provider-delivered intervention in the context of a “regular” visit. It is the second largest randomized, clinical trial of brief alcohol intervention set in the United States, with the largest being Fleming and colleagues’ study with 774 participants.\(^9\) However, intervention in the latter study was carried out during 2 specially scheduled visits with the physician, followed by a telephone call from the clinic nurse 1 week after each visit. In the present study, that the very brief intervention occurred as part of a regular visit to a PC provider, not as a special alcohol visit, makes it more generalizable to a “real-world” setting. Six-month follow-up occurred for 91% of the study sample. The generalizability of these results extends to the PC population studied. Alcohol-dependent patients were not excluded from this study, but only 2% of the sample reported symptoms of alcohol dependency (ie, symptoms of physical withdrawal from alcohol or reported unsuccessful attempts to cut down on drinking). Patients with notable psychiatric illness, such as psychoses and active suicidality, were excluded.

There were several limitations to the study. The outcomes were based on self-report, which raises questions about their validity. However, research indicates that bias attributed to self-report is minimized by (1) telling the patient that this is a research project (results are not entered into his or her medical record); (2) masking alcohol questions by embedding them in questions about other health habits such as weight, exercise, and smoking; and (3) using structured, standardized alcohol report measures that collect multiple measures of alcohol usage and include corroboration by collateral report.\(^23,24\) Another limitation is that our sample included few minorities and is not able to establish the effectiveness of this intervention for minority populations.

The 1990 Institute of Medicine report\(^29\) observes that, because there are many more high-risk drinkers than there are alcohol-dependent drinkers (roughly 4 times as many), the focus of intervention should be on patients with mild to moderate alcohol problems. Project Health demonstrates that screening and a very brief, low-intensity, patient-centered counseling intervention delivered by a PC provider during a regularly scheduled visit can have a significant impact on this population of drinkers. The challenge remains to assess the optimal intensity and frequency of these interventions to maximize and extend the duration of their effectiveness on modifying the behavior of the high-risk drinker.

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