Brief Physician Advice for Problem Alcohol Drinkers

A Randomized Controlled Trial in Community-Based Primary Care Practices

Michael F. Fleming, MD, MPH; Kristen Lawton Barry, PhD; Linda Baier Manwell; Kristen Johnson, MA; Richard London, MD

Objective.—Project TrEAT (Trial for Early Alcohol Treatment) was designed to test the efficacy of brief physician advice in reducing alcohol use and health care utilization in problem drinkers.

Design.—Randomized controlled clinical trial with 12-month follow-up.

Setting.—A total of 17 community-based primary care practices (64 physicians) located in 10 Wisconsin counties.

Participants.—Of the 17 695 patients screened for problem drinking, 482 men and 292 women met inclusion criteria and were randomized into a control (n=382) or an experimental (n=392) group. A total of 723 subjects (93%) participated in the 12-month follow-up procedures.

Intervention.—The intervention consisted of two 10- to 15-minute counseling visits delivered by physicians using a scripted workbook that included advice, education, and contracting information.

Main Outcome Measures.—Alcohol use measures, emergency department visits, and hospital days.

Results.—There were no significant differences between groups at baseline on alcohol use, age, socioeconomic status, smoking status, rates of depression or anxiety, frequency of conduct disorders, lifetime drug use, or health care utilization. At the time of the 12-month follow-up, there were significant reductions in 7-day alcohol use (mean number of drinks in previous 7 days decreased from 19.1 at baseline to 11.5 at 12 months for the experimental group vs 18.9 at baseline to 15.5 at 12 months for controls; t=4.33; P<.001), episodes of binge drinking (mean number of binge drinking episodes during previous 30 days decreased from 5.7 at baseline to 3.1 at 12 months for the experimental group vs 5.3 at baseline to 4.2 at 12 months for controls; t=2.81; P<.001), and frequency of excessive drinking (percentage drinking excessively in previous 7 days decreased from 47.5% at baseline to 17.8% at 12 months for the experimental group vs 48.1% at baseline to 32.5% at 12 months for controls; t=4.53; P<.001). The χ^2 test of independence revealed a significant relationship between group status and length of hospitalization over the study period for men (P<.01).

Conclusions.—This study provides the first direct evidence that physician intervention with problem drinkers decreases alcohol use and health resource utilization in the US health care system.

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From the Department of Family Medicine (Dr Fleming and Ms Johnson) and the Center for Addiction Research and Education (Dr Fleming and Ms Manwell), University of Wisconsin Medical School, Madison; Department of Veterans Affairs, Serious Mental Illness Treatment Research and Evaluation Center, and the Department of Psychiatry, University of Michigan, Ann Arbor (Dr Barry); and the Family Health Plan Cooperative, Milwaukee, Wis (Dr London).

Reprints: Michael Fleming, MD, MPH, 777 S Mills St, Madison, WI 53715.

ALCOHOL USE disorders are an important public health problem. Alcohol use is associated with a number of adverse health and economic effects.[1] Problem drinking is associated with increased mortality rates and with premature mortality. Estimates indicate that 9 to 22 years of life are lost for an individual death from alcoholic liver disease compared with 2 years for cancer and 4 years for heart disease.[2] Fetal alcohol effects occur in 1 in 1000 live births,[3] and the total cost of alcohol-related deaths exceeds $75 billion per year in the United States.[4] As a result of these findings, the testing of effective alcohol abuse prevention strategies has become an important national research priority.

For editorial comment see p 1079.

One method of prevention is to use brief intervention techniques in clinical settings to reduce alcohol use in nondependent problem drinkers. These clinically based interventions include assessment and direct feedback, contracting and goal setting, behavioral modification techniques, and using written materials such as self-help manuals.[5-7] A number of trials, conducted primarily in Europe, have examined the efficacy of brief advice in reducing alcohol use.

Kristenson et al[8] reported the results of a trial conducted in Malmö, Sweden, in the late 1970s. The subjects, advised to reduce their alcohol use in a series of visits, subsequently demonstrated significant reductions in γ-glutamyl transferase levels and health care utilization for up to 5 years after the brief interventions. The Medical Research Council (MRC) trial, conducted in 47 general

practitioners' offices in Great Britain,[9] found significant reductions in alcohol use by the intervention group compared with the control group 12 months following the intervention. The World Health Organization Trial, conducted in 10 countries, found similar differences in alcohol use between the control and intervention groups.[10] Meta-analyses conducted by Bien et al[11] and Kahan et al[12] found an effect size of 20% to 30% in studies conducted in health care settings.

This article presents the results from Project TrEAT (Trial for Early Alcohol Treatment), the first large US clinical trial conducted in community-based primary care practices to test the efficacy of brief physician advice in reducing alcohol use by problem drinkers. This randomized controlled trial reports 1-year outcome data. The research procedures and measures were similar to those used in the MRC trial.[9]

METHODS

Protocol

Physician–Clinic Site Recruitment.—Physicians were recruited in 1992 through the Wisconsin Research Network, Madison, local community hospitals, managed care organizations, and personal contacts. Physicians who participated in the trial met the following criteria: (1) trained in family medicine or internal medicine; (2) practicing medicine at least 50% time; (3) based in a community primary care clinic outside a university or Department of Veterans Affairs medical center; (4) amenable to participating in a training program; and (5) amenable to following the research protocol. Physicians or their practices were paid $300 for participation in the trial.

A total of 64 family physicians and general internists participated in the trial. The 17 clinics, located in rural and urban areas in south central and southeastern Wisconsin, varied from solo sites to large health maintenance organization (HMO) groups. The 46 male physicians and 18 female physicians had a mean age of 46 years with an average of 13 years in practice. All physicians were board eligible or board certified in family medicine or internal medicine. A total of 34 physicians (53%) had received prior training in alcohol use disorders in medical school and residency. Of the physicians, 22 practiced in a staff-model HMO in Milwaukee County; 15 practiced in 3 preferred provider organization models located in Dane County; and the remaining 27 physicians were in private practices located in small rural communities.

Study Population.—All adult patients aged 18 to 65 years were asked to complete a health screening survey by reception personnel as they arrived for regularly scheduled appointments to see their primary care physicians. The rate of patient refusal varied by clinic with a range of 2% to 30% and a weighted mean of 13% for an 87% response rate. All patients who screened positive and who had signed a consent form were contacted by telephone by 1 of 10 researchers and invited to participate in a face-to-face interview to determine their eligibility for the trial. The characteristics of the sample are reported in Table 1.

Inclusion Criteria.—Problem drinkers were defined as men who drank more than 14 drinks a week (168 g of alcohol) and women who drank more than 11 drinks a week (132 g of alcohol). Patients were excluded from participation in the study if they were pregnant, younger than 18 years or older than 65 years, had attended an alcohol treatment program in the previous year, reported symptoms of alcohol withdrawal in the last 12 months, received advice from their physician in the previous 3 months to change their alcohol use, drank more than 50 drinks per week, or reported symptoms of suicide. Patients were paid a total of $50 if they completed the required procedures. Informed consent was obtained from patients prior to the face-to-face interview. The research protocol was reviewed and approved by the University of Wisconsin Human Subjects Committee.

Intervention Protocol.—The brief intervention protocol consisted of a workbook that contained feedback regarding current health behaviors, a review of the prevalence of problem drinking, a list of the adverse effects of alcohol, a worksheet on drinking cues, a drinking agreement in the form of a prescription, and drinking diary cards. The intervention was based on protocols developed for the MRC trial. Two 15-minute visits with the physician were scheduled 1 month apart (brief intervention and reinforcement session). Each patient received a follow-up telephone call from the clinic nurse 2 weeks after each meeting with the physician.

Outcome Variables.—The primary outcome variables of interest were changes in alcohol use (previous 7-day use, binge drinking, excessive drinking), health care utilization (hospital days and emergency department visits), and changes in health status measures (smoking status, depression, motor vehicle crashes, and unintentional injuries). The variables were selected a priori and were based on the findings of previous trials.[8-10] Biological measures such as γ-glutamyl transferase were not included owing to low sensitivity in this population.[2]

Research Procedures.—All patients aged 18 to 65 years with regularly scheduled appointments between April 1, 1992, and April 1, 1994, were asked to complete the health screening survey. The survey was designed as a general lifestyle questionnaire in order to increase patient acceptance of the research procedures and to minimize the intervention effect of the alcohol questions.[13] The survey contained 4 sets of parallel questions on exercise, smoking, weight, and alcohol use.[14] Subjects who screened positive for problem drinking were invited to participate in a research interview.

The face-to-face 30-minute research interview took place in each patient's primary care clinic and was conducted by 1 of 10 trained researchers. This assessment interview, the Research Lifestyle Interview, included a 7-day timeline follow-back procedure,[15] number of episodes of binge drinking in the past 28 days using the timeline procedures, number of weeks of abstinence in the past 3 months, symptoms of alcohol withdrawal (lifetime and previous year), and treatment for alcohol problems (lifetime and previous year). Additional questions included the frequency of licit and illicit drug use, injuries, emergency department visits, hospitalizations, limitations of daily activities, health status,[16] and family function.[17] The Diagnostic Interview Schedule[18] for current and lifetime depression, childhood conduct disorder, and antisocial personality disorder was administered along with the SCL-90 anxiety scale[19] and a family history schedule developed by Andreasen et al.[20]

Subjects assigned to the control group received a health booklet on general health issues and were followed up at 6 and 12 months. They were instructed to address any health concerns in their usual manner. Patients in the experimental group were given the same booklet and scheduled to see their personal physician for the brief intervention treatment.

Physicians were trained to administer the intervention protocol through role playing and general skills techniques in educational programs at each of the 17 clinics. The physicians also received additional training in booster sessions that occurred at least twice during the trial, as subjects were randomized into the trial over a 9-month period. Physicians were asked to complete a form following each intervention visit to document that the patient had received the protocol and had contracted to reduce his or her alcohol use.

Follow-up procedures included a telephone interview at 6 and 12 months by one of the researchers not assigned to the subject's clinic. Family members were contacted at 12 months to corrobo-

rate patient self-report. Medical record reviews were completed after the 12-month follow-up telephone interview.

Analysis.—Statistical analyses of the data were conducted to investigate alcohol consumption and health care utilization among study participants. The analyses examined changes in behavior over time by comparing outcome measures at the baseline survey and at the 6-month and 12-month follow-up reports. The *t* tests of difference between means and the χ^2 tests of independence provided estimates of significant differences in outcome measures between the experimental and control groups. A logistic regression model was estimated to examine the independent effect of treatment status on alcohol use after controlling for other variables. Analyses were conducted separately for men and women and by group status (experimental, control).

Assignment

The unit of randomization was the individual patient. Randomization of subjects to the experimental and control groups was carried out separately for men and women in each physician's practice using a computer-generated allocation method. Each physician had both control and experimental patients in his or her practice. The goal of the trial was to have 6 to 8 control patients and 6 to 8 experimental patients for each physician in the study.

Masking (Blinding)

One of the goals of the trial was to blind subjects assigned to the control groups to minimize the intervention effect of the research procedures. The subjects randomized into the control group were told the trial focused on health behaviors including alcohol. All research procedures including the follow-up patient and family member interviews asked parallel questions on smoking, exercise, weight, and alcohol use.

The physicians and their staff were not told which of their patients were randomized into the control group. While it could be expected that the physicians in the trial would identify alcohol problems in the control subjects as a result of their brief intervention training, only 50 control subjects (13%) reported a physician intervention in the 12 months following randomization. To avoid interviewer bias at the 6- and 12-month follow-up interviews, researchers were rotated for the telephone interviews so that they did not interview any patients from the clinics to which they were assigned.

Medical record audit showed that 4 patients in the control group (3 men and 1 woman), 1 man in the experimental group, and 1 man in the failed experimental group (those assigned to treatment but who did not follow up with the intervention visit to the physician, n=6) received formal treatment in an alcohol treatment program during the 1-year follow-up period. There was no mention of referral to Alcoholics Anonymous.

Table 1.—Demographic Characteristics and Health Status by Group and Sex*

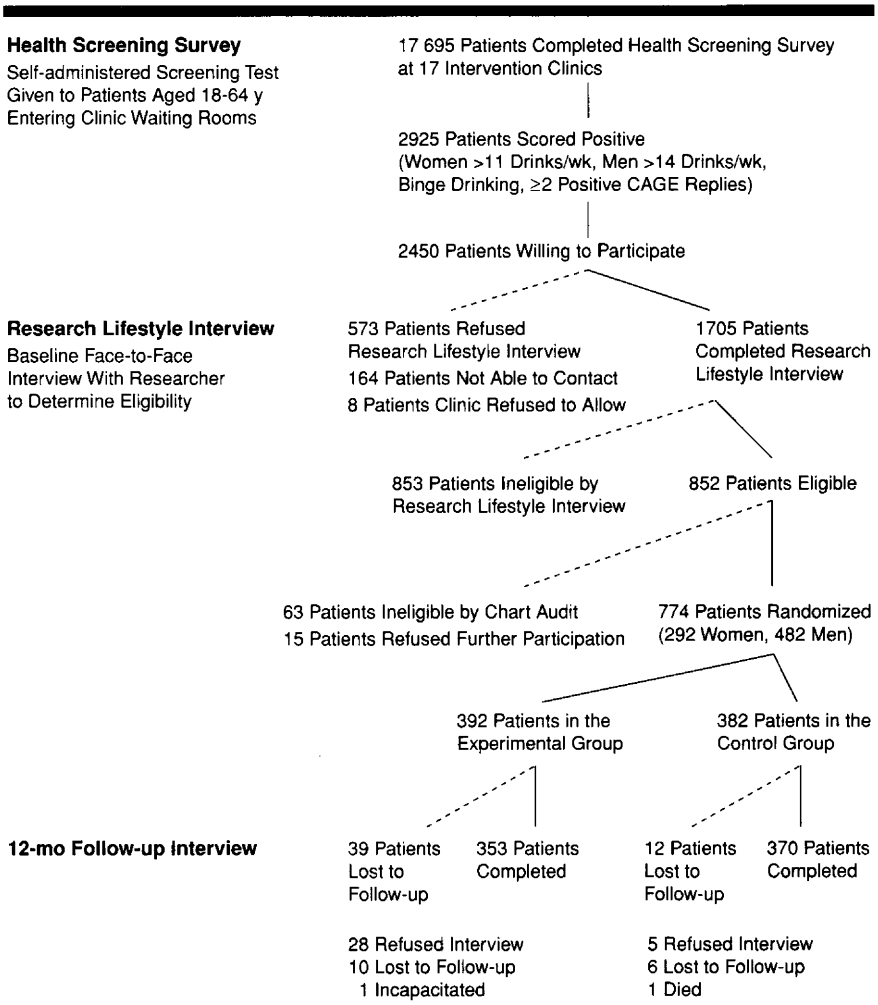
Characteristics	No. (%)			
	Men		Women	
	Treatment (n=244)	Control (n=238)	Treatment (n=148)	Control (n=144)
Age, y				
18-30	49 (20.2)	61 (26.0)	64 (43.5)	51 (35.7)
31-40	66 (27.2)	59 (25.1)	38 (25.9)	51 (35.7)
41-50	58 (23.9)	50 (21.3)	23 (15.6)	26 (18.2)
51-65	70 (28.8)	65 (27.7)	22 (15.0)	15 (10.5)
Ethnicity				
White	221 (94.4)	213 (92.6)	126 (88.1)	123 (88.5)
Hispanic	3 (1.3)	3 (1.3)	3 (2.1)	1 (0.7)
African American	6 (2.6)	6 (2.6)	9 (6.3)	10 (7.2)
Other	4 (1.7)	8 (3.5)	5 (3.5)	5 (3.6)
Marital status				
Never married	40 (16.6)	52 (22.4)	41 (28.9)	43 (30.1)
Widowed, divorced, separated	28 (11.6)	24 (10.3)	23 (16.2)	30 (21.0)
Married, living with partner	173 (71.8)	156 (67.2)	78 (54.9)	70 (49.0)
Education				
High school or less	86 (36.3)	89 (39.0)	68 (47.6)	60 (42.6)
Some college	95 (40.1)	93 (40.8)	50 (35.0)	61 (43.3)
College degree or more	56 (23.6)	46 (20.2)	25 (17.5)	20 (14.2)
Occupation				
Professional	72 (30.9)	57 (25.4)	32 (22.7)	34 (24.5)
Technical-mechanical	57 (24.5)	49 (21.9)	6 (4.3)	2 (1.4)
Student	1 (0.4)	8 (3.6)	14 (9.9)	10 (7.2)
Labor-machine	44 (18.9)	49 (21.9)	16 (11.3)	22 (15.8)
Retired	27 (11.6)	31 (13.8)	6 (4.3)	2 (1.4)
Farm	1 (0.4)	2 (0.9)	0	1 (0.7)
Sales-services	25 (10.7)	21 (9.4)	20 (14.2)	20 (14.4)
Homemaker	1 (0.4)	3 (1.3)	32 (22.7)	27 (19.4)
Unemployed	5 (2.1)	4 (1.8)	1 (0.7)	6 (4.3)
Mental health†				
Depression in lifetime	68 (28.0)	68 (28.9)	69 (47.3)	75 (52.8)
Depression in last 30 d	29 (12.0)	18 (7.6)	31 (21.1)	30 (21.4)
Childhood conduct disorder	28 (11.5)	35 (14.7)	16 (10.9)	9 (6.3)
Antisocial personality disorder	25 (10.3)	28 (11.8)	11 (7.5)	7 (4.9)
Family health				
Parents with alcohol/drug problem	76 (31.1)	88 (37.0)	55 (37.2)	67 (46.5)
Siblings with alcohol/drug problem	65 (26.6)	59 (24.8)	55 (37.2)	58 (40.3)
Health behaviors				
Exercised in last 6 mo	177 (72.8)	184 (77.6)	100 (67.6)	91 (63.6)
Smoked in last 6 mo	133 (54.5)	120 (50.4)	89 (60.1)	80 (55.6)
Used mood altering drugs in last 6 mo	60 (24.6)	71 (29.8)	54 (37.0)	48 (33.3)
Used marijuana in last 6 mo	38 (15.6)	51 (21.4)	32 (21.9)	33 (22.9)
Used cocaine in last 6 mo	7 (2.9)	9 (3.8)	9 (6.1)	9 (6.3)

*Sample totals vary slightly across variables. Percentages are based on numbers shown in parentheses relative to other data points for that variable.
†Percentage reflects the patients in whom symptoms were present.

RESULTS

Participant Flow and Follow-up

A total of 17 695 subjects from 17 clinics completed the health screening survey (Figure). Of those, 2450 subjects screened positive (more than 14 drinks per week for men, more than 11 drinks per week for women, more than 5 drinks 4 or more times in previous 30 days, and 2 or more positive answers to the 4 questions from a standard screening instrument used to assess the possibility of a drinking problem called CAGE[21]) and were invited to participate in a face-to-face interview at their physicians' offices. A total of 1705 patients completed the Research Lifestyle Interview with 16.6% meeting current criteria for alcohol dependence based on criteria from the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R)*.[22]



Trial profile.

A total of 774 subjects met all inclusion criteria and were randomized into an experimental group (n=392) and a control group (n=382). Most of the subjects who did not meet inclusion criteria did so because their alcohol use in the previous 7 days was below the selected cutoff limit. The timeline follow-back procedure was used in the Research Lifestyle Interview to assess daily alcohol use in the previous 7 days and provided more accurate information than the health screening survey. Other reasons for exclusion included recent suicide ideation, symptoms of alcohol dependence, alcohol treatment in the previous year, and severe medical problems.

A total of 307 subjects completed the intervention protocol; 9 received only 1 physician visit. A total of 85 persons randomized to the experimental group failed to keep their appointment with the physician and did not receive the physician intervention. These subjects were scheduled at least 3 times by the researchers. Primary reasons given by these patients for not following through with the scheduled intervention included lack of time, family illness, transportation problems, and inability to take time off from work. This group was not statistically different at baseline from the persons who completed the intervention on age, sex, alcohol use, health services utilization, employment status, marital status, education, or frequency of mental illness. Of the 85 subjects who did not receive the intervention, 77 participated in the 12-month follow-up interview. All persons initially randomized to the experimental group (n=392) remained in this group for the analysis.

Of the 774 subjects enrolled in the trial, 723 completed the 12-month follow-up procedures. Of the 51 subjects who did not complete the 12-month follow-up interview, 33 refused the interview, 16 were lost to follow-up, 1 died, and 1 had a stroke. The greater number of persons in the experimental group who refused the 12-month follow-up interview may be related to their resistance to change their alcohol use.

Family member interviews were conducted in order to corroborate subjects' self-report. Of family members, 612 (79%) completed the 12-month interview. Family members of subjects in both the control and experimental groups consistently reported lower amounts of alcohol use than the subjects.

Analysis

Patient Characteristics.—Minimal differences were found between the experimental and control groups on a number of potential confounding variables (Table 1). The sample consisted of 482 males and 292 females. The race/ethnicity distribution of the sample is similar to the distribution for primary care patients throughout Wisconsin. The age distribution was similar for each decade. The population was well educated with the majority of the sample having attended college. Only 2% reported being unemployed. A family history of alcohol problems was more commonly reported in the female sample.

Over half of the sample (n=422) reported tobacco use at baseline. The category "used mood altering drugs in the last 6 months" included marijuana, cocaine, amphetamines, LSD, illicit narcotics, and prescription drugs such as alprazolam (Xanax), chlordiazepoxide hydrochloride (Librium), diazepam (Valium), and opioids. Higher total rates of drug use in women are related to an increased use of prescribed benzodiazepines. The rates of self-reported marijuana and cocaine use in the last 6 months were higher than general population samples and may reflect higher rates in primary care clinical samples. Rates of major depression (based on the Diagnostic Interview Schedule and *DSM-III-R* criteria) were higher in women.

Alcohol Use Outcome Measures.—The major alcohol use outcome variables were average drinks per week, binge drinking, and excessive drinking. The average drinks per week, the total number of drinks in the last 7 days, was determined by timeline follow-back procedures.[15] As shown in Table 2, there were large decreases in all alcohol use variables in all groups at 6 and 12 months. Reductions in drinking over time were significant within each group, but the experimental group reduced their alcohol use more than the control group.

The greatest reduction in alcohol consumption over time occurred among women in the experimental group. These women decreased their alcohol use by almost one half, drank to excess and binge drank in far fewer numbers, and significantly decreased their average number of binge episodes per month. At baseline, women in the experimental group drank 15 drinks per week, but this figure was reduced by 47% to 8

Table 2.—Alcohol Consumption at Baseline and Follow-up by Treatment Status*

Status	All Patients				Men				Women			
	Treatment (n=392)	Control (n=382)	t Score	P Value	Treatment (n=244)	Control (n=238)	t Score	P Value	Treatment (n=148)	Control (n=144)	t Score	P Value
No. of Drinks in Previous 7 d												
	Mean (SD)	Mean (SD)			Mean (SD)	Mean (SD)			Mean (SD)	Mean (SD)		
Baseline	19.14 (12.26)	18.94 (11.84)	0.22	...	21.67 (12.85)	21.95 (12.39)	0.60	...	15.05 (10.02)	15.69 (10.13)	0.52	...
6 mo	11.57 (10.94)	14.98 (11.12)	4.10	<.001	13.84 (11.99)	17.12 (12.51)	2.78	<.005	7.91 (7.73)	11.54 (7.23)	3.99	<.001
12 mo	11.48 (11.31)	15.46 (12.93)	4.33	<.001	13.62 (12.39)	16.86 (13.49)	2.6	<.005	8.03 (8.26)	13.20 (11.67)	4.16	<.001
% Reduction												
Base to 6 mo	39.54	20.88	...	...	36.12	22.02	...	...	47.48	26.45	...	...
Base to 12 mo	40.02	18.35	...	...	37.16	23.17	...	...	46.65	15.89	...	...
No. of Binge Drinking Episodes in Previous 30 d												
	Mean (SD)	Mean (SD)			Mean (SD)	Mean (SD)			Mean (SD)	Mean (SD)		
Baseline	5.65 (5.95)	5.34 (5.03)	0.76	...	6.13 (6.58)	5.40 (4.98)	1.30	...	4.88 (4.70)	5.23 (5.13)	0.57	...
6 mo	2.88 (4.86)	3.93 (4.80)	2.90	<.005	3.33 (5.35)	4.37 (5.29)	2.04	<.025	2.14 (3.94)	3.22 (3.80)	2.29	<.02
12 mo	3.07 (5.23)	4.21 (5.52)	2.81	<.005	3.43 (5.52)	4.48 (5.66)	1.95	<.05	2.50 (4.70)	3.79 (5.27)	2.11	<.02
% Reduction												
Base to 6 mo	49.13	26.32	...	...	45.65	19.08	...	...	56.19	38.39	...	...
Base to 12 mo	45.67	21.05	...	...	44.08	17.12	...	...	48.89	27.60	...	...
Binge Drinking in the Previous 30 d												
	No. (%)	No. (%)			No. (%)	No. (%)			No. (%)	No. (%)		
Baseline	288 (85.46)	317 (86.61)	0.44	...	177 (85.10)	197 (87.17)	0.62	...	111 (86.05)	120 (85.71)	0.08	...
6 mo	200 (59.35)	266 (72.68)	3.77	<.001	133 (63.94)	168 (74.34)	2.36	<.005	67 (51.94)	98 (70.00)	3.08	<.005
12 mo	188 (55.79)	261 (71.31)	4.33	<.001	118 (56.73)	167 (73.89)	3.82	<.001	70 (54.26)	94 (67.14)	2.17	<.025
% Reduction, mean												
Base to 6 mo	30.56	16.09	...	...	24.86	14.72	...	...	39.64	18.33	...	...
Base to 12 mo	34.72	17.67	...	...	33.33	15.23	...	...	36.94	21.67	...	...
Drinking Excessively in the Previous 7 d												
	No. (%)	No. (%)			No. (%)	No. (%)			No. (%)	No. (%)		
Baseline	160 (47.48)	176 (48.09)	0.16	...	95 (45.67)	101 (44.69)	0.21	...	65 (50.39)	75 (53.57)	0.52	...
6 mo	67 (19.88)	115 (31.42)	3.52	<.001	46 (22.12)	65 (28.76)	1.59	...	21 (16.28)	50 (35.71)	3.69	<.001
12 mo	60 (17.80)	119 (32.51)	4.53	<.001	38 (18.27)	70 (30.97)	3.08	<.005	22 (17.05)	49 (35.00)	3.39	<.001
% Reduction, mean												
Base to 6 mo	58.13	34.66	...	...	51.58	35.64	...	...	67.69	33.33	...	...
Base to 12 mo	62.50	32.39	...	...	60.00	30.69	...	...	66.15	34.67	...	...

*Excessive drinking was defined as having more than 20 drinks per week for men and more than 13 drinks per week for women; binge drinking is defined as having more than 4 drinks for women and 5 drinks for men in 1 occasion. Ellipses indicate not applicable.

drinks per week after 12 months. Two thirds fewer women drank to excess at the time of the 12-month survey. While women in the control group also decreased their use, the relative difference between the groups varied from 16% to 35% and was statistically significant ($P<.05$) at both follow-up points.

Men in the experimental group reduced their alcohol consumption slightly less than their female counterparts, but decreases were reported across all alcohol use measures. Twelve months after the baseline survey, men in the experimental group demonstrated a 37% reduction in 7-day alcohol use, a 60% decrease in the number who drank to excess, and a 44% decline in the frequency of binge drinking. On average, men in the experimental group reduced their weekly alcohol consumption by 8 drinks (from 21.67 to 13.62) and decreased the frequency of binge episodes from 6 per month to 3 per month. Reductions in alcohol consumption were consistently greater among men in the experimental group. These changes were statistically significant ($P<.01$) at all but 1 point of measurement (percentage drinking to excess at 6 months).

The results from a logistic regression model (Table 3) show that other demographic characteristics and health behaviors do not account for differences in alcohol consumption between the groups; the only variable significantly predicting a 20% or greater reduction in drinking was exposure to the physician intervention. Smoking, age, depression, conduct disorder, and adult antisocial personality disorder did not significantly affect a reduction in drinking. Individuals in the experimental group were 2 times more likely to reduce their drinking by 20% or more (odds ratio, 2.15; 95% confidence interval, 1.58-2.93). In contrast, other variables examined did not make individuals any more (or less) likely to reduce their alcohol consumption by 20%.

Health Care Utilization.—Table 4 examines patterns of health care utilization by sex and group status. In interviews at baseline and at 6 and 12 months, study participants were asked to report the length of any hospitalizations and the number of visits to an emergency department during the previous 6 months. Neither men nor women reported significantly different numbers of visits to the emergency department during the course of the study; the numbers of visits deviate only slightly from each other at all time points, and there were no significant associations between group status and emergency department use.

Utilization of health care facilities differs significantly between the experimental and control groups for days of hospitalization (Table 4). Men in the control group experienced substantially longer hospitalizations during the study period than those in the experimental group (314 vs 178 days). Although an assessment of whether physician intervention significantly reduces hospitalization over time awaits analysis of long-term follow-up surveys, χ^2 tests indicate that hospital utilization is significantly related to group status. Additional analyses performed after temporarily remov-

Table 3.—Logistic Regression Model of 20% or More Reduction in Drinking*

Characteristics	Adjusted Odds Ratio (95% Confidence Interval)
Women	1.08 (0.77-1.51)
Smoking in last 6 mo	0.73† (0.53-1.01)
Age, y	
18-30	1.07 (0.83-1.39)
31-40	0.94 (0.73-1.22)
41-50	0.88 (0.66-1.17)
51-65	1.12 (0.83-1.51)
Depressed in last 30 days	0.73 (0.49-1.09)
Experimental	2.15‡ (1.58-2.93)
Child conduct disorder	1.30 (0.87-1.94)
Adult antisocial personality	1.18 (0.67-2.06)

*Overall predictive power, 60%.
†$P \leq .06$.
‡$P \leq .001$.

Table 4.—Health Care Utilization by Group and Sex

Status	All Patients		Men		Women	
	Treatment (n=392)	Control (n=382)	Treatment (n=244)	Control (n=238)	Treatment (n=148)	Control (n=144)
Self-reported No. of emergency department visits (No. of patients) in last 6 mo						
Baseline	75 (58)	80 (65)	49 (38)	47 (47)	26 (20)	33 (24)
6-mo follow-up	47 (40)	70 (56)	29 (25)	46 (37)	18 (15)	24 (19)
12-mo follow-up	60 (47)	62 (50)	33 (28)	39 (34)	27 (19)	23 (16)
	χ^2=2.45 (P>.10)		χ^2=2.60 (P>.10)		χ^2=1.48 (P>.10)	
Self-reported No. of days of hospitalization (No. of patients) in last 6 mo						
Baseline	93 (18)	42 (17)	84 (13)	37 (13)	9 (5)	5 (4)
6-mo follow-up	35 (8)	164 (21)	29 (5)	159 (14)	6 (3)	21 (7)
12-mo follow-up	91 (22)	146 (17)	65 (13)	118 (13)	26 (9)	16 (4)
	χ^2=89.53 (P<.001)		χ^2=93.01 (P<.001)		χ^2=11.85 (P<.01)	

ing 4 individuals with hospital stays longer than 6 weeks—more than 1 month longer than any other reported hospitalization—were not appreciably changed. Another potential factor influencing higher rates of hospital days in the control group are primary care visits. A preliminary analysis of outpatient visits showed no significant difference by group status.

The number of women hospitalized in the sample was small, and the numbers were not stable. Many of the hospital days in women were related to obstetrical care. While the sample excluded women who were pregnant at the beginning of the trial, 10 women became pregnant after randomization.

Health Status Measures.—Other outcome variables showed no significant changes in general health rating, mean number of cigarettes smoked, or number of depressive symptoms after 12 months for men or women in either group.

COMMENT

Project TrEAT found significant reductions in alcohol use and health care utilization in men drinking more than 14 drinks per week and women drinking more than 11 drinks per week. After 12 months there was a 14% reduction of alcohol use by men in the experimental group and a 31% reduction by women in the experimental group. There were also significant reductions in the proportion of male and female subjects who were drinking excessively. Men in the experimental group experienced lower rates of binge drinking than control group men. As expected, large reductions in use occurred at the 6-month point after intervention. These changes were maintained at the 12-month follow-up. With the exception of a larger reduction in 7-day alcohol use in the female sample, these findings are consistent with the findings of the MRC trial.[9] The changes in health care utilization were significant and suggest a treatment effect. The men in the experimental group experienced a greater than 2-fold difference in the total number of hospital days in the 12 months following the intervention when compared with the control group.

This trial has a number of strengths. Project TrEAT is the first large-scale alcohol trial with a diverse sample of community-based, primary care practices in rural and urban settings in the United States. The involvement of 4 managed care organizations with physicians in community-based practices makes the study unique. As a result of using community-based physicians who traditionally provide more than 90% of the care in the United States, the findings may be applicable to primary care practices throughout the United States. The patient sample represents an employed population of adults in a state with a strong economy and a high rate of alcohol use. Wisconsin is third only to Alaska and the District of Columbia in total per capita alcohol consumption.

Project TrEAT is the third largest brief intervention trial reported in the world literature. The WHO[10] and the MRC[9] trials had samples of 1655 and 909 subjects, respectively. The number of women in our study (n=292) was similar to the number of women in the WHO (n=299) and MRC (n=268) studies. We had a high physician retention rate and a patient follow-up rate of 93% at 12 months, the highest rate of all brief intervention alcohol trials. Corroborative family member interviews suggest patient self-report was a valid estimate of alcohol use. Control procedures were maintained throughout the trial with only 13% of the control subjects receiving alcohol consumption advice from their physicians during the 12-month follow-up period.

A number of methodological issues that are potential limitations to the study should be considered when interpreting our results. Reliance on self-report of alcohol consumption as one of the primary outcome measures is an important consideration. Research conducted by a number of investigators indicates that self-reported alcohol consumption is more reliable than other methods of inquiry or testing.[23-25] Methods used in this trial to minimize self-report bias included: (1) informing patients that the researchers administering the follow-up interviews were from the University of Wisconsin; (2) reassuring subjects that the information provided to the researchers was confidential; (3) using follow-up questionnaires containing parallel questions regarding weight, exercise, sleeping patterns, alcohol use, and smoking to lessen the impact of the alcohol questions; and (4) using multiple measures of alcohol use.

Another methodological issue is the concern that persons who received the physician intervention may have wanted to "please their physicians" by subsequently reporting lower rates of alcohol use. In the absence of the use of a biological measure to assess recent alcohol use, family member interviews were conducted at 12 months with 79% of the sample to corroborate subject self-report. The family member interviews did not reveal any systematic difference from subject self-report by group status. This finding suggests that patient responses were not significantly affected by a desire to please the physician.

The use of self-report data for changes in health care utilization is another potential limitation of the study. Traditionally, at least 3 sources can be used to assess changes in utilization including claims data, medical record reviews, and self-report. The trial was not able to use claims data due to access and cost restraints. We estimate that the subjects in the trial had over 20 different health care insurance carriers. When we examined medical record data to estimate changes in utilization, we found that patients reported greater numbers

of emergency department visits and hospital days than those recorded in the medical records. Patients reported 33% more emergency department visits and 40% more hospital days. The κ statistic comparing self-report with medical records was 0.536 for emergency department visits and 0.44 for hospital visits. The Yules Y for emergency department visits was 0.54 and 0.60 for hospital visits. The reason for this visit discrepancy may be related to a lack of routine reporting from emergency departments and hospitals to primary care physicians' offices. Also, some patients may have gone to out-of-area hospitals or emergency departments to prevent their physicians, insurance companies, or employers from being notified.

A limitation of studies conducted in community-based clinical settings is the follow-through of subjects in receiving the intervention protocol. Nearly 22% of the subjects randomized to the experimental group did not receive a physician intervention. This is a common finding in alcohol and mental health intervention trials[11,26] and is related to time issues, illness, travel distance, and loss of interest in participating in the research trial. It is important to note that 77 of the 85 subjects who did not receive the intervention participated in the follow-up interviews. The inclusion of this group in the analysis provides a more conservative estimate that strengthens confidence in the results of the trial.

The generalizability of the results is limited to those populations included in the study. The results of brief intervention techniques may not apply to people treated for an alcohol use disorder in the past year, people with suicidal ideation, or those who drink on average more than 50 drinks per week. The trial specifically excluded patients with alcoholism, and the effectiveness of brief intervention was not tested among this population. Current standards of care require more intensive, specialized treatment for persons who meet *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*,[27] criteria for alcohol dependence. The effectiveness of the brief intervention technique may also differ for minority populations. Although the race/ethnicity of the sample matched the population of Wisconsin and the Midwest in general, African Americans, Asians, and Hispanic Americans were underrepresented. Intervention protocols may need to be adapted according to cultural beliefs and expectations.

The 20% reduction in alcohol use in the control groups was interesting. A majority of the other trials have similar reductions in alcohol use.[11,12] The reason for this change is not known but may be related to regression to the mean, historical changes in alcohol use, and the intervention effect of the research procedures. It is our impression that research procedures can have a significant intervention effect. Each control subject was asked about his or her alcohol use 4 times over the 12-month period.

This trial indicates that brief advice protocols can provide a successful strategy for changing drinking behavior and improving health outcomes for at-risk and problem drinkers in primary care settings. Since 70% of people in the United States visit their physician at least once every 2 years, brief physician advice could have enormous implications for the US health care system. This trial supports the implementation of screening, assessment, and brief intervention for all patients who seek health care services in primary care community-based settings.[28]

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