

Prevention of Depression with Primary Care Patients: A Randomized Controlled Trial¹

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The prevention of major depression is an important research goal which deserves increased attention. Depressive symptoms and disorders are particularly common in primary care patients and have a negative impact on functioning and well-being comparable with other major chronic medical conditions. The San Francisco Depression Prevention Research project conducted a randomized, controlled, prevention trial to demonstrate the feasibility of implementing such research in a public sector setting serving low-income, predominantly minority individuals: 150 primary care patients free from depression or other major mental disorders were randomized to an experimental cognitive-behavioral intervention or to a control condition. The experimental intervention group reported a significantly greater reduction in depressive levels. Decline in depressive levels was significantly mediated by

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decline in the frequency of negative conditions. Group differences in the number of new episodes (incidence) of major depression did not reach significance during the 1-year trial. We conclude that depression prevention trials in public sector primary care settings are feasible, and that depressive symptoms can be reduced even in low-income, minority populations. To conduct randomized prevention trials that can test effects on incidence with sufficient statistical power, subgroups at greater imminent risk have to be identified.

KEY WORDS: cognitive-behavioral; depression; primary care; prevention.

The lifetime prevalence of mood disorders in the United States has been estimated to be 17% by recently completed epidemiological studies (Kessler et al., 1994). Current prevalence estimates range from 4.6 to 10.3% (Kessler et al., 1994; Myers et al., 1984). Several indices indicate that the rates of depression may be increasing (Klerman & Weissman, 1989). Recent findings show that depressive symptoms, with or without depressive disorder, can impair functioning and well-being to levels comparable with or worse than chronic medical conditions such as hypertension, diabetes, angina, arthritis, back problems, lung problems, and gastrointestinal disorders (Wells et al., 1989). Although there have been major advances in the treatment of depression, significant problems remain (Muñoz, Hollon, McGrath, Rehm, & VandenBos, 1994). For example, less than 20% of individuals meeting criteria for affective disorders seek treatment from mental health specialists (Shapiro et al., 1984) and between 20 and 50% of those who begin psychiatric treatment in controlled trials terminate treatment prematurely (DiMascio et al., 1979; Simons, Levine, Lustman, & Murphy, 1984). In addition, only about 40% of those completing treatment remain relatively free of symptoms 1 year after treatment (Simons, Murphy, Levine, & Wetzel, 1986). Given the high prevalence of depression and limitations of treatment approaches, research is needed to develop methods to prevent depression.

Treatment outcome studies indicate that interventions focused on cognitive and behavioral factors are effective in the treatment of depressed outpatients (McLean & Hakstian, 1979; Murphy, Simons, Wetzel, & Lustman, 1984; Rush, Beck, Kovacs, & Hollon, 1977; Steinbrueck, Maxwell, & Howard, 1983; Weissman, Jarrett, & Rush, 1987) and that they may help to prevent relapse (Hollon, DeRubeis, & Seligman, 1992; Simons et al., 1984). Cognitive behavioral treatments focus on identifying those thoughts and actions that have the most impact on the individual's mood and on teaching the patient to modify them in order to obtain greater control over

the feelings of depression. The educational nature of these approaches lends itself readily to preventive interventions (Muñoz, 1987).

Depression can be conceived of as a continuous phenomenon, in which symptoms constituting the major depressive syndrome may wax and wane until, for reasons that are not yet totally understood, they cross a threshold at which we label the person's condition a major depressive episode. Because the threshold is defined in terms of a combination of number, severity, and duration of symptoms, it makes conceptual sense to attempt to decrease these factors in order to prevent the eventual crossing over into a clinical episode. Moreover, the Agency for Health Care Policy and Research (AHCPR) Depression Guideline Panel reports that after one episode of major depression, the likelihood of another episode is 50%, after two episodes, 70%, and after three episodes 90% (Depression Guideline Panel, 1993). If this increased risk is due to a process such as "kindling" (Post, Rubinow, & Ballenger, 1984), in which the organism becomes susceptible to dysregulation in response to formerly subthreshold stimuli after entering a dysregulated state, then it is very important to prevent the first episode of major depression to avert a recurrent pattern of depressive episodes.

The Institute of Medicine recently published a report on prevention intervention research in which three levels of preventive interventions are described: universal, selective, and indicated (Mrazek & Haggerty, 1994, pp. 22-26). *Universal preventive interventions* are targeted to the general public, *selective preventive interventions* to subgroups of the population whose risk is higher than for the population as a whole, and *indicated preventive interventions* to high-risk individuals identified as having minimal but detectable signs or symptoms foreshadowing mental disorder. Prior to the current outcome study, our group had conducted and evaluated a universal preventive intervention using television segments to reduce depressive symptoms in the general population. We found that those with initially higher self-reported depression levels who watched the televised segments reported lower symptom levels after the segments were shown compared to those who did not watch the segments (Muñoz, Glish, Soo-Hoo, & Robertson, 1982). That study was done entirely with a representative sample of the community, but watching the segments was a self-selected process, without a randomization procedure. For the current study, we chose to move to the level of selective preventive interventions, that is, to pinpoint a subgroup in the population at higher risk than the general public. We also chose to implement a true experimental design: a randomized, controlled prevention trial.

The outcome trial reported here evaluated an educational intervention based on social learning theory (Bandura, 1977) which utilized cogni-

tive and behavioral methods (Lewinsohn, Muñoz, Youngren, & Zeiss, 1986) tested earlier in depression treatment studies (Zeiss, Lewinsohn, & Muñoz, 1979). Medical outpatients from primary care clinics serving low-income and predominantly minority persons were chosen as the selected population at high risk for depression for the following reasons: First, epidemiological studies show that although only one out of five clinically depressed individuals obtains treatment from mental health specialists, over 75% do seek some type of health care (Shapiro et al., 1984). Second, the current prevalence of clinical depression has been reported to be between 9 and 14% in several studies of medical outpatients (Hoepfer, Nycz, Cleary, Regier, & Goldberg, 1979). Finally, low-income and minority populations show higher levels of depressive symptoms, as well as high levels of stressful life events (Roberts, 1987). It seems likely, then, that persons at early stages of depression and, thus, at high risk for developing clinical episodes of depression would frequent these primary care facilities.

The present study was conducted to being to test methods to prevent depression (operationalized both in terms of symptom levels and clinical episodes). The strategy chosen was to identify a high-risk population, screen out those already meeting diagnostic criteria for major depression and dysthymia (in order to engage in a true preventive trial), and provide those *not* clinically depressed with an intervention intended to reduce the likelihood of clinical episodes of depression by teaching them self-control mood management methods. Because individual characteristics were not used as inclusion criteria to enter the study (other than being a patient in the primary care clinics), the intervention does not meet the Institute of Medicine definition of *indicated* preventive intervention (Mrazek & Haggerty, 1994).

The explicit theoretical assumption underlying this approach was that major depressive episodes are the result of failures in emotion regulation (Gross & Muñoz, in press). Keeping symptom levels low in a high-risk population by teaching individuals self-control approaches to the management of their own mood states was hypothesized to decrease the number of individuals who eventually cross the threshold into a clinical episode. Social learning self-control approaches used in the intervention involved a focus on mood monitoring and on identifying thoughts, behaviors, and interpersonal interactions that are related to mood for each individual. Thus, in addition to testing whether we produced reductions in depressive symptoms and a lower incidence of clinical depression in the experimental condition, we also specified and measured specific cognitions and behaviors which we considered mediators of mood management, measured the changes in the variables, and then tested whether changes in these variables were related to changes in depressive symptom level.

METHOD

Participants

Participants were recruited from primary care clinics at San Francisco General Hospital and the University of California, San Francisco Medical Center in 1983 and 1984. Persons with clinic appointments during the previous 3 months were contacted either in person or by mail and invited to participate in a study on mood and health. All participants met these criteria: (a) provided informed consent, (b) were between 18 and 69 years of age, (c) were literate in English or Spanish, (d) were not currently receiving mental health treatment, (e) had a chart open for at least 6 months at the primary care clinic, and (f) agreed to participate in four follow-up interviews over a 1-year period.

The randomized sample consisted of 93 women and 57 men, of whom 10.1% were Asian (67% of them from the Philippines), 23.7% African American, 24.3% Latino [mostly from Nicaragua (39%) and El Salvador (39%)], 35.1% white, and 6.8% other. Their mean age was 52.5 years, mean income \$11,500, and mean years of education 12.1. Their unemployment rate was very high (67.8%). Eighteen percent had never married, 2% reported living with a partner, 37.3% were married, 28% were separated or divorced, and 14.7% were widowed. Table I presents demographic characteristics for participants by randomization condition.

Procedure

Prescreening lasted 2 to 4 weeks and included three contacts. At the first contact (either face-to-face or by mail) the study was described, the consent form signed, demographic information was obtained, and a brief self-report depression measure, the Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977) was administered. At the second contact, the Beck Depression Inventory (BDI; Beck, Ward, Mendelsohn, Mock, & Erbaugh, 1961) and the Diagnostic Interview Schedule (DIS; Robins, Helzer, Croughan, & Ratcliff, 1981) were administered in a 2-hour session. At the third contact, the cognitive-behavioral questionnaires and other measures were completed. At the end of this session, participants were informed as to whether they met eligibility criteria for inclusion in the study. Patients meeting current criteria (i.e., within the last 6 months) for major depression, mania, bipolar disorder, drug or alcohol abuse and/or dependence, or lifetime diagnosis for schizophrenia or organic brain syndrome, or

Table I. Demographic Characteristics of Class and Control Groups^a

	Class (<i>n</i> = 72)	Control (<i>n</i> = 78)
Sex		
Male	26	31
Female	46	47
Marital status		
Never married	14	13
Married	29	27
Separated	3	5
Divorced	15	19
Widowed	11	11
Living with	0	3
Employed		
Yes	18	30
No	53	48
Status of unemployed:		
Looking for work	13	8
Student	2	1
Housewife	5	6
Disabled	21	18
Retired	10	13
Other	2	2
Ethnic group		
Asian	6	9
Black	14	21
Latino	16	20
White	30	22
Native American	1	0
Other	4	5
Native language		
English	44	44
Spanish	17	21
Other	9	13
Age		
<i>M</i>	51.4	53.4
<i>SD</i>	12.6	11.5
Education		
<i>M</i>	12.6	11.6
<i>SD</i>	3.4	3.8
Income		
<i>M</i>	11,200	11,800
<i>SD</i>	9,700	12,700

^aThe subtotals do not always add up to the total *n* per group due to missing data. All group differences were nonsignificant by chi-square or *t* tests.

who were judged to be in need of treatment (for example, suicidal) were excluded from the study and referred for treatment.

Those who met all criteria for inclusion were then randomly assigned (with stratification by sex) to either the experimental or the control condition. The experimental group received the class intervention, which consisted of eight weekly 2-hour sessions.

Postassessment occurred for participants in both conditions within 2 weeks of the last intervention session administered to the experimental group. It consisted of the BDI, CES-D, the cognitive-behavioral measures and other questionnaires from the third screening session, administered during a 2-hour session. The 6-month assessment occurred 6 months from the initial screening date. The BDI, CES-D, and the cognitive-behavioral measures were administered during a 2-hour session. The 1-year follow-up occurred 12 months from the initial screening date. The BDI and the 1-year DIS were administered during a 2-hour session. The CES-D and the cognitive-behavioral measures were administered during a subsequent 2-hour session.

The experimental condition consisted of a course on cognitive behavioral methods to gain greater control of one's mood. The instructors were doctoral level psychologists, who followed a protocol (the Depression Prevention Course; Appendix A in Muñoz & Ying, 1993) in the form of a syllabus which included student outlines for each of the sessions as well as instructor's notes. The detailed instructor notes assured fidelity of intervention coverage and comparability across all classes. The syllabus was a simplified version of social learning self-control methods (Lewinsohn et al., 1986) used in an earlier treatment outcome study (Zeiss et al., 1979). The techniques were adapted to a low-income, predominantly minority population. A Spanish-language version was also prepared. The course was conducted in a small-group format, with no more than 10 persons per group.

The course covered the following topics: an introduction to depression, social learning theory, and self-control approaches (e.g., learning to monitor daily mood level); how thoughts, activities, and interpersonal interactions affect mood; how to identify and change those thoughts, activities, and contacts with people that most affect each participant's mood level; how to determine if one's mood actually changes when one increases or decreases specific thoughts, behaviors, or interpersonal contacts; relaxation training; and planning one's life goals so that the probability that one will become depressed is as low as possible given one's circumstances (Muñoz & Ying, 1993, pp. 243-279).

The English-speaking control group was divided into two conditions, a no-intervention group and an information-only control condition that

watched a 40-min videotape presentation of the same ideas presented in the course. The videotape condition was intended to examine whether mere exposure to the ideas in the course would be sufficient to reduce depressive symptoms. (A Spanish version of the videotape was not available.) No differences were found between these two conditions, and they were thus combined into a single control group for analysis.

Measures

Symptoms of Depression

Levels of depressive symptomatology were assessed by two widely used self-report scales: the BDI (Beck et al., 1961) and the CES-D (Radloff, 1977). Prevention research addresses both epidemiological and clinical issues, thus it was considered desirable to measure depression levels using instruments utilized in both community samples (CES-D) and clinical samples (BDI).

The BDI has been used extensively in treatment outcome research. BDI scores can range from 0 to 63, with greater scores signifying greater intensity of depression. A review of studies using the BDI reports a mean score of 4.54 ($SD = 4.46$) for nondistressed groups (normal control groups), 7.18 ($SD = 6.47$) for general populations (primarily collegiate samples), and means of 26 prior to treatment and 12 after treatment for clinically depressed samples (Nietzel, Russell, Hemmings, & Gretter, 1987).

The CES-D has been used primarily in epidemiological research. CES-D scores can range from 0 to 60. The national mean in a representative sample of adults 25–74 years of age has been reported to be 8.7 ($SD = 8.4$, Sayetta & Johnson, 1980).

Diagnoses

Major depression and dysthymia were identified using the DIS (Robins et al., 1981), a computer-scored structured interview designed to be conducted by lay interviewers. The investigators received training in its use from its developers (Robins et al., 1981). In addition to screening out potential participants who were already clinically depressed, the DIS was used to identify participants who became clinically depressed during the 1-year follow-up.

Cognitive-Behavioral Measures

Five cognitive-behavioral scales were utilized. The three measures utilized to assess cognition were the Personal Beliefs Inventory (PBI; Muñoz, 1977), the Subjective Probabilities Questionnaire (SPQ; Muñoz, 1977); and the Cognitive Events Schedule (CES; Muñoz, 1977). The behavioral measures included the Pleasant Activities Scale (PAS; MacPhillamy & Lewinsohn, 1971), and the Social Activities Questionnaire (SAQ; Youngren, 1978; Youngren, Zeiss, & Lewinsohn, 1975; Zeiss et al., 1979).

The 30-item PBI (Form M-1) measured the extent of "irrational beliefs" (Ellis, 1962; Ellis & Harper, 1961), and was postulated to mediate depression. It was developed by Muñoz by adopting 15 belief items from Hartman's (1968) Personal Beliefs Scale, and incorporating 15 additional items furnished by Gerald Kranzler of the University of Oregon. The items were scored on a 5-point scale reflecting 1 (*high disagreement*) to 5 (*high agreement*).

The SPQ measured the degree of optimism (17-item SPQ+ subscale) and pessimism (13-item SPQ- subscale). These items were previously identified by Muñoz (1977) to most effectively distinguish depressed and non-depressed individuals ($p < .001$). Respondents indicated the chances, from 0 to 100%, that the 30 items were true or likely to become true.

The CES measured the frequency of covert reinforcement and punishment, that is, the rate with which individuals experienced positive and negative thoughts in the preceding 30 days. Twenty-one items assessed positive thought (making up the CES+ subscale) and 43 items assessed negative thought (making up the CES- subscale). Each item was rated on a 3-point scale; 1 (*thought did not occur in the past 30 days*); 2 (*thought occurred a few times, i.e., 1 to 6 times*); and 3 (*thought occurred often, i.e., 7 or more items*). Muñoz (1977) had found depression to be negatively correlated with positive thoughts and positively correlated with negative thoughts ($p < .05$).

The PAS assessed the number of pleasant activities and their subjective enjoyability in the last month. It was a 49-item subset of the 320-item Pleasant Events Schedule (MacPhillamy & Lewinsohn, 1971) found to be associated with mood for at least 10% of the psychiatric sample studied by Lewinsohn, Biglan, and Zeiss (1976). The items were scored similarly to the CES.

The 46-item SAQ examined the extent of interpersonal interactions in the last 30 days. It was constructed on the basis of face validity from Youngren et al.'s (1975) 160-item Interpersonal Events Schedule. Youngren (1978) found depressed patients to score significantly lower on the SAQ than normal controls. The psychometric properties of these measures in

the present sample have been presented elsewhere (Muñoz & Ying, 1993, pp. 90-98). For example, coefficient alphas were as follows: Personal Beliefs Inventory, .63; Subjective Probability Questionnaire, .86 for SPQ+ and .64 for SPQ-; Cognitive Events Schedule, .85 for CES+ and .91 for CES-; Pleasant Activities Schedule, .93; and the Social Activities Questionnaire, .89.

RESULTS

A detailed description of the screening process, including demographic characteristics of the sample and selection factors according to language of respondent, has already been reported (Muñoz & Ying, 1993, pp. 102-114; Muñoz, Ying, Armas, Chan, & Gurza, 1987). A total of 707 subjects met these initial inclusionary criteria and agreed to be screened. However, only 292 of these subjects completed the DIS in the second screening. The large attrition is due to the fact that the first screening is relatively undemanding. Subjects fill out a few forms while waiting to see their physician (in the case of face-to-face recruitment) or at home (mailing recruitment). In contrast, the second screening requires the subject to make a trip to the hospital for the explicit purpose of the study. Of the 292 who completed the DIS, 103 (35.3%) were excluded because they failed to appear for the third screening, and 158 were eligible for randomization. Of these, 95% agreed to be randomized. The final sample has been shown to be comparable on demographic characteristics to clinic populations at the recruitment sites (Muñoz & Ying, 1993). Of the 150 randomized subjects, 72 were assigned to the class condition, and 78 to the control condition.

Tests of the results of the randomization procedure on distribution of key variables across experimental groups prior to the intervention revealed that the groups were comparable in terms of most relevant variables. There were no significant differences between the experimental groups in demographic characteristics (Table I).

Medical status was analyzed by examining the aggregate number of active medical diagnoses, medications prescribed, clinic visits, and hospitalizations ascertained through chart reviews of the year preceding entry into the study. Significant differences between groups were not found.

By and large, the groups did not differ in their history of psychiatric disorder. The only exception was Panic Disorder which reached marginal significance (class: 5/72, control: 0/78, $p < .06$). No differences were found in the initial depression level as measured by the CES-D or BDI. For the class participants, the mean CES-D score was 15.63 ($SD = 11.31$) and the mean BDI score was 12.58 ($SD = 8.63$); and for the control condition par-

ticipants, the mean CES-D score was 14.98 ($SD = 11.36$) and the mean BDI score was 11.43 ($SD = 7.29$). It should be noted that these mean scores are much higher than those reported for the CES-D and BDI in previous community-based studies, suggesting that this sample, although not meeting criteria for major depression or dysthymia, was experiencing elevated depression symptoms.

Of the 72 participants assigned to the class condition, half attended 7 or 8 class sessions, while one fifth did not attend any class, and the remainder (30%) attended from 1 to 6 sessions. Persons with higher CES-D scores were more likely to attend (see Muñoz & Ying, 1993, pp. 133-134). Follow-up rates for assessment interviews were 92% at post, 90% at 6 months, and 92% at 1 year. The two experimental groups did not differ in the likelihood of being reached for follow-up assessments.

Seven participants met criteria for major depression or dysthymia during the year following their initial Diagnostic Interview Schedule. The overall incidence for major depression in the group for whom we were able to obtain 1-year follow-ups ($n = 139$) was 4.3% ($n = 6$). One person met criteria for dysthymia (0.7%). Combined incidence for both depressive disorders was 5%.

Of the 6 cases of major depression, 4 occurred in the control group, and 2 in the class condition (of these, one had attended two classes and the other none). The participant who met criteria for dysthymia was a class participant who had attended all eight sessions. Fisher's exact test performed for incidence of major depression by randomization condition was not significant ($p = .375$). It is important to note that this test was performed according to the original randomization assignment to each of the conditions, regardless of whether they received the intervention. We feel this is the appropriate test in a randomized trial.

We have reported analyses testing the effect of number of classes attended and outcomes on the CES-D and BDI: attending more sessions yielded a greater drop in CES-D at post ($p = .02$) and BDI at 1-year follow-up ($p = .01$), but not at other assessment points. Since these represent only two of a possible six follow-up points, it appears that the total number of classes attended may be less important than being exposed to some critical amount of the materials even if some classes were missed. Number of sessions attended did not significantly predict to incidence of major depression (Muñoz & Ying, 1993, pp. 139-140).

As recommended by Baron and Kenny (1986), we tested three models to determine the mediational effect of the cognitive-behavioral variables by (a) examining the effect of condition of assignment on cognitions and behaviors; (b) assessing the effect of condition of assignment on depression

level; and (c) testing the effect of the assignment condition and cognitive-behavioral variables on depression level.

Table II shows the results of the first model. The condition of assignment significantly affected change in cognitions and behaviors at several follow-up assessments. At post, compared to the control condition participants, the class condition participants reported experiencing fewer negative thoughts (CES-, b coefficient = -2.82 , $p = .03$); and a greater increase in pleasant activities (PAS, b coefficient = 4.42 , $p = .01$) and social activities (SAQ, b coefficient = 3.53 , $p = .01$). At 6-months follow-up, the class condition participants reported a significantly greater increase in positive thoughts (CES+, b coefficient = 2.62 , $p = .01$) and pleasant activities (PAS, b coefficient = 7.84 , $p = .0001$). At 1-year follow-up, they reported a marginally greater decline in SPQ- (b coefficient = -3.31 , $p = .06$) than the control condition participants. In summary, there was evidence that the

Table II. Change in Cognitions and Behaviors at Follow-Up Assessment Periods as Predicted by Preintervention Score and Condition of Assignment

Variables ^a	Post		6 months		1 year	
	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>
PBI						
Prescore	-0.57	.0001	-0.51	.0001	-0.44	.0001
Class condition	-0.07	.48	-0.99	.23	-1.19	.17
SPQ+						
Prescore	-0.38	.0001	-0.44	.0001	-0.46	.0001
Class condition	2.74	.13	2.07	.20	-1.84	.25
SPQ-						
Prescore	-0.66	.0001	-0.66	.0001	-0.64	.0001
Class condition	-1.99	.18	-2.02	.18	-3.31	.06
CES+						
Prescore	-0.27	.0001	-0.32	.0001	-0.29	.0001
Class condition	0.86	.23	2.62	.01	0.10	.47
CES-						
Prescore	-0.62	.0001	-0.64	.0001	-0.69	.0001
Class condition	-2.82	.03	-0.32	.42	-1.29	.23
PAS						
Prescore	-0.25	.0001	-0.33	.0001	-0.41	.0001
Class condition	4.42	.01	7.84	.0001	2.67	.14
SAQ						
Prescore	-0.17	.01	-0.29	.0001	-0.36	.0001
Class condition	3.53	.01	1.94	.08	0.69	.35

^aControl condition participants make up the deleted group. All tests for conditions are one-tailed.

class condition participants became less pessimistic, had more positive (self-rewarding) and fewer negative (self-punishing) thoughts, and engaged in more pleasant and social activities at one or more follow-up assessments.

Table III presents the results of the second model, that is, the effect of condition of assignment on change in CES-D and BDI scores at the follow-up points. Above and beyond the contribution of the pre-CES-D score to the change scores, condition of assignment did not make a significant contribution at post and 6-month follow-up. At 1-year follow-up, class condition participants showed marginally ($p = .06$, one-tailed test) greater decline (by 2.51 points) on the CES-D than the control condition participants.

In the case of the BDI, the class condition participants reported significantly greater decline on BDI depression level at all follow-up points (2.11 points, $p = .02$ at post, 2.71 points, $p = .003$ at 6-months, and 1.73 points, $p = .04$ at 1-year follow-up). This supports the hypothesis that the experimental intervention had a positive effect in terms of reducing significant levels of depression as measured by the BDI.

Finally, Tables IV and V shows the results of the last model, that is, the effect of the assignment condition and change in cognition and behavior on depression level at various assessment periods. The indirect mediating effect of the cognitive-behavioral variables on outcome was calculated using the product of their b coefficients in the first and last models and divided by their variance (Baron & Kenny, 1986). Greater decline in CES-D depression level (indicated by greater negative change scores) was significantly predicted by increasing positive thoughts (CES+, b coefficient = $-.19$, $p = .05$) and decreasing negative thoughts (CES-, b coefficient = $.16$, $p = .01$), and decreasing pleasant activities (PAS, b coefficient = $.13$, $p = .05$) at post; decreasing negative thoughts (b coefficient = $.29$, $p = .0001$) and

Table III. CES-D and BDI Change Score at Follow-Up Assessment Periods as Predicted by Preintervention Score and Condition of Assignment

Variables ^a	Post		6 months		1 year	
	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>
CES-D						
Prescore	-0.58	.0001	-0.70	.0001	-0.77	.0001
Class condition	-1.91	.10	-1.46	.17	-2.51	.06
BDI						
Prescore	-0.43	.0001	-0.47	.0001	-0.56	.0001
Class condition	-2.11	.02	-2.71	.003	-1.73	.04

^aControl condition participants make up the deleted group. All tests for condition are one-tailed.

Table IV. Mediation Effect of Change in Cognitions and Behaviors on Change in CES-D Score at Corresponding Follow-Up Assessment periods

Variables	Post		6 months		1 year	
	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>
Pre-CES-D	-0.55	.0001	-0.62	.0001	-0.67	.0001
Class condition ^a	-1.40	.17	-0.19	.45	-2.08	.09
Change score						
PBI	0.01	.45	-0.04	.32	-0.09	.17
SPQ+	-0.04	.24	-0.01	.44	-0.07	.07
SPQ-	-0.05	.17	0.05	.17	0.06	.15
CES+	-0.19	.05	0.01	.45	0.03	.40
CES-	0.16	.01	0.29	.0001	0.13	.02
PAS	0.13	.05	-0.19	.01	-0.10	.07
SAQ	-0.03	.38	0.10	.14	-0.03	.35

^aControl condition participants make up the deleted group. All tests are one-tailed.

Table V. Mediation Effect of Change in Cognitions and Behaviors on Change in BDI Score at Corresponding Follow-Up Assessment Periods

Variables	Post		6 months		1 year	
	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>	<i>b</i>	<i>p</i>
Pre-BDI	-0.38	.0001	-0.45	.0001	-0.46	.0001
Class condition ^a	-1.69	.05	-2.46	.01	-1.60	.03
Change score						
PBI	0.02	.37	-0.05	.17	-0.05	.19
SPQ+	-0.01	.38	-0.03	.19	-0.05	.03
SPQ-	0.05	.08	0.03	.16	-0.03	.18
CES+	-0.12	.06	-0.02	.42	-0.05	.21
CES-	0.11	.01	0.16	.0001	0.22	.0001
PAS	0.03	.30	-0.02	.33	-0.06	.06
SAQ	-0.04	.26	-0.01	.43	0.02	.35

^aControl condition participants make up the deleted group. All tests are one-tailed.

increasing pleasant activities (*b* coefficient = $-.19$, $p = .01$) at 6 months; and decreasing negative thoughts (*b* coefficient = $.13$, $p = .02$) at 1-year follow-up. All of the findings were in the predicted direction, except for the PAS at post.

In the case of the BDI, improvement in depression level (also indicated by higher negative change scores) was mediated by decreasing negative thoughts at post (*b* coefficient = $.11$, $p = .01$), 6 months (*b* coefficient = $.16$, $p = .0001$), and 1-year follow-up (*b* coefficient = $.22$, $p = .0001$);

and increasing optimism (SPQ+, b coefficient = $-.05$, $p = .03$) at 1-year follow-up. All relationships are in the predicted direction.

DISCUSSION

The significance of this study lies in its being the first randomized, controlled, study of a prevention intervention for major depression. A cognitive-behavioral intervention significantly reduced depressive symptoms as measured by the BDI in an initially nonclinically depressed population. In addition, we found some support for changes in cognitions mediating changes in depression symptoms level. Our comments focus on what can be learned from this first depression prevention trial, both in terms of the limitations of the present study and the implications of our experience for future work.

Some of our colleagues have suggested that by selecting patients from public sector primary care clinics we may have limited the strength of the intervention and rendered it less effective due to possible debilitating physical health factors. Their point is that social and economic conditions (e.g., the large proportion of unemployment) among the poor urban groups which formed a substantial proportion of our sample may have diluted the individually oriented issues addressed in the intervention. We feel, however, that it is precisely these groups that most need prevention interventions. The hardships inherent in poverty, illness, and low societal status due to racism and other prejudice increase the likelihood that persons predisposed to depression will eventually develop the disorder. Approximately 10% of new episodes of major depression can be attributed to the effect of poverty (Bruce, Takeuchi, & Leaf, 1991). Although the Depression Prevention Course specifically addressed aspects of both external (objective) and internal (subjective) reality and attempts to improve the participants' ability to engage in the healthy management of their personal reality (see Muñoz & Ying, 1993, pp. 234-236), no attempt is made specifically to modify socioeconomic factors. Future prevention trials ought to consider the inclusion of interventions which address environmental stresses in addition to psychological processes. A good example of such an approach is the work of Price, van Ryn, and Vinokur (1992) in teaching unemployed persons job search skills to reduce the likelihood of depression in this population.

Prevention efforts are also especially appropriate for those groups that are less likely to consider utilizing mental health treatment services due to fear of being labeled a psychiatric patient. It is also vital to focus attention on developing and evaluating prevention strategies for groups that are unlikely to benefit from the treatment system, for example, because

they have trouble finding culturally and linguistically appropriate therapists. If prevention programs were to reduce the incidence of major depression in the Spanish-speaking population by 20%, this would be the equivalent of providing five times as many Spanish-speaking therapists as are estimated to be currently available in the United States (Muñoz & Ying, 1993, pp. 185-193).

With regard to measurement, reliance on self-report (interviews and questionnaires) is problematic. The key symptoms of the depressive syndrome are subjective: depressed mood or diminished interest or pleasure. However, there are no currently available valid objective measures for depression. Future studies may benefit from measures of mood and functioning provided by significant others, or objective measures of the effect of the depression on such variables as job attendance, medical utilization, or measures of development of children under the case of the participant. We also recognize that the reliability and validity of the DIS has been questioned. However, at the time the study began (1983), it was the state-of-the-art research instrument for assessing the presence of various DSM disorders in community surveys, and had been adopted by the National Institute of Mental Health for the Epidemiological Catchment Area study. Even today, the DIS is still widely used. We felt it was the best choice at the time, and we still do not feel that its use represents a fatal flaw.

Another measurement-related challenge is that of culturally appropriate measures. Ethnic minorities may conceptualize and experience symptoms differently from European Americans (Vega & Rumbaut, 1991). There are questions regarding the applicability of Western diagnostic systems on minority groups. Yet, to assess presence of major depression, we chose to utilize the existing DIS-DSM-III convention, in part because we lacked the resources to create a separate and potentially ethnically more sensitive diagnostic system for each ethnic subsample in this study. We faced the dilemma of limiting our randomized prevention trial to the white middle-class populations that conceptualized and developed these measures or including low-income minorities in a study with measures that may not be culturally centered. A third alternative, of course, was delaying the randomized trial while we developed psychometrically rigorous measures for each of the ethnic groups we hoped to study. We decided to proceed with our main objective, attempting, whenever possible, to use measures that had been used with minority samples in the past, and to utilize standard methods for translation of measures (such as the forward-and-back-translation paradigm). We also attempted to use bilingual and bicultural personnel for data collection and administering of the intervention to non-English-speaking participants. (For further discussion of how the Depression Prevention Research Project team addressed issues of implemen-

tation of prevention intervention research with diverse populations, see Muñoz, 1986; Muñoz, Chan, & Armas, 1986; Muñoz et al., 1987; and Muñoz & Ying, 1993, pp. 173-181). Finally, we used the data collected in the trial to provide information regarding the characteristics of the measures on each of the major ethnic groups so future researchers could benefit from our experience (see, e.g., Azocar, Areán, Miranda, & Muñoz, 1993; Miranda, Muñoz, & Shumway, 1990; Muñoz & Ying, 1993). We are not completely satisfied with our choice. However, the following statement from Maccoby has given us some solace: "You can either work on only the most important problems that you can handle *with precision*, or you can work on the *most important problems* with the best of inadequate research methods" (Maccoby & Alexander, 1979, p. 100). Carrying out this prevention trial with a multiethnic population was very important for us. And we did so in as precise a manner as we could, given time and resource constraints. Clearly, this problem goes beyond prevention research, and is inherent to applied research in general.

Another intriguing measurement issue was the difference in patterns of change found between the BDI and the CES-D. The combined results of the second and third models in our analyses show that change in BDI score was more likely to be a direct result of the intervention (with significant changes at all of the follow-up assessments), while the CES-D score was relatively more likely to be mediated by change in cognitions and behaviors. This may be secondary to the difference in the content of the measures and emphasis of the intervention. The CES-D is more affect-focused and the BDI is more cognition-oriented. In the intervention, we emphasized that changing one's affect directly is difficult and more easily indirectly accomplished through modifying one's cognitions and behaviors. Indeed, the findings support that (depressed) cognition is more directly modifiable while (depressed) affect is indirectly modified. While class participants demonstrated change in the predicted direction on various cognitive-behavioral variables at various follow-up points, no variable was consistently significant across all three assessment periods. For instance, while the number of pleasant activities increased at post and 6 months, it was no longer significantly different than that found in the control condition by 1 year. This deserves further investigation with a larger sample. These findings also suggest that our interventions produced a general but not a robust change in the mediating variables. Strengthening the intervention to more reliably modify the cognitive behavioral mechanisms hypothesized to be related to depression symptoms would theoretically produce more powerful and long-lasting effects on mood. With regard to mediational effects, we found the reduction of negative cognitions consistently led to a reduction in both the CES-D and BDI depression levels in the class condition participants across

all follow-up points. Future depression prevention studies ought to further investigate the utility of reduction of depression-related cognitions as an important preventive intervention.

At the design level, these findings support the feasibility of using prevention trials to test the theories behind preventive interventions. As stated in the introduction, the Depression Prevention Course was based on a social learning, self-control theoretical perspective. The measurement of distal outcomes alone would have been a waste of an opportunity to test the hypotheses behind the intervention. Although our results are mixed in terms of how successful we were in modifying the cognitive and behavioral variables targeted in our intervention, the preponderance of the findings support the association between changes in thoughts and activities and mood levels. The theoretical framework on which the intervention was based appears valid. Thus, future work can emphasize improving interventions, so that the mediating variables are more predictably modified, or improving measures so that they are more sensitive to planned changes. A more radical departure might involve individualizing the length of the interventions so that, rather than having a specific number of sessions, training is done to criterion, that is, until the targeted cognitions and behaviors are successfully modified in each individual. The latter modification would lend itself well to a test of the attributable risk due to depressogenic cognitions and behaviors, that is, the proportion of the incidence that could be averted if an intervention were completely successful in changing the relevant thought and activity patterns. It would also provide information on the range of applicability of cognitive behavioral methods by documenting the proportion of individuals for whom changes in thought and behavior are impossible to produce within a reasonable amount of time, and how this proportion can be increased, for example, by the addition of interventions focusing on socioeconomic variables, such as jobs, housing, safety, and so on.

The ultimate goal of prevention trials is the reduction of new cases of clinical episodes. The current study was clearly intended as a prevention trial: We set out to reduce both the incidence of major depression as well as depression symptom levels. The incidence rate (5%) resulted in the most important limitation of the study, namely, insufficient sample to yield adequate statistical power to test differences in the number of new cases. Although the current *prevalence* of depression in the primary care sample examined (even after excluding those receiving mental health treatment) was clearly very high (21.5% for major depression and dysthymia combined), the *incidence* was unknown prior to conducting the study, and turned out to be insufficient to provide adequate power with the sample size available. There are very few estimates of incidence of clinical depres-

sion in any population, and those that are available vary widely (Boyd & Weissman, 1982; Eaton et al., 1989). Even so, the majority of incidence rates are well below those found in the current study: 28 out of 31 rates reported by Boyd and Weissman (1982) were under 500 per 100,000/year, or less than .005. By comparison, the .05 rate found in the current study is 10 times as great. The annual incidence rate found in the ECA project, using the DIS and DSM-III criteria, and thus directly comparable methodologically to the current study, was 1.59 (Eaton et al., 1989) or about a third the rate in our prevention trial. It appears, then, that although the group studied *was* a high-risk group, an even higher risk subgroup was needed to adequately test reductions in incidence. For example, if a subgroup could be identified with a 1-year incidence of 20%, and the experimental group's incidence could be reduced by half (to 10%), a study with 312 subjects (156 per group) would yield power of .80 ($\alpha = .05$, one-tailed) to detect a moderate effect (Hulley & Cummings, 1988; Muñoz, 1993). In the current study, a simple rule of having scored over 16 on the CES-D twice during the year identified a subsample with an incidence rate of 17%. Another method to increase incidence, of course, is to lengthen the time period being studied.

To address the need to identify subgroups within high-risk populations which are at *imminent* high risk, the field should consider conceptualizing depressive symptoms as attributable risk factors for major depression (Dryman & Eaton, 1991; Horwath, Johnson, Klerman, & Weissman, 1992), and, as the recent report by the Institute of Medicine (Mrazek & Haggerty, 1994) suggests, attempt to reduce that risk factor as a way to eventually prevent episodes of major depression. Development of screening instruments that can assess current symptom level routinely in primary care settings, especially those that are linguistically and culturally appropriate (Muñoz, González, & Starkweather, 1995), may be particularly useful in this effort. Those identified by the screener as having a current clinical depression should be referred for treatment for depression, and those with high levels of depressive symptoms should be considered at high risk and referred to prevention interventions. The latter group would be appropriate for what the Institute of Medicine report calls *indicated* preventive interventions (Mrazek & Haggerty, 1994). An analysis of the subsample with high symptom levels (those who scored 18 or above on the BDI), shows that the Depression Prevention Course resulted in significant reductions in depressive symptoms, somatic symptoms, and missed medical appointments in the experimental group (Miranda & Muñoz, 1994).

As the field of depression prevention research matures, it will ultimately focus on measured effects on frequency, duration, and intensity of depressive *episodes*. Although the findings are less robust than we had

hoped for, the present study supports the utility of an intervention focused on teaching initially nonclinically depressed individuals cognitive-behavioral self-control skills to reduce depressive symptomatology. Although the frequency of new cases was lower in the individuals who actually received the intervention, incidence was too low to produce sufficient power to adequately test this hypothesis. Of course, high levels of depressive symptoms are worth preventing on their own right, as suggested by their major impact on functioning and well-being (Wells et al., 1989).

Our perspective on the Depression Prevention Research Project is that we have shown that a randomized, controlled, prevention trial is feasible in a public sector primary care setting serving predominantly low-income minority individuals. We have also shown that such randomized trials do not need to exclude non-English-speaking members of the group being studied. (A small pilot study was also conducted in Cantonese and Mandarin, see Chan, Ying, & Muñoz, 1986.) We have shown that depressive symptoms can be lowered significantly in such a population, and that this reduction appears to be related to several of the cognitive behavioral variables targeted by the intervention. Whether such a reduction in depressive symptoms will reliably result in a significant reduction in incidence is yet to be demonstrated. To do so, we recommend that an even higher risk subsample within this population be identified, that is, that we move from a *selective* to an *indicated* level of preventive intervention (see Mrazek & Haggerty, 1994, pp. 22-26). We believe that focusing on high symptom levels that are still subthreshold for major depression is a reasonable strategy for finding subgroups at imminent high risk. Additional factors such as family history, high levels of stressful life events, and lack of confidants or other support systems might be useful in identifying groups at even higher risk. A significant reduction in incidence of major depressive episodes in a randomized, controlled, trial has been reported in a sample of high school students selected because they had high depressive symptoms (Clarke et al., 1995).

At a more general level, the present study supports the recommendations of the Institute of Medicine report that funding for "research on preventive interventions aimed at major depressive disorder should be increased immediately and substantially" (Mrazek & Haggerty, 1994, p. 481) because it is likely to yield results relatively soon, compared to other major mental disorders. Interest in the prevention of depression is beginning to yield serious attempts to conceptualize the issues and suggest ways to achieve progress (Lowry, 1984; Mrazek & Haggerty, 1994, pp. 86-93, 163-171; Muñoz, 1987; Muñoz & Ying, 1993). Ideally, prevention intervention trials focused on reducing incidence of specific mental disorders will be-

come more numerous, and their designs will gradually show the rapid improvement manifested by treatment outcome study designs.

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