

# Toward evidence-based Internet interventions: A Spanish/English Web site for international smoking cessation trials

Ricardo F. Muñoz, Leslie L. Lenert, Kevin Delucchi, Jacqueline Stoddard, John E. Perez, Carlos Penilla, Eliseo J. Pérez-Stable

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The Internet provides a medium to administer and evaluate evidence-based interventions for highly prevalent public health problems worldwide. The authors report a series of four Internet smoking cessation studies conducted in English and Spanish. These studies examined both outcome (self-reported 7-day abstinence) and mechanisms related to outcome (the impact of major depressive episodes [MDEs] on the likelihood of quitting). Over 4,000 smokers from 74 countries entered the studies. Studies 1 and 2 evaluated a standard smoking cessation guide (the “*Guía*”). Studies 3 and 4 were randomized trials comparing the *Guía*+ITEMs (individually timed educational messages) to the *Guía*+ITEMs+a mood management course. ITEMs were E-mails inviting participants back to the site at specific times. Online follow-up assessments resulted in completion rates of 44%–54% at 1 month and 26%–30% at 6 months in studies 1 and 2. Incentives and follow-up phone calls increased these rates to 70%, 66%, 65%, and 62% at 1, 3, 6, and 12 months in study 4. At 6 months, self-reported 7-day abstinence rates using missing=smoking data were 6% in studies 1 and 2, 10%–14% in study 3, and 20%–26% in study 4. The *Guía*+ITEMs condition tended to have higher quit rates, which reached significance at the 12-month follow-up in study 3 and at the 3-month follow-up in study 4. Smokers with past (but not current) MDEs tended to be the most likely to abstain and those with current MDEs the least likely. This trend reached significance in studies 1 and 4.

## Introduction

The National Institute of Mental Health Psychosocial Intervention Development Workgroup (Hollon et al., 2002) recently called for the use and evaluation of nontraditional delivery methods to increase accessibility of psychosocial interventions. This article reports on a research program consonant with these objectives. Our goals are to demonstrate that (a) the World Wide Web can be used to carry out *outcome research* (including randomized controlled

smoking cessation trials) and thus yield evidence-based Internet interventions, (b) Web-based studies can examine *mechanisms* related to outcome, in this case, how depression is related to the likelihood of quitting, and (c) the Web is truly a worldwide tool that can be used by health researchers to cross national borders and surmount language barriers, for example, reaching English- and Spanish-speaking smokers across the globe.

By the 2030s an estimated 10 million people worldwide will die each year from tobacco-related diseases (Peto & Lopez, 2000). Most of these individuals are probably smoking currently. By the year 2000 the annual number of smoking-related premature deaths worldwide had already reached 4.8 million (Ezzati & Lopez, 2003), with approximately 440,000 deaths in the United States alone (Centers for Disease Control and Prevention, 2003). Comorbidity with depression may play a significant role in smoking behavior and in quitting (Hall,

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Ricardo F. Muñoz, Ph.D., Kevin Delucchi, Ph.D., Carlos Penilla, M.S., Eliseo J. Pérez-Stable, M.D., University of California, San Francisco; Leslie L. Lenert, M.D., University of California, San Diego, La Jolla, CA; Jacqueline Stoddard, Ph.D., National Cancer Institute, Bethesda, MD; John E. Perez, Ph.D., University of Massachusetts, Boston, MA.

Correspondence: Ricardo F. Muñoz, Department of Psychiatry, University of California, San Francisco, San Francisco General Hospital, 1001 Potrero Avenue, Suite 7M, San Francisco, CA 94110, USA. Tel: + 1 (415) 206-5214; Fax: +1 (415) 206-8942; E-mail: munoz@itsa.ucsf.edu

Muñoz, Reus, & Sees, 1993). Depression is itself a major public health problem, accounting for 11% of disability worldwide (Murray & Lopez, 1996). Because both of these prevalent health conditions can simultaneously exacerbate human suffering, there is reason to study them together and to develop effective interventions that can reach those affected around the globe.

Many of the public health problems producing the greatest burden of disease involve either individual behavior that requires behavior change or emotional dysregulation that can be treated successfully with learning-focused interventions. Individual behavior is itself the problem in smoking, alcohol and other drug abuse, unhealthy diets, and inadequate exercise. Depression and anxiety, though not necessarily caused by individual behavior, respond well to interventions focused on changes in thinking and behavior. However, the number of service providers trained to administer such interventions is limited. Therefore, arguments have been made (a) to extend their reach by means of adjuncts, including printed matter and mass media approaches, and (b) to evaluate their impact, systematically comparing the cost effectiveness of traditional face-to-face interventions with that of these population-focused approaches (A. Christensen, Miller, & Muñoz, 1978; Hollon et al., 2002). The potential of mass media to provide behavioral health interventions to entire populations across different countries is beginning to be tapped (Bandura, in press). And, because the Internet (unlike radio and television) permits two-way communication easily, its potential to evaluate interventions as they are being provided is particularly promising.

Cessation programs delivered via the Internet hold great promise because of their broad reach and convenience. Recent pilot studies of Internet-based smoking cessation interventions have indicated the potential impact of such interventions, showing 1-month quit rates (7-day abstinence) of 18% or more among participants (Feil, Noell, Lichtenstein, Boles, & McKay, 2003; Lenert et al., 2003).

The interventions tested in this report are from a study identified in a recent review (Lawrence, Graber, Mills, Meissner, & Warnecke, 2003) as the only published smoking cessation randomized trial (Muñoz, Marín, Posner, & Pérez-Stable, 1997) reporting significant differences for Hispanic smokers in the United States. Adding a mood management component significantly increased abstinence rates in a trial using interventions delivered via surface mail. Here, we evaluated a Web-based version of the smoking cessation guide used in that study (the “*Guía*,” described below) and an expanded Web-based version of the mood management intervention.

This report focuses on (a) outcomes, defined as point prevalence (self-reported 7-day abstinence

rates) for smokers recruited via the Internet, (b) mechanisms, namely, the impact of major depression on the likelihood of quitting, and (c) the similarities and differences between English-speaking samples (studies 1 and 3) and Spanish-speaking samples (studies 2 and 4).

## Methods

Studies 1, 2, 3, and 4 were Internet-based self-help smoking cessation trials conducted sequentially. Each subsequent study contains improvements derived from our experiences with the former. They are described in the order performed, highlighting the major differences among them. Studies 1 and 2 are described together. They were exploratory studies, testing the *Guía* within a one-condition design with online 1- and 6-month follow-up assessments. Studies 3 and 4 also are described together. They were randomized trials comparing the *Guía* plus ITEMs (individually timed educational messages, described below) to the *Guía* plus ITEMs plus a mood management course. Studies 3 and 4 involved additional cohort maintenance procedures, including online and phone follow-up assessments at 1, 3, 6, and 12 months. The results of the four studies are then presented sequentially.

### *Studies 1 and 2: Procedures*

Two self-help smoking cessation Web sites were constructed to conduct one-group intervention outcome studies with follow-ups at 1 and 6 months. Study 1 was conducted in English. Study 2 was conducted in Spanish. The sites were designed to recruit participants, obtain official informed consent, obtain initial assessment data, provide a standard smoking cessation intervention, and obtain follow-up data at 1 and 6 months after enrollment, all via the Web. For a preliminary report providing greater detail on the sites and on the first 538 English-speaking participants recruited, see Stoddard et al. (2005).

### *Studies 1 and 2: Participants*

English-speaking participants for study 1 were recruited from April 11, 2000, to January 31, 2002 (Table 1 shows progression through the study). Three recruitment methods were used: (a) Press releases about the study, (b) links from search engines, and (c) an E-mail message to members of a major health-related Web site. Spanish-speaking participants for study 2 were recruited from September 21, 2000, to January 31, 2002. Three recruitment methods were used: (a) Press releases about the study, (b) links from search engines, and (c) brief announcements on health information sites.

**Table 1.** Progression of participants through four Internet smoking cessation studies.

	Study 1	Study 2	Study 3		Study 4	
Design	One-condition, two online follow-up assessments		Randomized trials: two conditions, four online and phone follow-up assessments			
Language	English	Spanish	English		Spanish	
Recruitment period	Apr. 11, 2000–Jan. 31, 2002	Sept. 21, 2000–Jan. 31, 2002	Mar. 1, 2002–Dec. 2, 2002		May 22, 2003–Sept. 25, 2003	
Screened	NA	NA	900		1239	
Eligible	NA	NA	607		728	
Consented	2987	799	351		399	
Completed baseline measures	2774	702	280		288	
			Randomized		Randomized	
			↙ ↘		↙ ↘	
Condition	<i>Guía</i> alone	<i>Guía</i> alone	<i>Guía</i> +ITEMs	<i>Guía</i> +ITEMs +MM	<i>Guía</i> +ITEMs	<i>Guía</i> +ITEMs + MM
Number randomly assigned	NA	NA	141	139	146	142
1-Month follow-up	1218	378	74	86	98	103
3-Month follow-up	<b>Not done</b>	<b>Not done</b>	52	47	95	96
6-Month follow-Up	723	211	46	50	90	96
12-Month follow-up	<b>Not done</b>	<b>Not done</b>	45	52	91	86

*Note.* *Guía*, smoking cessation guide; ITEMS, individually timed educational messages (sent via E-mail with link to site); MM, mood management intervention (eight-lesson cognitive-behavioral course provided at the rate of one lesson per week); NA, not applicable.

Interested individuals logged on to the Web site and responded to an 11-item eligibility questionnaire. Eligibility included being 18 years of age, smoking one or more cigarettes daily, using E-mail at least once weekly, and planning to quit within the next 3 months. Those eligible were presented with an online institutional review board-approved consent form. Those consenting were presented with baseline questionnaires and, upon completion, a standard smoking cessation guide (*Guía*, described below) and individually tailored smoking cessation advice based on their responses to online questionnaires. Those not eligible or not consenting were provided access to the *Guía*. No further data were collected from them. Thus, subjects had little incentive to falsify data to view the intervention. Consented participants were provided usernames and passwords to log on and review the *Guía* as often as they wished. They were contacted again via e-mail 1 and 6 months later with a link to a follow-up questionnaire to determine smoking status.

#### Studies 1 and 2: Materials

**Assessment instruments.** The baseline questionnaires included (a) a demographics section, (b) questions addressing smoking patterns, (c) the Fagerström Test for Nicotine Dependence (FTND), (d) the Major Depressive Episode (MDE) Screener, and (e) the Center for Epidemiologic Studies Depression Scale (CES-D).

The FTND (Heatherton, Kozlowski, Frecker, & Fagerström, 1991) is a six-item, self-report measure of nicotine dependence. It has shown acceptable

internal consistency ( $\alpha=.61$ ) and documented association with biochemical indices of tobacco intake (carbon monoxide, nicotine, and cotinine levels).

The MDE Screener (also called the “Mood Screener”; Miller & Muñoz, 2005, p. 141) was used to ascertain prevalence of major depressive episodes. It screens for the nine *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition (*DSM-IV*; APA, 1994) symptoms for MDEs. Participants score positive for a MDE if they have had five or more of the nine symptoms (including symptom 1 or 2) and the symptoms *interfered with their life or activities a lot* at any point during their lifetime (past MDE) or in the last 2 weeks (current MDE). The MDE Screener agrees well with the PRIME MD (Spitzer et al., 1994) screener in English and Spanish speakers (kappas of .75) (Muñoz, McQuaid, Gonzalez, Dimas, & Rosales, 1999). It also showed good predictive validity in terms of being associated with higher quit rates for participants it categorized as having a history of past (but not current) major depression when they were provided with a mood management intervention (Muñoz et al., 1997). Three diagnostic groups were defined using the MDE Screener: (a) “No MDE history” comprises those reporting never having experienced a major depressive episode, (b) “past MDE” includes those with a history of MDEs but not a current MDE, and (c) “current MDE” includes participants meeting MDE criteria during the last 2 weeks.

The CES-D (Radloff, 1977) was used to ascertain level of depressive symptoms. It is a 20-item self-report depression scale that yields a continuous depression score (range=0–60) with higher scores

signifying greater levels of depression. The national mean score in U.S. adults (Sayetta & Johnson, 1980) was 8.7 ( $SD=8.4$ ). CES-D scores have been shown to be related to smoking status in Latinos (Pérez-Stable, Marin, Marin, & Katz, 1990) and to predict the likelihood of quitting in earlier studies (Anda et al., 1990).

*Intervention.* The smoking cessation intervention (*Guía*) was the “*Guía para dejar de fumar*” (National Cancer Institute, 2002). This evidence-based intervention was developed and tested as a Spanish-language brochure (Pérez-Stable, Sabogal, Marin, Marin, & Otero-Sabogal, 1991). It was translated into English and adapted as a Web-based brochure for this study. It covers reasons to stop smoking, how to prepare to quit, what to do in case of relapse, how to refuse cigarettes from friends and family, and information on pharmacological aids such as nicotine replacement agents and bupropion. Additional advice for smoking cessation was individually tailored based on responses to the baseline questionnaires. Participants with high levels of nicotine addiction were encouraged to use nicotine replacement therapies. Participants with responses suggesting depression were encouraged to visit a physician to discuss treatment of depression prior to smoking cessation efforts.

*Follow-up.* At 1 and 6 months after entry, participants received an automated E-mail with a link to a follow-up questionnaire. Self-reported 7-day abstinence was defined as a “no” response to the question “Have you smoked 1 or more cigarettes in the last 7 days?” “Observed” rates are based only on participants who completed follow-ups. “Missing=smoking” rates code missing follow-up data as smoking.

#### *Studies 3 and 4: Procedures*

Two smoking cessation Web sites were constructed to conduct randomized controlled studies comparing a standard smoking cessation intervention (*Guía*+ITEMs) to the same guide plus a mood management intervention (*Guía*+ITEMs+MM). Study 3 was conducted in English. Study 4 was conducted in Spanish. Follow-ups occurred at 1, 3, 6, and 12 months. We considered the follow-up rates found in studies 1 and 2 insufficient to adequately evaluate a randomized trial. Therefore, we instituted a system of monetary incentives for returning to the site and phoned participants if they did not complete follow-up data online. The greater cost of these procedures necessitated limiting the sample size of the study to a maximum of 300 participants.

#### *Studies 3 and 4: Participants*

English-speaking participants for study 3 were recruited from March 1, 2002, to December 2, 2002, and Spanish-speaking participants for study 4 were recruited from May 22, 2003, to September 25, 2003, via press releases and standard links from search engines. Interested individuals logged on to the Web sites and responded to an 11-item eligibility questionnaire. Eligibility included being 18 years of age, smoking five or more cigarettes daily, using E-mail at least once weekly, and planning to quit within the next month.

Those eligible were presented with an online institutional review board-approved consent form. The consent form explained that participants would receive up to US\$30 in incentives, payable in cash at the end of the study: \$1 for each time they visited the site per week for 8 weeks, with a \$2 bonus if they did so all 8 weeks, plus \$5 for completing each of four follow-up questionnaires. Those consenting completed baseline questionnaires. Those not eligible or not providing consent were provided access to the *Guía*. No further data were collected from them.

#### *Studies 3 and 4: Materials*

*Assessment instruments.* The baseline questionnaires were the same as for studies 1 and 2. Results were used to automatically implement stratified randomization by gender and MDE status (no MDE history, past MDE, and current MDE) to the two conditions.

*Interventions.* The *Guía* was the smoking cessation guide used in studies 1 and 2, augmented with a self-monitoring tool used to track daily consumption of cigarettes. The second condition added to the *Guía* was an eight-lesson social-learning-oriented (Bandura, 1977) mood management course (Lewinsohn, Muñoz, Youngren, & Zeiss, 1992) designed to improve quit rates. The course included instructions on how to use the materials; self-monitoring screens to record cigarettes smoked, mood and anxiety levels, pleasant activities, helpful and harmful thoughts, and contacts with helpful people; and relaxation instructions. Lessons were made available one per week to simulate how such lessons would be delivered in a traditional smoking cessation group.

To increase the likelihood that participants would log on to the site beyond the initial recruitment visit, ITEMs were E-mailed to all randomized participants 7 days, 3 days, and 1 day before the quit date set by the participant, and 1, 3, 7, 14, and 21 days after the quit date. The messages included encouraging comments and links to relevant sections of the assigned intervention, such as planning for the quit day, the

early quit period, how to stay quit, and relapses, if any. (See Lenert, Muñoz, Perez, & Banson, 2004, for more details.)

*Follow-up.* At 1, 3, 6, and 12 months after entry, participants received an E-mail with a link to the follow-up questionnaires. If the E-mail did not result in data entry, research assistants were notified to administer the questionnaires by phone. Self-reported 7-day abstinence was defined as a “no” response to the question “Have you smoked 1 or more cigarettes in the last 7 days?” Because of a programming problem, some E-mail reminders were not sent, leading to a lower-than-optimal follow-up rate for study 3. To improve follow-up rates in study 4, we sent participants a welcoming letter via surface mail on entrance into the study and corrected the programming problem with the follow-up reminder E-mail messages.

### Data analyses

We compared 7-day smoking abstinence rates at each assessment point, the primary outcome, using Pearson’s chi-square test. Parallel analyses were conducted in which missing follow-up data were coded as “smoking.” Tests were considered significant at a *p* level of less than .05, unless otherwise stated.

### Results: Study 1

#### Participant characteristics

Demographic, smoking history, and depression variables are presented in Tables 2 and 3 for the 2,774 participants who completed the baseline questionnaires. Participants reported being from 64 countries, with 10.6% from outside the United States. Over two-thirds of the participants were women, the

**Table 2.** Demographic characteristics for four Internet smoking cessation studies (2000–2003).

Variable	Study 1	Study 2	Study 3	Study 4
	English (N=2,774)	Spanish (N=702)	English (N=280)	Spanish (N=288)
	%	%	%	%
Sex				
Men	30.5	65.5	32.1	58.7
Women	69.5	34.5	67.9	41.3
Ethnicity				
Latino	2.4	55.1	5.0	33.8
White	82.2	41.8	76.3	62.0
Asian	1.4	0.7	3.2	0.4
African American	3.0	0.1	5.0	0.4
Native American	1.8	0.0	1.1	0
Multiethnic	2.1	1.1	2.2	0.7
Other	7.1	1.2	7.2	2.8
Education				
High school or less	44.3	14.5	35.4	22.6
Some college	29.2	17.8	29.3	24.0
College grad	19.5	46.0	25.4	39.2
Graduate degree	7.1	21.6	10.0	14.2
Employed				
Full time	53.0	71.2	61.4	67.3
Part-time	6.9	13.9	9.6	14.6
Not currently	30.3	11.9	19.3	16.7
Not ever	9.9	3.0	9.6	1.4
Income, US \$				
<10,000	4.0	16.0	2.9	28.4
10,000–15,000	4.5	15.1	4.0	16.4
15,000–20,000	6.1	13.9	7.6	13.1
20,000–35,000	21.7	20.7	19.9	17.5
35,000–50,000	23.9	12.8	25.4	12.3
50,000–75,000	20.7	9.4	23.2	4.5
75,000–100,000	10.8	5.3	8.3	3.7
>100,000	8.3	6.9	8.7	4.1
Marital status				
Single	17.7	31.3	25.1	33.5
Living with	9.2	8.6	10.0	11.5
Married	52.5	49.0	48.0	43.6
Separated	2.4	3.6	2.9	5.9
Divorced	16.1	7.1	12.2	4.9
Widowed	2.2	0.4	1.8	0.7

*Note.* Table based on those with no missing data in the relevant variables.

**Table 3.** Smoking history, history of major depression, and depression symptoms in four Internet smoking cessation studies (2000–2003).

	Study 1	Study 2	Study 3	Study 4
	English (N=2,774)	Spanish (N=702)	English (N=280)	Spanish (N=288)
Smoking history	Mean (standard deviation)			
Age (years)	41.7 (11.1)	36.5 (9.4)	38.4 (10.8)	35.0 (9.5)
Age, first cigarette	15.3 (4.3)	15.6 (3.6)	15.6 (4.7)	16.0 (3.4)
Age, regular smoker	17.7 (4.0)	18.4 (3.8)	18.3 (4.4)	18.4 (4.7)
Cigarettes/day	23.7 (11.3)	22.9 (11.0)	20.3 (9.7)	22.8 (10.2)
FTND score	5.5 (1.8)	5.1 (1.8)	5.4 (2.5)	5.5 (2.3)
Quit confidence	6.4 (2.2)	6.6 (2.2)	7.0 (2.1)	7.4 (1.7)
Methods used to quit in last 6 months	Percent using			
Nicotine gum	44.9	31.3	30.4	2.1
Nicotine patch	55.0	19.1	33.9	1.7
Nicotine inhaler	5.5	1.1	3.2	0
Nicotine spray	1.1	0.1	0.4	0
Bupropion (Zyban)	16.8	3.0	18.2	1.0
Stop smoking group	11.7	5.0	4.3	0
Hypnosis	20.6	4.0	6.4	0
Acupuncture	6.0	6.3	2.9	0.4
Motivational tapes	17.4	6.7	6.4	1.0
Other self-help	9.5	26.5	1.8	1.4
Web site	Not asked	Not asked	0.4	1.0
None	Not asked	Not asked	42.9	12.5
Depression variable	Percent			
Major depressive episodes (MDE)				
No MDE history	61.3	58.8	69.6	65.2
Past MDE	21.7	17.4	18.9	18.1
Current MDE	17.0	23.8	11.4	16.7
CES-D score, mean (standard deviation)	17.8 (12.3)	17.8 (13.0)	16.2 (12.0)	15.9 (11.9)

Note. Table based on those with no missing data in the relevant variables. CES-D, Center for Epidemiological Studies Depression Scale; FTND, Fagerström Test for Nicotine Dependence.

mean age of the sample was 41.7 years ( $SD=11.1$ ), and 42.7% were “heavy smokers” (Lasser et al., 2000), reporting smoking more than 24 cigarettes daily. Nicotine dependence was comparable with that found in traditional smoking cessation studies (FTND score,  $M=5.5$ ,  $SD=1.8$ ). Scores on the CES-D were high, with 50.7% scoring 16 or above; and 17.0% screened positive for a current MDE and an additional 21.7% for a past MDE.

#### Outcomes at follow-ups

*Follow-up rates (Table 1).* Of those completing baseline questionnaires, 43.9% provided follow-up data at 1 month and 26.1% at 6 months.

*Abstinence rates (Table 4).* Observed rates were 17.5% at 1 month and 24.2% at 6 months. Missing=smoking rates were 7.7% at 1 month and 6.3% at 6 months.

**Table 4.** Self-reported 7-day abstinence for each of the interventions (percentages).

Follow-up point	Study 1	Study 2	Study 3		Study 4	
	Guía alone	Guía alone	Guía+ITEMs	Guía+ITEMs+MM	Guía+ITEMs	Guía+ITEMs+MM
Observed rates						
1 month	17.5	9.8	32.4	26.7	34.3	23.3
3 month	Not done	Not done	32.7	36.2	42.7	29.2
6 month	24.2	18.5	41.3	28.0	42.2	29.6
12 month	Not done	Not done	53.3	23.1	36.3	33.7
Missing=smoking rates						
1 month	7.7	5.3	17.0	16.5	23.3	16.9
3 month	Not done	Not done	12.1	12.2	28.1	19.7
6 month	6.3	5.6	13.5	10.1	26.0	20.4
12 month	Not done	Not done	17.0	8.6	22.6	20.4

Note. 7-day abstinence was defined as a “no” answer to the question “Have you smoked 1 or more cigarettes in the past 7 days?” Observed rates were calculated as the number reporting 7-day abstinence divided by the number of participants who responded at each follow-up point. Missing=smoking rates were calculated as the number reporting 7-day abstinence divided by the total number of participants assigned to the condition. *Guía*, smoking cessation guide; ITEMs, individually timed educational messages (sent via E-mail with link to site); MM, mood management intervention (eight-lesson cognitive-behavioral course provided at the rate of one lesson per week).

**Table 5.** Major depressive episode (MDE) history per study and 7-day abstinence rates by MDE history.

MDE status	Study 1			Study 2			Study 3			Study 4		
	No MDE history	Past MDE	Current MDE	No MDE history	Past MDE	Current MDE	No MDE history	Past MDE	Current MDE	No MDE history	Past MDE	Current MDE
	61.3	21.7	17.0	58.8	17.4	23.8	69.6	18.9	11.4	65.2	18.1	16.7
	Percentage meeting criteria for each diagnostic group											
	Observed rates											
Follow-up point	17.7	19.9	12.0	10.5	12.0	6.0	28.8	31.3	29.4	28.8	34.2	21.9
1 month		Not done			Not done		35.6	41.2	11.1	32.3	50.0	32.1
3 month	24.1	26.7	19.2	21.3	18.6	10.9	36.8	40.0	0	34.8	46.2	25.8
6 month		Not done			Not done		37.9	34.8	37.5	32.7	52.8	22.6
12 month	Missing=smoking rates											
1 month	7.6	10.5	4.3	5.6	7.4	3.0	16.4	18.9	15.6	20.3	25.0	14.6
3 month		Not done			Not done		13.3	13.2	3.1	21.4	38.5	18.8
6 month	6.1	9.0	3.8	6.3	6.6	3.0	12.8	15.1	0	21.9	34.6	16.7
12 month		Not done			Not done		12.8	15.1	9.4	19.3	36.5	14.6

*Note.* MDE status was obtained using the MDE Screener (Miller & Muñoz, 2005, p. 141). To meet criteria for past MDE, respondents must report having experienced five or more of the nine MDE symptoms (including 1 or 2) from the *DSM-IV* criteria for MDE, and these symptoms must have lasted 2 weeks or more and interfered with their life or activities a lot. Of those meeting criteria for past MDE, those meeting these criteria in the last 2 weeks are designated as having a current MDE. Otherwise, respondents are assigned to the no MDE history group. 7-day abstinence was defined as a “no” answer to: “Have you smoked 1 or more cigarettes in the past 7 days?” Observed rates were calculated as the number reporting 7-day abstinence divided by the number of participants who responded at each follow-up point. Missing=Smoking rates were calculated as the number reporting 7-day abstinence divided by the total number of participants assigned to the condition. For Studies 3 and 4, rates were collapsed across conditions.

*Effect of depression status on abstinence (Table 5).* To correct for multiple comparisons, we used a *p* level of .017 (.05/3) for pairwise comparisons among MDE groups. Observed rates yielded no significant differences among the three MDE groups. Missing=smoking figures showed that, at 1 month, smokers with no MDE history had significantly higher abstinence rates than did those with current MDE (*OR*=1.87; 95% *CI*=1.15–3.02, *p*=.0101) and those with past MDE had significantly higher rates than did those with current MDE (*OR*=2.64, 95% *CI*=1.57–4.43, *p*=.0001). At the 6-month follow-up, those with past MDE had significantly higher abstinence rates than did those with current MDE (*OR*=2.48, 95% *CI*=1.44–4.30, *p*=.0008), and those with no history of MDE had significantly lower rates than did those with past MDE (*OR*=0.65, 95% *CI*=0.46–0.92, *p*=.014). CES-D score at baseline did not predict smoking status 1 or 6 months later.

**Results: Study 2**

*Participant characteristics*

Demographic, smoking history, and depression variables are presented in Tables 2 and 3 for the 702 participants who completed the baseline questionnaires. Participants reported being from 29 countries, with 99.1% from outside the United States. The largest numbers were from Spain (231), Venezuela (153), Argentina (77), Mexico (75), and Peru (56). Only 34.5% of the participants were women, the mean age of the sample was 36.5 years (*SD*=9.4), and 40.2% were heavy smokers (more

than 24 cigarettes daily). Nicotine dependence was comparable with that found in study 1 (FTND score, *M*=5.1, *SD*=1.8). Scores on the CES-D were high, with 47.7% scoring 16 or above; 23.8% screened positive for a current MDE and an additional 17.4% for a past MDE.

*Outcomes at follow-ups*

*Follow-up rates (Table 1).* Of those completing baseline questionnaires, 53.8% provided follow-up data at 1 month and 30.1% at 6 months.

*Abstinence rates (Table 4).* Observed rates were 9.8% at 1 month and 18.5% at 6 months. Missing=smoking rates were 5.3% at 1 month and 5.6% at 6 months.

*Effect of depression status on abstinence (Table 5).* As in study 1, a pattern emerged in which the past MDE group had the highest abstinence rate (in three of four comparisons) and the current MDE group the lowest (in four of four comparisons), but none of the comparisons by MDE status yielded significant differences. CES-D score at baseline did not predict smoking status 1 or 6 months later.

**Results: Study 3**

*Participant characteristics*

Demographic, smoking history, and depression variables are presented in Tables 2 and 3 for the 280 English-speaking participants who completed the

baseline questionnaires. Participants were from 11 countries, with 86% from the United States. Over two-thirds of the participants were women, the mean age of the sample was 38.4 years ( $SD=10.8$ ), and 30.0% were heavy smokers (more than 24 cigarettes daily). Nicotine dependence was comparable with that found in studies 1 and 2 (FTND score,  $M=5.4$ ,  $SD=2.5$ ). Scores on the CES-D were high, with 44% scoring 16 or above; 11.4% screened positive for a current MDE and an additional 18.9% for a past MDE.

#### *Outcomes at follow-ups*

*Follow-up rates (Table 1).* Follow-up data were provided by 57.1%, 35.4%, 34.3%, and 34.6% of those completing baseline questionnaires and randomized, for the 1-, 3-, 6-, and 12-month follow-ups, respectively.

*Abstinence rates (Tables 4 and 5).* Using observed data, we found that *Guía*+ITEMs yielded significantly higher quit rates at the 12-month follow-up ( $\chi^2=9.46$ ,  $p=.002$ ). Using missing=smoking data, we found that *Guía*+ITEMs yielded significantly higher quit rates at the 12-month follow-up ( $\chi^2=4.40$ ,  $p=.036$ ). Differences among MDE groups did not reach significance. CES-D score at baseline was significantly related to observed smoking status at 3 months (point-biserial coefficient =  $-.28$ ,  $p=.005$ ), and missing=smoking status at 3 months ( $r=-.17$ ,  $p=.0054$ ) and 6 months ( $r=-.12$ ,  $p=.0347$ ), with more depression predicting less abstinence.

*Efficacy analysis.* Comparing those completing half (four or more) of the eight mood management lessons versus those completing three or fewer, respectively, we observed abstinence rates of 38.6% versus 14.3%, 36.7% versus 35.3%, 31.3% versus 22.2%, and 25.0% versus 20.0% at the 1-, 3-, 6-, and 12-month follow-ups, respectively. These differences were significant at the 1-month assessment ( $p=.0108$ ). Missing=smoking rates were 30.9% versus 7.1%, 20.0% versus 7.1%, 18.2% versus 4.8%, and 14.6% versus 4.8%. These differences were all significant at a  $p$  level of less than .05.

#### **Results: Study 4**

##### *Participant characteristics*

Demographic, smoking history, and depression variables are presented in Tables 2 and 3 for the 288 Spanish-speaking participants who completed the baseline questionnaires. Participants were from 21 countries, with only 1 from the United States. Most were from Spain (164), Argentina (33), and

Mexico (14). Some 41% of the participants were women, the mean age of the sample was 35.0 years ( $SD=9.5$ ), and 35.8% were heavy smokers (more than 24 cigarettes daily). Nicotine dependence was comparable with that found in studies 1, 2, and 3 (FTND score,  $M=5.5$ ,  $SD=2.3$ ). Scores on the CES-D were high, with 44.3% scoring 16 or above; 16.7% screened positive for a current MDE and an additional 18.1% for a past MDE.

#### *Outcomes at follow-ups*

*Follow-up rates (Table 1).* Follow-up data were provided by 69.8%, 66.3%, 64.6%, and 61.5% of those completing baseline questionnaires and randomized, at the 1-, 3-, 6-, and 12-month follow-ups, respectively.

*Abstinence rates (Tables 4 and 5).* For observed data, the *Guía*+ITEMs yielded significant higher quit rates at the 3-month follow-up ( $\chi^2=3.82$ ,  $p=.0505$ ). Missing=smoking data yielded no significant differences by condition. Differences among MDE groups for observed data reached significance only at the 12-month follow-up ( $\chi^2=7.35$ ,  $p=.025$ ). For missing=smoking data, significant differences were seen at the 3-month follow-up ( $\chi^2=7.38$ ,  $p=.025$ ) and at the 12-month follow-up ( $\chi^2=8.86$ ,  $p=.012$ ). CES-D scores at baseline were not significantly related to smoking status.

*Efficacy analysis.* Comparing those completing half (four or more) of the eight mood management lessons versus those completing three or fewer, respectively, we observed abstinence rates of 30.7% versus 12.2%, 30.5% versus 27.0%, 31.0% versus 27.5%, and 41.5% versus 21.2% at the 1-, 3-, 6-, and 12-month follow-ups, respectively. These differences were significant at 1 month. Missing=smoking rates were 26.8% versus 7.0%, 25.3% versus 14.1%, 25.3% versus 15.5%, and 31.0% versus 9.9%. These differences were significant at the 1-month and 12-month assessments.

#### **Discussion**

These four studies illustrate the potential and the limitations of randomized controlled trials conducted over the Internet. We have shown that (a) randomized smoking cessation trials can be successfully conducted via the Web and can yield evidence-based Internet interventions with abstinence rates comparable with those of traditional interventions, (b) Internet studies can go beyond providing estimates of outcome, shedding light on mechanisms that affect the likelihood of quitting, such as a history of major

depression, and (c) unlike traditional research and intervention methods, Internet research can reach participants across national and linguistic boundaries at little additional cost. Once we developed the English and Spanish Web sites, smokers with Web access from anywhere in the world were able to join our study. Moreover, these individuals included a substantial proportion of heavy smokers (30% to 41.5% of the sample) and persons with high FTND scores (means of 5.1 to 5.5).

Study 1 demonstrated the feasibility of recruiting a sizable sample of English-speaking smokers via the Web (2,774, including 308 from outside the United States), screening for eligibility, obtaining informed consent, administering baseline questionnaires, and following up 1 and 6 months later via E-mail. However, online follow-up rates were low. Abstinence rates were moderate for those completing follow-ups but much lower when using the conservative missing=smoking convention. Low follow-up rates set a ceiling for the latter rates: With a 30% follow-up rate, for example, the maximum missing=smoking rate is 30%, even if 100% of responders have quit. Missing=smoking figures revealed an interesting pattern: Those with past MDE had significantly higher quit rates than did those with current MDE at both 1 and 6 months, and than those with no MDE history at 6 months.

Study 2 demonstrated the feasibility of recruiting a sizable international sample of Spanish-speaking smokers (702 participants from 29 countries, including 10 countries not represented in study 1). However, once again, follow-up rates were low and continued to decline at longer follow-up times. Abstinence rates were generally lower than those for the English sample. Once again, past MDE at baseline tended to yield the highest abstinence rates and current MDE the lowest, but this trend did not reach significance. Having found that conducting Internet-based smoking cessation outcome studies in English and Spanish was feasible, we proceeded to conduct randomized trials and to experiment with methods to increase follow-up rates.

Study 3 demonstrated the feasibility of conducting a randomized smoking cessation trial over the Web in English. The monetary incentives and phone calls improved follow-up rates over studies 1 and 2, but they were still lower than desirable, in part because of a programming problem. The *Guía*+ITEMs condition yielded significantly higher quit rates at 12 months. Observed abstinence rates increased greatly over studies 1 and 2, and missing=smoking rates basically doubled, reaching the teens. Though MDE status was not significantly related to abstinence, current MDE at baseline showed a trend toward lower abstinence rates, particularly at the 3- and 6-month follow-ups.

Study 4 demonstrated the feasibility of conducting a randomized smoking cessation trial over the Web in Spanish. The initial welcoming letter, incentives, and more consistent phone calls improved follow-up rates over studies 1, 2, and 3. Abstinence rates increased over studies 1 and 2 for those completing follow-ups, and even when the conservative missing=smoking convention was used, they reached a high of 26% at 6 months for the *Guía*+ITEMs condition. The influence of MDE status retained the pattern seen in study 1. At every follow-up point, the group of smokers reporting past MDE at baseline had the highest abstinence rate and those with current MDE the lowest. These differences reached statistical significance at the 12-month follow-up (observed) and at the 3- and 12-month follow-ups (missing=smoking).

These studies have the following limitations: First, the self-selected nature of the samples limits generalizability of the study to smokers seeking smoking cessation assistance via the Web. Second, all data were self-reported; thus, social desirability may influence those responding to the follow-up questions (but probably not more than in face-to-face situations). Third, because of the study's large size and international scope, we did not verify smoking abstinence with biochemical indices (e.g., salivary nicotine or cotinine). However, the Society for Research on Nicotine and Tobacco Subcommittee on Biochemical Verification (2002) suggests that biochemical verification is not necessary in population-based or minimal-intervention trials. Fourth, because they were conducted sequentially, each study improving on the weaknesses of the prior study, the results across the four studies are not directly comparable. Most important, they reflect gradual improvements in cohort maintenance efforts, which have a major impact on missing=smoking abstinence rates.

We found several differences between the English- and Spanish-language samples. For example, a majority of the participants were women in the former and men in the latter. Educational levels were higher in the Spanish-speaking group, suggesting that access to the Internet is currently more concentrated in higher socioeconomic groups in the Spanish-speaking countries. Cessation methods such as nicotine replacement therapy, bupropion, smoking cessation groups, hypnosis, and motivational tapes were more likely to be used by English-speaking participants.

On the other hand, similarities between the groups were also notable. Smoking histories were similar, with mean age at first cigarette being 15 years and age at which participants smoked regularly 18 years. Mean cigarettes per day were consistently over one pack (20 cigarettes), and mean FTND scores were

consistently high. The proportion of smokers screening positive for past MDEs hovered around 20% across the four samples. Current MDE rates ranged from 11% to 24%. CES-D scores provided concurrent support for the high prevalence of depression symptoms in smokers, with means at or above the traditional cutoff score of 16 for “significant symptoms.”

Follow-up rates were low when cohort maintenance was done entirely online. Letters, incentives, and phone calls increased these rates to the 62%–70% range by study 4.

The effect of MDE status on abstinence rates yielded significant differences in study 1 and at the 3- and 12-month follow-ups in study 4. The surprising trend that those with past MDE had the highest quit rates suggests that collapsing current MDE and past MDE groups into one history-positive MDE group will obscure potential mechanisms by which MDEs affect quit rates. Perhaps individuals with mood regulation problems use nicotine operationally, that is, to regulate their mood. When in the midst of a current MDE, they find it significantly more difficult to quit, but when not, they find it easier to quit than those with no history of MDE.

ITEMs increased the effectiveness of the *Guía*. E-mail reminders to return to elements of the site strategically chosen to coincide with where users were in relation to their quit date appeared to increase quit rates in both conditions. However, not only did we fail to replicate our earlier finding (Muñoz et al., 1997) that a mood management intervention increased quit rates, but the addition of an eight-lesson mood management intervention (at least when provided at the rate of one lesson per week) often reduced quit rates, at times significantly so. Those who persevered, using half or more of the eight lessons tended to quit at higher rates, however. The results certainly demonstrate that including additional content with an online intervention may not translate into increased effectiveness, and that some additions of content could reduce effectiveness.

We conclude that randomized controlled trials involving international samples are feasible over the Internet. Our highest 6-month smoking cessation rates (26% for the *Guía*+ITEMs intervention in study 4) were comparable with commonly accepted interventions such as smoking cessation groups (27% for American Lung Association groups, and 24% for American Cancer Society groups; Lando, McGovern, Barrios, & Etringer, 1990) and pharmacological interventions (22% for the nicotine patch; Fiore, Smith, Jorenby, & Baker, 1994). Methods to achieve high follow-up rates must be improved. Empirical studies of Internet interventions for other prevalent public health problems at a global level

also should be pursued (H. Christensen, Griffiths, & Jorm, 2004; Clarke et al., 2005).

Internet-based interventions can be delivered to anyone with Internet access at any time of the day or night, at a very low cost per additional user. In the United States, 80% of Internet users have accessed health or medical information on the Web (Fox & Fallows, 2003). Internet penetration into other countries and other languages is increasing rapidly. Estimates of Internet use by language suggest that, eventually, there will be 885 million Chinese speakers, 508 million English speakers, and 332 million Spanish speakers on the Internet (Global Reach, 2004). Together, these three languages will provide access to 27% of the world's population. The potential public health impact of providing evidence-based Internet interventions to such a large proportion of humanity deserves concerted efforts by international health agencies.

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