

Strike While the Iron Is Hot: Can Stepped-Care Treatments Resurrect Relapsing Smokers?

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The efficacies of 2 group counseling step-up treatments for smoking cessation, cognitive–behavioral/skill training therapy (CBT) and motivational interviewing/supportive (MIS) therapy, were compared with brief intervention (BI) treatment in a sample of 677 smokers. Differential efficacy of the 2 step-up treatments was also tested in smokers at low and high risk for relapse (no smoking vs. any smoking during the first postquit week, respectively). All participants received 8 weeks of nicotine patch therapy. BI consisted of 3 brief individual cessation counseling sessions; CBT and MIS participants received BI treatment and 6 group counseling sessions. Neither CBT nor MIS treatment improved long-term abstinence rates relative to BI. Limited support was found for the hypothesis that high-risk smokers would benefit more from MIS than CBT. Other hypotheses were not supported.

Recent epidemiologic data show that nearly 70% of the 47 million adult smokers in the United States in 1995 wanted to quit smoking and about 46% of daily smokers made a quit attempt lasting at least 1 day (Centers for Disease Control and Prevention, 1997). However, among smokers who attempt to quit without using any kind of intervention, only 7.5% remain smoke-free for more than 5 months (Wetter et al., 1998). Behavioral and pharmacologic (e.g., nicotine gum, nicotine patch, and bupropion) smoking cessation interventions have been shown to be efficacious both singly and in combination (e.g., Fiore, Smith, Jorenby, & Baker, 1994; Hall et al., 1998; Hurt et al., 1997; Jorenby et al., 1999; Richmond, Kehoe, & de Almeida Neto, 1997; Wetter et al., 1998). Comprehensive meta-analyses conducted for the Agency for Health Care Policy and Research (AHCPR) Smoking Cessation Clinical Practice Guideline (Fiore et al., 1996; Wetter et al., 1998) showed that intensive counseling or use of the nicotine patch increased long-term abstinence rates (>5 months) to approximately 18% (Wetter et al., 1998). Newer smoking cessation medications such as bupropion appear promising, with long-term (12-

month) cessation rates ranging between 23% and 35% (Hurt et al., 1997; Jorenby et al., 1999). However, relapse to smoking remains a significant problem even with the most efficacious new pharmacotherapies.

Some evidence suggests that smoking cessation counseling treatments may have peaked in efficacy over the past 10–15 years (Shiffman, 1993). In fact, a recent analysis suggests that multi-componential smoking cessation treatments have yielded declining abstinence rates over the past 15 years (Irvin & Brandon, 1999). It is possible that cessation treatment efficacy is declining either because treatment components (e.g., skill training) have been so widely disseminated that their effects have diminished because of repeated exposure or because the population of smokers now comprises more difficult-to-treat individuals (e.g., smokers with psychiatric comorbidities; Hughes, 1996). Regardless of the causes, smoking cessation treatments do not produce sustained abstinence in the majority of treated individuals, and efficacy rates appear to be stagnating or declining with the passage of time.

The prevalence of smoking, in conjunction with the absence of highly efficacious interventions, has spawned interest in new smoking treatment strategies. *Stepped-care intervention* has been mentioned frequently as a promising method to allocate treatment in a cost-effective manner. In stepped-care strategies, different intensities of treatment are available for initial treatment (e.g., depending on dependence level and psychiatric comorbidity), and more intensive treatments may be added in response to lapses or other difficulties (see Abrams, Clark, & King, 1999; Orleans, 1993; Thompson, Fries, Hopp, Bowen, & Croyle, 1995). This strategy should, in theory, enhance efficacy because it provides additional treatment in response to need.

A second allocation strategy is that of *treatment matching*. In this strategy, different smokers receive different treatments, with smoker–treatment matching occurring on the basis of each smoker’s vulnerabilities to treatment failure or relapse (Abrams et al., 1999; Lichtenstein, 1997; Niaura, Goldstein, & Abrams, 1994; Velicer et al., 1993; Zelman, Brandon, Jorenby, & Baker, 1992).

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Thus, in theory, a smoker receives a treatment that is ideally suited to his or her needs.

Although stepped-care and matching strategies have been identified as important topics for study (Abrams et al., 1996; Fiore et al., 1996), few studies have been published that assess the potential value of these approaches. In terms of stepped-care strategies, the only published research involves studies in which participants initially took 2-mg nicotine gum and were later given the option of taking 4-mg nicotine gum (e.g., Campbell, Prescott, & Tjeder-Burton, 1991; Kornitzer, Kittel, Dramaix, & Bourdoux, 1987; Lando, Kalb, & McGovern, 1988). To our knowledge, only one study has systematically manipulated pharmacotherapy contingent on cessation difficulties. Russell et al. (1993) reported that a nicotine patch dose increase for individuals who were still smoking after the quit day enhanced initial quitting (at Week 3) but had no effect at later timepoints. However, to the best of our knowledge, no published studies have evaluated the impact of increased counseling as a function of treatment response.

A relatively large body of research exists with respect to treatment matching strategies. For example, several studies that categorized smokers as low or high in nicotine dependence have documented the benefit of 4-mg nicotine gum (vs. 2-mg gum) for smokers high in nicotine dependence (e.g., Herrera et al., 1995; Tonnesen et al., 1988). Other matching studies have investigated the efficacy of matching treatments based on vulnerability for affective distress (e.g., Hall, Munoz, & Reus, 1994; Hall et al., 1998). Affectively vulnerable smokers constitute a clinically important subgroup because they are less likely than other smokers to quit successfully with conventional treatments. Several of Hall's studies (Hall et al., 1994, 1996, 1998) have examined whether cognitive-behavioral therapy with a mood-management component is more efficacious for smokers with a history of depression than "health education therapy." Results were generally supportive of the potential value of cognitive-behavioral therapy among smokers with a history of depression (Hall et al., 1994, 1998). However, a limitation of these particular studies is that therapy contact time was not equivalent in the contrasted treatment groups. In fact, Hall et al. (1996) failed to find a difference between cognitive-behavioral therapy and health education therapy when contact time was made equivalent.

Although the above research is supportive of a matching approach based on affective vulnerability, important questions remain about the mechanisms and merit of this approach. For instance, in some studies, treatment content and intensity are confounded, thus clouding causal inference. In addition, some interventions comprise a variety of components, making it difficult to attribute efficacy to a single element.

Most cognitive-behavioral treatments include both skill training and intratreatment social support, and the recent AHCPR meta-analyses showed that both of these components boost long-term abstinence rates (Fiore et al., 1996; Wetter et al., 1998). Without the explicit decoupling of these two components, it is difficult to ascribe causal impact to either. For instance, Zelman et al. (1992) found that a concentrated focus on skill training actually resulted in lower long-term abstinence rates among affectively vulnerable smokers compared with support counseling. However, these smokers were helped by an intervention that emphasized intratreatment support. Conversely, smokers who were not affectively vulnerable experienced greater success in long-term cessation when they were given skill training and less success when given the supportive

treatment. This finding raises the possibility that affectively focused cognitive-behavioral treatments actually improve outcomes not because of skill training per se, but instead because they are more supportive than comparison treatments (e.g., health education).

Present Study

The present study had two major aims. The first was to determine whether an intensive stepped-care treatment would aid smokers at high risk for relapse. For purposes of this study, we define *stepped-care treatment* or *step-up treatment* as the addition of intensive group counseling treatment at 1 week postcessation. The second aim was to determine whether the content of the two step-up treatments made any difference. This second aim is relevant to the matching hypothesis; that is, certain patients will benefit more from one sort of treatment than from another sort.

To address the efficacy of stepped-care treatment, we gave all smokers a brief cessation treatment similar to one that might be used in a primary-care setting. Then, some participants were randomly assigned to receive a more intensive stepped-care treatment, one that involved intensive group counseling. We predicted that smokers who were assigned to stepped-care treatment would achieve higher long-term abstinence rates than would smokers who received only the brief intervention. In particular, we predicted that the stepped-care treatments would benefit those smokers at high risk for relapse. We identified smokers as being at *high risk* if they engaged in any smoking (even a single puff) during the 1st week postquit. We chose this risk criterion because it predicts cessation failure accurately (e.g., Kenford et al., 1994) and because it can be used easily in a primary-care/clinic setting. Although we assumed that *low risk* smokers (those not smoking in the 1st week) might also benefit from the intensive step-up treatments, our a priori prediction regarding stepped-care efficacy focused on the high-risk participants.

Although we assumed that stepped-care treatments could help a foundering smoker, we also believed that the impact of such a treatment could be related to its content. Therefore, it seemed something of a gamble to explore the efficacy of only one type of content in our exploration of stepped-care efficacy; thus, we used two distinct types of stepped-care contents to avoid a confound between the occurrence of stepped-care treatment and the content of stepped-care treatment.

Although our risk assessment strategy does a good job of identifying who is at heightened risk for relapse, it does not, by itself, guide decisions about the content of stepped-care interventions. There is substantial evidence that negative affect greatly increases a smoker's risk of relapse (e.g., Brandon, 1994; Glassman et al., 1990; Hall, Munoz, Reus, & Sees, 1993; Piasecki, Kenford, Smith, Fiore, & Baker, 1997). Therefore, the contents of both step-up treatments were ones that had proved effective with affectively vulnerable smokers. Although both step-up treatments involved group therapy, one group emphasized skill training (cognitive-behavioral therapy), whereas the other group emphasized social support and motivation.

The cognitive-behavioral treatment was based on the treatment used by Hall and her colleagues in the treatment of smokers with a history of depression (e.g., Hall et al., 1994, 1998). The supportive-motivational treatment was based on the supportive treatment successfully used by Zelman et al. (1992) in treating

Table 1
Study Timeline and Treatment Protocol

Day/week	Session or contact	Treatment	Participants
Week -2	Orientation session	None	All
Week -1	Prequit clinic visit	Brief individual counseling; nicotine patches dispensed (for quit day)	All
Day 1	Quit day clinic visit	Brief individual counseling; nicotine patches dispensed (for 1st week)	All
Days 2-7	Daily diary completed at home	None	All
Day 8	Postquit clinic visit	Brief individual counseling; random assignment to brief intervention (no subsequent treatment), MIS, or CBT treatments; nicotine patches dispensed (7 weeks)	All
Week 2	Group counseling Session 1	90-min treatment session	MIS and CBT
Week 2	Group counseling Session 2	90-min treatment session	MIS and CBT
Week 3	Group counseling Session 3	90-min treatment session	MIS and CBT
Week 3	Group counseling Session 4	90-min treatment session	MIS and CBT
Week 4	Group counseling Session 5	90-min treatment session	MIS and CBT
Week 5	Group counseling Session 6	90-min treatment session	MIS and CBT
Week 6	Follow-up assessment (phone)	No treatment; assessment only	All
Week 13	Follow-up assessment (phone)	No treatment; assessment only	All
Week 26	Follow-up assessment (phone)	No treatment; assessment only	All
Week 52	Follow-up assessment (phone)	No treatment; assessment only	All

Note. MIS = motivational interviewing/supportive group counseling; CBT = cognitive-behavioral/skill training group counseling.

affectively vulnerable smokers. It contained motivational elements similar to those contained in Zelman et al.'s treatment and was consistent with the principles of motivational interviewing (Miller, 1996; Miller & Rollnick, 1991). As in Zelman et al.'s research, this treatment minimized skill-training activity during counseling sessions (e.g., no identification of high-risk situations; Zelman et al., 1992).

Our *a priori* predictions were that, in general, smokers receiving step-up treatments would have better outcomes than other smokers because they would benefit from more intense treatment (e.g., Fiore et al., 1996; Wetter et al., 1998). However, we also predicted that high-risk smokers would benefit more from the supportive-motivational treatment than from the cognitive-behavioral treatment. This prediction was based on the notion that high-risk smokers would be high in negative affect, and therefore, as in Zelman et al. (1992), would benefit more from the supportive-motivational intervention.¹

Method

Participants

A total of 677 volunteer participants (388 female and 289 male; mean age = 42.2 years) were randomized to treatment and were included in intent-to-treat analyses. All of the participants were at least 18 years of age, had smoked at least 10 cigarettes per day for the previous year, and reported motivation to quit smoking. Participants received free smoking cessation treatment (including behavioral treatment and nicotine patches) in exchange for their participation. No monetary compensation was provided to participants. This study was approved by the Human Subjects Committee (HSC) of the University of Wisconsin—Madison, and participants were treated in accordance with the "Ethical Principles of Psychologists and Code of Conduct" (American Psychological Association, 1992). Prior to participation, participants signed an informed-consent form approved by the HSC.

Design and Procedure

Study timeline and overall design. Table 1 provides an overview of the study timeline; Figure 1 provides an overview of the behavioral interventions used in the study. Smokers attended orientation and prequit sessions prior to their target quit day (TQD). Brief (5–10 min) individual smoking cessation counseling and nicotine patches were provided to all smokers at the prequit and quit-day clinic visits. Participants returned 1 week following their TQD for a postquit session, at which time participants were stratified on relapse risk on the basis of self-reported smoking (not biochemically confirmed) during the postquit week (low risk = no smoking during postquit Week 1; high risk = any smoking during postquit Week 1). Within each relapse-risk group, participants were then randomized to one of three treatment conditions: brief intervention, cognitive-behavioral/skill-training group counseling (CBT), or motivational interviewing/supportive group counseling (MIS; see section below on *Behavioral Treatments and Nicotine Patch Therapy*).

Participants in the brief intervention condition received brief individual counseling during the 1-week postquit session, but no additional counseling was provided thereafter. Participants in the two counseling groups received brief individual counseling during the 1-week postquit session and then met for six group sessions during the 4-week period following the postquit session. All of the participants who were randomized received additional nicotine patches for 7 weeks (see below). Additionally, follow-up assessments of all participants were made by means of telephone contact at Weeks 6, 13, 26, and 52; biochemical verification of self-

¹ The two step-up treatments used in the present study were similar, but not exactly the same, as the treatments used in Zelman et al.'s (1992) study. The supportive-motivational treatment used in Zelman et al. had a motivational component, but this component was not based on motivational interviewing as was true of the present study. In addition, the skill-training treatment in Zelman et al. was not targeted at negative affect and its relation to smoking as it was in the present study.

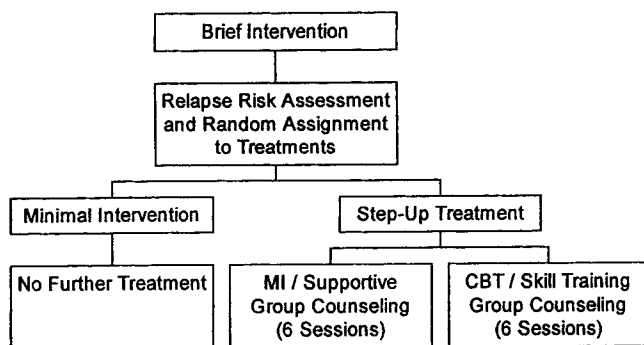


Figure 1. Behavioral treatment procedures. All participants received 8 weeks of nicotine patch therapy. MI = motivational interviewing; CBT = cognitive-behavioral therapy.

reported abstinence was made at Weeks 26 and 52. No formal smoking cessation counseling was provided during follow-up telephone contacts.

Recruitment. Potential study participants were recruited through press conferences, announcements on local radio stations, advertisements in local newspapers, and informational sheets placed in public places. Interested individuals called a central telephone number for additional information about the study and were asked questions about their smoking history, health, and other relevant information to assess eligibility for the study. Inclusion criteria were 18 years of age or older, must have been smoking at least 10 cigarettes per day, and must have been smoking at this level for at least 1 year. Exclusionary criteria were recent (within 3 months) cardiac arrhythmia, heart attack, stroke, cardiac surgery, or balloon angioplasty; serious mental disorders such as schizophrenia and bipolar disorder; pregnancy, breastfeeding, or likely to become pregnant in the next 3 months; current use of nicotine patches or nicotine gum; use of exclusionary medications (e.g., antipsychotics and lithium); and serious contact allergies to skin adhesives or serious skin sensitivity.

Smokers meeting eligibility requirements for the study were invited to group orientation meetings. Approximately 830 smokers attended orientation meetings and, of these, 799 signed the consent form. A total of 782 participants returned for the prequit clinic visit, of which 777 continued to be eligible. A total of 741 smokers returned for the quit-day clinic visit and were scheduled to return 1 week later for the postquit clinic visit, at which time randomization to one of three treatment conditions took place. Five participants who were taking exclusionary psychoactive medications were dropped from the study prior to the beginning of treatment. A total of 677 participants (91% of smokers attending the quit-day clinic visit) returned for the 1-week postquit session and were randomized to the treatment conditions.

Behavioral Treatments and Nicotine Patch Therapy

All of the participants were given three brief individual counseling sessions with one session occurring 10 days prior to quitting (prequit visit), one on their quit day, and one occurring at 1-week postquit. Also, all of the participants received a pamphlet on quitting smoking, "Clearing the Air" (National Cancer Institute, 1988) at the prequit visit. At the postquit visit, participants' risk status was determined as described above. Within each risk group, participants were randomly assigned to three treatment conditions, including the two step-up treatments, skill training and supportive-motivational counseling. The two step-up treatments each consisted of six group counseling sessions subsequent to the postquit visit. The brief intervention participants received only the brief individual smoking cessation counseling sessions (prequit, quit day, and 1-week postquit) with no follow-up counseling of any kind.

Participants randomized to CBT or MIS groups attended a total of six 90-min sessions during Weeks 2–5 of the quit attempt. Over this 4-week

period, two sessions per week occurred for the first 2 weeks and one session per week occurred for the final 2 weeks. Group leaders were six doctoral graduate students in clinical psychology who were supervised by a licensed psychologist (T.B.B.). Groups ranged in size from 6 to 10 participants. Detailed treatment manuals for CBT and MIS were developed by the senior investigator (T.B.B.) and were used by group leaders during the course of the study. Manuals included principles of therapeutic change and specific strategies for each therapeutic approach.

CBT. CBT was based on the cognitive-behavioral treatment developed by Hall et al. (1994) for smokers with a history of depression. For the present study, this treatment was modified to be somewhat more relevant to smokers in general. However, the manual stressed the important role that negative affect plays in smoking cessation and relapse and included interventions to address negative affect. Group leaders followed specific guidelines for conducting each session and assigned homework for participants to complete between group sessions. CBT treatment focused on the development of smoking cessation skills acquired through instruction, modeling, and homework practice. Session 1 addressed coping with withdrawal, Session 2 dealt with managing negative mood states, Session 3 examined thought patterns associated with difficulty in managing negative moods, Session 4 reviewed strategies for increasing positive thoughts, Session 5 addressed ways to deal with anger (e.g., relaxation exercises), and Session 6 dealt with issues of social support and dysfunctional thinking that can increase the likelihood of relapse. Each participant in CBT received a copy of a manual that included the homework assignments and other information related to smoking cessation.

MIS. MIS therapy was based on the therapeutic principles developed by Miller and Rollnick (1991) for treating addictive behavior. This approach assumes that participants already have the skills necessary to achieve abstinence but that they are ambivalent about change. The therapist serves as a consultant to foster intrinsic motivation to help participants resolve their ambivalence about quitting. Strategies used by the consultant-therapist include identifying participants' goals, assessing progress toward meeting goals, uncovering ambivalence and encouraging its expression, expressing empathy, promoting and reinforcing statements of confidence and self-efficacy, and resolving ambivalence. Sessions were structured as follows: check-in time during which each participant shares recent cessation experiences with the group, open-ended questions, provision of relevant information (e.g., about withdrawal), summary of session, and encouragement of commitment to continue coming to group. Participants were not asked about high-risk situations or coping strategies, and no information or feedback was provided concerning these topics. In contrast to CBT participants, MIS participants received neither a treatment manual nor homework assignments.

Nicotine patch therapy. Participants in all three treatment groups received 8 weeks of nicotine patch therapy (ProStep; Lederle Laboratories, Pearl River, NY) consisting of 6 weeks of 22-mg/24-hr nicotine patch therapy and 2 weeks of 11-mg/24-hr nicotine patch therapy. All of the participants were instructed on proper use of the patch at the prequit clinic visit and were advised to contact study staff if any adverse side-effects occurred.

Measures

A set of standardized assessments was administered at most sessions. These included expiratory breath carbon monoxide (CO), the Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988), and the Wisconsin Smoking Withdrawal Scale (WSWS; Welsch et al., 1999). In addition, other measures were collected prior to the quit day, including the Stress Reaction scale of the Multidimensional Personality Questionnaire (New Zealand version, MPQ-NZ-SR; Krueger, Caspi, Moffitt, Silva, & McGee, 1996), the Fagerstrom Test for Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), the Depression Proneness Inventory (DPI; Alloy, Abramson, Metalsky, & Harlages, 1990), a revised version of the Affective Information Processing Questionnaire (AIPQ-R; Wetter, Brandon, & Baker, 1992), Personal Projects Analysis

relevant to smoking cessation (Little, 1989), and the Primary Care Evaluation of Mental Disorders psychiatric diagnostic system (PRIME-MD; Spitzer et al., 1994).

At the 1-week postquit session, the Response Style Questionnaire (Just & Alloy, 1997; Nolen-Hoeksema & Morrow, 1993), the AIPQ-R, and the Beck Depression Inventory (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) were administered. Information on patch use and smoking was also collected during subsequent group counseling treatment sessions and during follow-up assessments. Finally, during the last CBT and MIS group counseling sessions, participants completed a Smoking Treatment Factors Questionnaire (STFQ; Zelman et al., 1992), a questionnaire on coping strategies (Smoking Inventory; Zelman et al., 1992), and an 11-item counselor rating form. Only the results for measures relevant to the primary hypotheses in the present study are reported in this article.

Abstinence from smoking. Self-reported smoking status was obtained at several timepoints during the study, including the orientation session, the prequit session, the quit-day session, the 1-week postquit session, the step-up group counseling treatment sessions (for CBT and MIS participants only), as well as during follow-up contacts for all participants at 6 weeks, 3 months, 6 months, and 1 year postquit. In general, self-reported smoking status was ascertained with questions about any smoking during the week prior to the assessment, yielding a 1-week point-prevalence abstinence measure. Biochemical verification of smoking status was made through expiratory breath CO testing administered at all timepoints except for the 6-week and 3-month follow-up contacts. A CO value less than 10 parts per million (ppm) was considered verification of self-reported smoking abstinence. Participants who reported abstinence from smoking at the 6-month and 1-year follow-up phone assessments were asked to meet with study staff for purposes of obtaining an expiratory breath CO measurement to confirm smoking abstinence biochemically. Missing data for either self-reported smoking status or CO verification at a given timepoint resulted in the participant being classified as smoking at the relevant timepoint. Smoking status and CO data for the brief intervention participants were not available at the 5-week assessment.

Counselor rating form. At the end of counseling Session 6, each group member completed an 11-item counselor rating form that assessed the participant's views of the counselor/therapist. Various counselor characteristics were rated, including the degree to which the counselor was perceived as being understanding, accepting, nonjudgmental, knowledgeable, and so on. Ten items were rated on a 5-point Likert scale, with endpoints determined by the nature of the question; one additional item that assessed overall helpfulness of the counselor was rated on a 1–100 scale.

Demographic and smoking history questionnaire. This self-report questionnaire elicited sociodemographic information about participants (e.g., sex, race, and general health) as well as smoking history, including prior use of nicotine gum or the nicotine patch. In addition, the questionnaire included questions about medical and psychiatric conditions, current medications, alcohol use, and confidence concerning the quit smoking attempt.

DPI. The DPI is a 10-item self-report measure of proneness or vulnerability to depression. Items are rated on a 7-point Likert-type rating scale and yield a summed score.

FTND. The FTND is a six-item self-report measure of nicotine dependence that ranges from 0 to 8, with higher scores indicative of heavier smoking.

MPQ-NZ-SR. The MPQ-NZ-SR is a 14-item self-report measure that assesses a traitlike affective style characterized by nervousness, vulnerability, sensitivity, and proneness to worry. Krueger et al. (1996) developed the Stress Reaction scale as part of a briefer version of the MPQ (Tellegen, 1982; Tellegen & Waller, in press). The MPQ Stress Reaction scale is one of three MPQ scales (the others are Aggression and Alienation) that form a superfactor called Negative Emotionality. The Stress Reaction scale was selected because it provides a brief, internally consistent (internal consistency coefficient = .80; Krueger et al., 1996) and valid measure of negative emotionality.

PANAS. The PANAS consists of 20 Likert-type items that measure positive and negative affect. Items are rated on a 5-point rating scale and yield two subscales that reflect the average of two sets of items tapping positive and negative affect. Two versions of the PANAS were used in the study: A "past week" version was used at the orientation session, the prequit session, the postquit session, during counseling Sessions 1, 3, 5, and 6, and during follow-up telephone calls, and a "past 24 hours" version used on the quit day and daily during the first week postquit.

PRIME-MD. The five modules of the PRIME-MD diagnostic system (i.e., mood, anxiety, alcohol, eating, and somatoform disorders) developed by Spitzer et al. (1994) are designed to provide diagnoses based on the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., *DSM-IV*; American Psychiatric Association, 1994). Only the mood, anxiety, alcohol, and eating disorders modules were administered in the present study. Also, in the present study, two versions of the PRIME-MD were administered to each participant: a "past month" version and a "past 5 years" version. For purposes of analysis, rates of *DSM-IV* diagnoses were determined on the basis of the presence of either a current (past month) or past (past 5 years) diagnosis of a given disorder.

STFQ. The STFQ is a revision of the theoretically derived 20-item questionnaire used by Zelman et al. (1992) that asks participants to rate the importance of various factors that helped them to quit smoking during treatment. Each item is rated on a 7-point Likert scale from 1 (*completely unimportant*) to 7 (*the most important*), with particular sets of items averaged to yield three main scales: nicotine patch, skills associated with quitting, and support (further subdivided into therapist- and group-derived support). The STFQ was administered at the final counseling session.

WSWS. The WSWS is a 28-item self-report questionnaire that assesses nicotine withdrawal. The WSWS contains seven subscales that measure theoretically relevant aspects of nicotine withdrawal; an overall withdrawal score can be computed as well. The response scale for the WSWS items consists of a 5-point Likert-type scale ranging from 1 = *strongly disagree* and 5 = *strongly agree*. Higher scores indicate higher levels of withdrawal. The WSWS subscales include Anger, Anxiety, Craving for Cigarettes, Difficulty Concentrating, Disturbed Sleep, Hunger, and Sadness.

Statistical Analyses and Hypotheses

Study design. Participants were randomly assigned to one of three treatment conditions (brief intervention, CBT, or MIS) following stratification based on relapse risk (low risk = no smoking during postquit Week 1; high risk = any smoking during postquit Week 1). Thus, this is a 2 (relapse risk) \times 3 (treatment group) independent groups factorial design with repeated measures of various kinds obtained at several timepoints during the course of the study. All participants who were randomized to treatment at the 1-week postquit visit were included in the analyses.

Baseline characteristics. Baseline differences for continuous variables were examined in a series of two-factor analyses of variance (ANOVAs) that included effects for treatment group, risk status, and their interaction. Categorical variables were examined in a corresponding series of two-factor logistic regression models using PROC CATMOD available in SAS Version 8 (SAS Institute, 1999).

Relapse-risk group differences. Because of the nature of the relapse-risk stratification, group differences on various participant characteristics were thought to be possible based on relapse risk. For example, high-risk smokers (defined as participants who smoked during the first postquit week) may be more severely dependent on nicotine or may have emotional vulnerabilities that contributed to their smoking during the postquit week. Thus, selected baseline characteristics including PRIME-MD *DSM-IV* diagnoses were examined in the two risk groups by collapsing across the three treatment groups within each risk group. Risk-group differences on baseline characteristics were examined by means of independent groups *t* tests ($\alpha = .05$, two-tailed) for continuous-level variables and chi-square tests of independence for categorical-level variables.

Treatment success. MIS treatment was designed to be supportive in terms of dealing with ambivalence about quitting and negative emotions

through consultation with the therapist and group discussion. In contrast, CBT focused primarily on skill-building through instruction, modeling, and homework assignments. On the basis of these contrasting emphases in the two treatment groups, we specified two predictions based on treatment matching (see Zelman et al., 1992): (a) MIS group counseling will produce higher abstinence rates in high-risk smokers compared with CBT group counseling, and (b) CBT group counseling will produce higher abstinence rates in low-risk smokers compared with MIS group counseling. We also predicted that step-up counseling, either CBT or MIS, should produce higher cessation rates than the brief intervention across risk groups. These three predictions were examined at three timepoints postquit: 5 weeks (the final week of group counseling), 6 months, and 1 year.

Testing of treatment matching was accomplished by evaluating the significance of the interaction between treatment group (MIS vs. CBT) and relapse-risk status (low vs. high) as well as planned comparisons. We computed two-factor logistic regression models using PROC CATMOD (SAS Institute Inc., 1999) to test main effects of treatment group and risk status and their interaction. In addition, we computed pairwise *a priori* comparisons to test the following: Among the high-risk smokers, we tested MIS versus CBT and MIS versus brief intervention at each of the timepoints; among the low-risk smokers, we tested CBT versus MIS and CBT versus brief intervention at each of the timepoints. We also computed comparisons of CBT and MIS versus brief intervention regardless of risk status. Pairwise comparisons were tested as planned comparisons ($\alpha = .05$) with no correction for multiple tests. Biochemically confirmed abstinence from smoking (see *Abstinence from smoking* measure above) at the various timepoints was used in all analyses.

Counselor ratings and smoking treatment factors. The counselor rating form was analyzed as follows: (a) treatment (CBT vs. MIS) and counselor main effects and interaction were assessed in a two-factor multivariate analysis of variance (MANOVA) that was computed using the set of 10 items that assessed various counselor characteristics as dependent measures, and (b) a similar two-factor univariate ANOVA was computed on the overall helpfulness item. Because counselor ratings were completed anonymously at the end of counseling Session 6 and groups included both low- and high-risk participants, risk status of participants was not available for inclusion in the analyses of the counselor rating form. Wilks's criterion was used to assess significance of main and interaction effects.

The three primary scales (nicotine patch, skill training, and support) of the STFQ and the two support subscales (group support and therapist support) were treated as separate dependent measures in ANOVAs that compared CBT versus MIS across risk groups and within each risk group. We predicted that low-risk participants in the CBT treatment group would have a significantly higher mean on the skill training factor compared with low-risk participants in the MIS treatment group. In addition, we predicted that high-risk participants in the MIS treatment group would have higher means on the support factors compared with high-risk CBT participants. These predictions were tested by means of focused comparisons of the relevant groups.

Results

Descriptive statistics (means, standard deviations, and percentages) for 14 baseline characteristics for the three treatment groups by risk status are presented in Table 2. Tests for baseline differences revealed significant risk status (low risk vs. high risk) group differences for the following variables: smoking rate, FTND, MPQ-NZ-SR, DPI, negative PANAS scale, positive PANAS scale, and WSWs total score.² All of these baseline variables would reasonably be expected to differ for individuals in the two risk groups and, therefore, were not included as control variables in subsequent analyses.

Other significant effects in tests of baseline differences included a treatment group main effect for MPQ-NZ-SR, $F(2, 668) = 4.2$,

$p < .05$, and a significant interaction between treatment and risk status for baseline CO, $F(2, 665) = 3.5$, $p < .05$, and FTND, $F(2, 664) = 3.3$, $p < .05$. None of these variables were included as control variables in subsequent analyses because the absolute differences among groups for these three variables were relatively small (see Tables 2 and 3). The large sample size ($N = 677$) probably increased the likelihood of finding small but statistically significant effects.

Table 3 presents results of tests of group equivalence on selected baseline variables by relapse-risk group. On the basis of these results, high-risk participants appeared to be more dependent on nicotine (more cigarettes smoked per day and higher FTND scores), to have scored higher on the nicotine withdrawal scale (baseline WSWs) prior to quitting, and to be more vulnerable to depression and negative emotions (higher scores on the MPQ-NZ-SR, DPI, and the negative PANAS). High-risk and low-risk participants did not differ in past nicotine replacement therapy (NRT) use (either nicotine gum or nicotine patch): 34% versus 27%, respectively (because of a clerical error, prior NRT use data were available for only about half of the total sample).

Table 4 presents the results of tests of relapse-risk group differences in the percentage of participants with current or past psychiatric diagnoses based on the PRIME-MD. Compared with low-risk participants, high-risk participants had significantly higher rates of *DSM-IV* major depression, dysthymia, and generalized anxiety disorder. High-risk participants also reported a significantly higher mean number of somatization symptoms on the PRIME-MD Patient Questionnaire compared with low-risk participants ($M = 6.0$ vs. 4.6 , respectively), $t(675) = -5.1$, $p < .0001$.

Potential differences in attendance rates in the two counseling treatments by risk group were examined in a two-factor between-subjects ANOVA. The mean number of sessions (out of a total of six sessions) attended by low-risk participants in the CBT treatment was 4.82 ; for low-risk MIS participants, $M = 4.69$; for high-risk CBT participants, $M = 4.47$; and for high-risk MIS participants, $M = 4.52$. No significant main or interaction effects were obtained in the two-factor ANOVA. For all group therapy participants, 320 out of 454 (71%) participants attended at least four of the six counseling sessions. The percentages of participants attending four or more sessions were 71% for low-risk/MIS, 75% for low-risk/CBT, 69% for high-risk/MIS, and 66% for high-risk/CBT. Session attendance did not significantly differ by risk status or treatment group.

Table 5 presents biochemically confirmed point-prevalence abstinence rates at 5 weeks (final counseling Session 6; data available for MIS and CBT participants only), 6 months, and 1 year postquit. There was no support for the hypothesis that either step-up counseling treatment would be superior to brief intervention. However, two-factor logistic regression analyses for each of the three timepoints revealed a significant interaction between treatment and relapse-risk status at the 6-month follow-up but not at 5 weeks or 1 year. Planned comparisons showed that this

² Because of a clerical error, only about half the total sample (337 of 677) have data for prior nicotine gum use and nicotine patch use. Because only about half the total sample have data for these variables, it was deemed inappropriate to include either or both of them as control variables despite the fact that tests for baseline differences suggested a main effect for risk-status group for both variables.

Table 2
Baseline Sample Characteristics by Treatment Group and Relapse-Risk Group

Variable	Treatment group					
	Brief intervention		Motivational interviewing		Cognitive-behavioral	
	Low risk (<i>n</i> = 121)	High risk (<i>n</i> = 102)	Low risk (<i>n</i> = 127)	High risk (<i>n</i> = 101)	Low risk (<i>n</i> = 122)	High risk (<i>n</i> = 104)
Gender (% women)	55	55	54	60	55	65
Race (% White)	95	94	96	92	95	98
Age (years)						
<i>M</i>	41.7	41.9	42.1	44.3	41.1	42.7
<i>SD</i>	12.0	11.9	12.1	11.8	9.9	10.9
Cigarettes smoked per day						
<i>M</i>	24.4	26.3	23.2	26.6	24.6	26.9
<i>SD</i>	9.6	11.9	8.6	9.9	10.6	9.5
No. of years smoking						
<i>M</i>	24.1	24.7	23.7	27.0	23.4	24.6
<i>SD</i>	11.8	11.3	11.8	11.7	9.4	10.6
Carbon monoxide (ppm)						
<i>M</i>	24.1	24.2	21.6	25.6	26.0	25.3
<i>SD</i>	10.9	9.4	9.0	10.8	10.4	9.7
FTND						
<i>M</i>	4.6	4.7	4.1	5.0	4.3	4.8
<i>SD</i>	1.7	1.6	1.6	1.6	1.6	1.5
MPQ-NZ stress reaction						
<i>M</i>	5.6	7.1	4.8	6.2	5.6	7.2
<i>SD</i>	3.8	3.7	3.7	3.5	3.3	4.1
Depression Proneness Inventory total						
<i>M</i>	28.6	33.6	28.1	33.4	29.1	35.8
<i>SD</i>	8.9	12.9	8.6	11.0	10.1	11.3
Negative PANAS score						
<i>M</i>	2.0	2.3	1.9	2.1	1.9	2.2
<i>SD</i>	0.8	0.8	0.7	0.8	0.7	0.7
Positive PANAS score						
<i>M</i>	3.5	3.4	3.5	3.3	3.5	3.4
<i>SD</i>	0.7	0.8	0.6	0.8	0.7	0.7
WSWS total score						
<i>M</i>	2.5	2.8	2.5	2.7	2.5	2.7
<i>SD</i>	0.5	0.6	0.5	0.5	0.5	0.5
Prior nicotine gum use (% yes) ^a	39	41	29	48	36	47
Prior nicotine patch use (% yes) ^a	46	39	47	58	26	54

Note. Values are percentages, means, and standard deviations. Low risk = no smoking during first postcessation week; high risk = smoking during first postcessation week; FTND = Fagerstrom Test of Nicotine Dependence; MPQ-NZ = Multidimensional Personality Questionnaire—New Zealand version; PANAS = Positive and Negative Affect Scale; WSWS = Wisconsin Smoking Withdrawal Scale.

^a Because of a clerical error, only about half the total sample (337 out of 677) have data for prior nicotine gum use and nicotine patch use.

significant interaction at the 6-month follow-up reflected a higher abstinence rate for high-risk smokers in MIS treatment compared with CBT (19% vs. 9%, respectively; $p < .05$). For the low-risk participants, there were no significant group differences at any of the timepoints. At all three timepoints, low-risk participants had higher rates of abstinence than high-risk participants (see Table 5).

Because Hall et al. (1998) and others have reported gender interaction effects (e.g., Gender \times Depression History) on abstinence, we conducted post hoc analyses to identify possible gender effects. No significant gender effects were found at any timepoint, although there may have been insufficient power to detect these effects. We also analyzed PANAS and WSWS scores over the period of stepped-care treatment to determine whether the two step-up treatments produced different patterns of effect on withdrawal. No significant differences were found.

To explore the possibility that other definitions of risk may provide support for our matching hypothesis, we conducted a

series of additional analyses in which *high risk* was defined in different ways: (a) high scores on the FTND, (b) high scores on the DPI, (c) high postquit negative affect as measured by the negative PANAS, and (d) past or current depression diagnosis from the PRIME-MD. None of these analyses yielded the predicted relations between risk status and response to step-up counseling treatments.

Counselor ratings were consistently high for all counselors. For example, for mean ratings for the 10 items that were rated on a 5-point Likert scale where 5 is the most positive rating, most of the item mean ratings were above 4. However, the two-factor MANOVA on counselor ratings yielded a significant counselor effect, $F(55, 920) = 2.00, p < .001$, and nonsignificant effects for the treatment main effect, $F(11, 198) = 1.29, p = .23$, and the Treatment \times Counselor interaction, $F(55, 920) = 1.08, p = .32$. Examination of the 10 individual counselor rating items revealed greater variation in item means among the counselors for two

Table 3
Selected Participant Characteristics by Relapse Risk Group

Variable	Low risk		High risk		<i>t</i>	<i>df</i>	<i>p</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Cigarettes smoked per day	24.1	9.6	26.6	10.5	-3.3	674	.0011
Years of daily smoking	23.7	11.1	25.4	11.2	-1.9	670	.05
Carbon monoxide (ppm)	23.9	10.2	25.0	10.0	-1.4	669	.15
FTND	4.3	1.7	4.8	1.6	-4.2	668	.0000
MPQ-NZ stress reaction	5.4	3.6	6.8	3.8	-5.0	672	.0000
Depression Proneness Inventory total	28.6	9.2	34.3	11.8	-6.9	571.4 ^a	.0001
Baseline negative PANAS score	1.9	0.7	2.2	0.8	-4.3	672	.0000
Baseline positive PANAS score	3.5	0.7	3.4	0.8	2.7	610 ^a	.008
Baseline WSWs total score	2.5	0.5	2.7	0.5	-5.6	672	.0000

Note. Low risk = no smoking during first postcessation week; High risk = smoking during first postcessation week; FTND = Fagerstrom Test of Nicotine Dependence; MPQ-NZ = Multidimensional Personality Questionnaire—New Zealand version; PANAS = Positive and Negative Affect Scale; WSWs = Wisconsin Smoking Withdrawal Scale.

^a Because group variances were unequal, an approximate *t* statistic was computed with a reduced number of degrees of freedom according to Satterthwaite's approximation (SAS Institute, 1999).

items concerning therapist enthusiasm and therapist knowledge. To evaluate the importance of these two items to the significant counselor effect, we recomputed the MANOVA omitting the two items; no significant main or interaction effects were found. Finally, a two-factor ANOVA on overall therapist performance (rated 0 to 100) revealed no significant main or interaction effects.

Focused comparisons of the STFQ provided support for the prediction that low-risk CBT participants would have a higher mean on the skill training factor than the low-risk MIS participants ($M = 4.67$ and $M = 4.20$, respectively), $t(181) = -2.96$, $p < .01$, but no support for the prediction that high-risk MIS participants would have a higher mean on the support factor than the high-risk CBT participants ($M = 4.70$ and $M = 4.72$, respectively), $t(132) = -0.08$, $p = .94$. Analysis of the two support subscales—therapist-derived support and group-derived support—also revealed no predicted group differences.

Discussion

This study was designed to test two types of predicted relations related to step-up treatments and treatment matching. Surprisingly, there was no evidence that intensive step-up counseling treatment,

of either type offered, actually benefited smokers. Compared with participants receiving the brief intervention, neither at-risk smokers nor smokers who maintained abstinence during the first postcessation week benefited from step-up treatment consisting of six counseling sessions delivered across Weeks 2–5 of the quit attempt. In addition, there was only modest support for predictions concerning treatment matching: At-risk and lapsing smokers derived greater benefit from a supportive-motivational treatment as predicted but only at the 6-month follow-up.

The absence of any beneficial effect of step-up treatment is perhaps the most notable and disappointing outcome of this work, and it begs for an explanation. One possible account is that the step-up treatments were inappropriate or were poorly delivered. These explanations seem unlikely for several reasons. First, the treatments were closely modeled after treatments that have yielded positive effects. For instance, the CBT treatment was closely modeled after the CBT for negative affect successfully used by Hall and her colleagues (Hall et al., 1994, 1998), with the manual being a modification of Hall's treatment manual. Moreover, a variety of findings attest to the successful implementation of the therapy. For example, the STFQ showed that participants in the

Table 4
PRIME-MD DSM-IV Diagnoses by Relapse-Risk Group

Diagnosis	% With current or past diagnosis		$\chi^2(1)$	<i>p</i>
	Low risk	High risk		
Major depression	12	50	113.1	.0001
Minor depression	12	17	3.5	.06
Dysthymia	2	10	20.6	.0001
Panic disorder	2	5	4.6	.03
Generalized anxiety disorder	5	20	39.6	.0001
Alcohol abuse/dependence	21	22	0.05	.83
Any eating disorder	0	1	2.4	.12

Note. PRIME-MD = Primary Care Evaluation of Mental Disorders (Spitzer et al., 1994); DSM-IV = Diagnostic and Statistical Manual of Mental Disorders (4th ed.; American Psychiatric Association, 1994).

Table 5
Biochemically Confirmed Point-Prevalence Abstinence Rates (% Abstinent)

Timepoint/ risk	% Treatment group abstinence			Planned comparisons					
	BI	MIS	CBT	MIS vs. CBT		MIS vs. BI		CBT vs. BI	
				χ^2	<i>p</i>	χ^2	<i>p</i>	χ^2	<i>p</i>
5 weeks									
Low	NA	55	57	0.13	.72	NA	NA	NA	NA
High	NA	32	30	0.09	.77	NA	NA	NA	NA
6 months									
Low	28	22	25	0.23	.64	1.2	.27	0.39	.54
High	14	19	9	4.5	.03	0.96	.33	1.3	.25
1 year									
Low	30	24	25	0.11	.74	1.2	.28	0.57	.45
High	18	13	10	0.55	.46	0.90	.34	2.83	.09

Note. Point-prevalence abstinence ascertained from the question, "Have you smoked any cigarettes within the past 7 days." Point-prevalence abstinence is based on biochemical confirmation (expiratory breath carbon monoxide [CO] <10 parts per million) of self-report of no smoking within the past 7 days. BI = brief intervention; MIS = motivational interviewing; CBT = cognitive-behavioral/skill-training group counseling; low risk = no smoking during postquit Week 1; high risk = any smoking during postquit Week 1. NA = not available. The 5-week timepoint assessment occurred at the final Counseling Session 6. For all chi-square tests, *df* = 1. Percentages of low- and high-risk participants with missing data (either self-reported smoking status or carbon monoxide measurement or both) at the 6-month and 1-year timepoints for BI participants ranged from 12% to 22%; for MIS participants, the percentages ranged from 18% to 24%; for CBT participants, the percentages ranged from 16% to 29%.

CBT treatment group reported greater skill acquisition compared with participants in the MIS treatment group. Likewise, counselors were rated very positively by group members. In addition, counseling attendance figures suggest that group members received adequate exposure to the step-up treatments.

Additionally, it cannot be claimed that the failure of the step-up treatment is due to an inappropriate selection of high-risk smokers. The high-risk participants relapsed at a higher rate than low-risk participants, and they scored higher on measures of dependence and negative affect. Moreover, we conducted a series of post hoc analyses to examine other possible ways to determine risk status (e.g., on the basis of FTND score). No matter how risk status was defined, participants receiving step-up treatments never had higher abstinence rates than brief intervention participants.

Few studies similar to the present study have been published, but one recent study by Razavi et al. (1999) also failed to find any benefit of an additional intervention following initial treatment. Razavi et al. provided initial smoking cessation treatment to 993 smokers who received nicotine patch therapy and a psychosocial support program for 3 months. At the end of the initial treatment, 349 abstinent participants (*abstinence* defined as no self-report of smoking for the past 4 weeks and a CO value \leq 10 ppm) were randomly assigned to one of three conditions: no further intervention (NG), 10 monthly group counseling sessions conducted by former smokers (SG), and 10 monthly group counseling sessions conducted by psychologists (PG). At the 12-month follow-up, no group differences in biochemically confirmed abstinence were found: 50% in Group NG, 53% in Group SG, and 58% in Group PG. Although the step-up strategy in this study differs in some respects from the present study, Razavi et al.'s failure to find increased benefit from additional intervention is strikingly similar to our results.

Our current conjecture is that the failure of the step-up treatments is due neither to attributes of the treatments nor to factors

such as participant characteristics. Rather, we believe the data speak to the merit of the step-up strategy used in the present study. That is, there is mounting evidence that the first few days of a quit attempt may crucially determine the eventual fate of that attempt. For example, Kenford et al. (1994) found that about 80% of all relapses begin with smoking that occurs in the first 1–2 weeks of a quit attempt. Westman, Behm, Simel, and Rose (1997) further truncated this cessation "critical period" by showing that smoking on the quit day is highly predictive of long-term relapse to smoking. In addition, data gathered by Zhu et al. (1996) suggest that the first 1–2 weeks postcessation may be a critical period for intervention.

In sum, it is our hypothesis that the seeds of relapse are sown very early in a cessation attempt, and once they take root, it is very difficult to dislodge them with more intensive counseling, especially if there is a delay in providing the step-up treatment. Thus, we believe that the 1-week delay in starting the group counseling, as occurred in our study, prevented the step-up treatments from having the intended beneficial impact. The present data are all the more damning to the type of stepped-care approach used in the present study because we used two distinct types of stepped-care contents, and neither improved outcomes. Our hypothesis about the negative impact of the delay in starting step-up treatment is supported by remarks made by many of the participants in those treatment groups. Examples of the remarks include, "Where were you when I needed you [earlier]?" or "If you want to improve this treatment, you could try starting these [counseling] sessions closer to our quit day."

We believe our data argue strongly against the promise of a particular type of stepped-care strategy, namely, one in which participants are moved up to a more intensive counseling strategy after the period of peak relapse risk has passed. However, there may be merit in other types of step-up treatments. For instance, the results do not speak to the merits of pharmacotherapy step-up

treatments, nor do they address the systematic escalation of treatment intensity across separate, sequential quit attempts. We must note, however, that there is little extant evidence that supports either of these approaches.

The second major issue addressed by this research was the matching hypothesis, that is, whether high-risk smokers would be especially aided by the MIS or the CBT treatment (see Zelman et al., 1992). The results provided only weak support for this notion. For high-risk participants, the MIS treatment was statistically superior to the CBT treatment only at the 6-month follow-up; MIS was never superior to brief intervention. Although these results do not strongly support a matching approach, the present study was probably not a fair test of this approach. Specifically, the delay in starting counseling treatment inherent in the stepped-care design may have undercut the therapeutic impact of the two counseling treatments.

It seems that a fair test of the step-up strategy and the matching hypothesis must await a study in which step-up treatment is delivered at a more optimal time, for example, responding immediately when smokers slip or experience significant distress related to quitting. Our measure of relapse risk—any smoking during the first postquit week—is a potentially important behavioral indicator that an individual may have difficulty maintaining continued abstinence. But a delay in implementing the step-up treatment, especially for those individuals who need step-up treatment in the first few days, may undermine the intended benefit of adding tailored or matched treatments designed to help at-risk individuals.

In sum, we did not find support for step-up treatments as implemented in the present study. We surmise that the delay in starting the more intensive treatment may have resulted in poorer outcomes, which suggests that “striking while the iron is hot” may be important in helping individuals who have early postcessation lapses. We also reported validity evidence for our measure of relapse risk showing that, compared with abstinent individuals, those who engage in any postquit smoking are more likely to have more severe nicotine dependence, current or past mood or other psychiatric disorders, and lower abstinence rates at the end of treatment and at long-term follow-up. These findings highlight the importance of assessing dependence level and psychiatric comorbidity in smokers to develop a more effective overall treatment strategy (e.g., offering higher dose NRT or providing more intensive behavioral treatment from the outset). In addition, our finding that high-risk smokers may benefit from MIS (as opposed to CBT), though not a consistent finding, is encouraging and suggests that future step-up studies that incorporate timely treatments matched to individuals’ needs may yield results supportive of the matching hypothesis.

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