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Title: A Comparison of Smoking Patterns between Counseling Assisted and Unassisted Heavy Smokers with Early Chronic Obstructive Pulmonary Disease.

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Smoking patterns were described and compared retrospectively for 5395 participants in the Lung Health Study at 12 and 24 months. 3592 participants were assigned to a special intervention (SI) group that received a counseling assisted smoking cessation intervention that included nicotine gum and 1803 participants were assigned to a usual care (UC) group that received no assistance in quitting smoking. Participants were smokers diagnosed with mild to moderate chronic obstructive pulmonary disease (COPD) and averaged 31.4 cigarettes/day at entry.

Significant differences were found regarding smoking outcomes and smoking patterns between groups as well as within each group. Counseling assisted participant's continuous abstinence rate at 24 months was 25.1% compared to 3.5% for unassisted smokers. Counseling assisted men were

more successful at remaining abstinent at 24 months (27.1%) compared to (21.8%) for counseling assisted women. No gender differences were found for unassisted smokers. Abstinence rates were biochemically validated.

Differences were also found in smoking patterns between groups for those unable to achieve continuous abstinence at 24 months. Counseling assisted participants smoked fewer cigarettes, made more quit attempts, smoked fewer months and stayed quit longer. Mixed results were found for baseline demographic and smoking history variables. Age started smoking, other smokers in the household, education and social support were not significant. Cigarettes smoked per day, previous quit attempts, longest period quit and alcoholic drinks per week were significant.

A Comparison of Smoking Patterns between Counseling Assisted and Unassisted Heavy Smokers with Early Chronic Obstructive Pulmonary Disease.

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A Comparison of Smoking Patterns between Counseling Assisted and Unassisted Heavy Smokers with Early Chronic Obstructive Pulmonary Disease

INTRODUCTION

Statement of the Problem

Overview

Cigarette smoking is the primary preventable cause of death in our society. In excess of 300,000 deaths annually occur in the United States alone that are attributed to cigarette smoking. Chronic obstructive pulmonary disease (COPD), lung cancer, other cancers, heart disease, and complications of pregnancy are just a few of the negative health effects that result from smoking. Nicotine, the active drug in cigarette smoke, has been shown to be an addicting agent just as cocaine and heroin, yet many fewer resources than those allocated for illegal drugs have been brought to bear on this problem and more research is necessary on how to effectively treat those most dependent on nicotine (Department of Health and Human Services [DHHS], 1988).

The Surgeon General's Report on chronic obstructive lung (pulmonary) disease (1984) describes COPD as a disease of the lungs and airways that results in obstruction of

airflow. Emphysema and chronic bronchitis are the two diseases most commonly referred to as COPD. It is a disease primarily limited to smokers. More than 90% of all people with COPD are smokers. The disease is progressive, but long time smokers who have substantial lung damage and decline in lung function can slow the rate of decline to that of non-smokers by becoming abstinent from cigarettes. They will not regain lung function lost due to damage to the lungs prior to quitting, however. The report goes on to conclude that smoking cessation is essential to decreased risk of mortality from COPD (Department of Health and Human Services [DHHS], 1984).

Issues in Smoking Cessation

Current trends in the smoking cessation literature suggest that organized smoking cessation programs are less effective in achieving smoking cessation than the efforts of smokers who quit on their own. In fact, for the majority of smokers who are motivated to quit, the method of choice is self help (Schachter, 1982). Fiore, et al., (1990) also indicated that most smokers quit without assistance but pointed to possible barriers to participation by smokers in cessation programs. Cost was the primary barrier cited. After a proliferation of smoking cessation programs over the last twenty years, these new trends toward self help call into question the appropriate role of smoking cessation

programs, particularly the more labor intensive counseling programs (Fiore, et al., 1990, Schachter, 1982). .

Relapse rates continue to be discouragingly high for all methods and are highest among heavy smokers, who smoke 20 or greater cigarettes per day regardless of the method of cessation (Cohen et al., 1989). Since heavy smokers most often refer themselves to programs due to difficulty in quitting on their own (Schachter, 1982) and are at greatest risk for chronic disease, a better understanding of abstinence and smoking patterns for heavy smokers becomes important in the decision to select the most effective smoking cessation intervention. Therefore, questions of the efficacy of self quitting or unassisted methods, compared to counseling assisted methods are especially relevant for heavy smokers (Glasgow & Lichtenstein, 1987).

Killen, Fortmann, Telch & Newman (1988) in their study of heavy vs light smokers pointed out that since relatively little appeared in the literature regarding the heavy smoker who was more nicotine dependent, more needed to be learned about this smoker if cessation methods were to be more effective. Choice of method becomes an even more important question when the allocation of resources is considered, since self quitting methods are significantly less expensive and more widely available than the more labor intensive behavioral counseling assisted programs (Altman, Flora, Fortmann & Farquhar, 1987; Glasgow & Lichtenstein, 1987;Goldstein, Niaura, Follick & Abrams, 1989).

Sample size is an additional problem when evaluating the real effect of smoking assistance programs both in terms of abstinence and relapse. Glasgow and Lichtenstein (1987) pointed out that most studies of smoking cessation have employed inadequate sample sizes given the dichotomous variable of smoking or not smoking. They also suggested that abstinence rates should take into account not only point prevalence but continuous abstinence rates following the completion of treatment as well as changes in smoking status over time. Other researchers have supported this notion and indicated that quitting smoking was a dynamic process that required evaluation of more than one attempt to quit and what was needed was large studies that followed smokers' behaviors over years rather than the just a few months as is often been the case in smoking cessation research. They also pointed out that the need for longer follow-up periods was due to the need to gather data on relapse that occurred after the first six months posttreatment and recommended that data be collected for a year or more before any critical analysis of a program effect could be made (Cohen et al., 1989; Curry, Marlatt, Peterson & Lutton, 1986; Evans & Lane, 1980; Hurt, Offord, Hepper, Mattson & Toddie, 1988; Lichtenstein & Mermelstein, 1985).

Study Sample

The Lung Health Study is an international clinical trial with ten centers in the United States and Canada and

funded by the National Heart, Lung and Blood Institute (NHLBI). All participants were diagnosed with early chronic obstructive pulmonary disease (COPD). SI participants received a state-of-the-art cognitive behavioral counseling intervention to stop smoking plus nicotine gum. UC participants were provided no assistance by the Lung Health Study to quit smoking and were referred to their usual source of medical care.

LHS provides such an unique opportunity to retrospectively compare the smoking patterns for 5385 heavy smokers motivated to quit who received random assignment to either a counseling assisted special intervention (SI) condition or an unassisted usual care (UC) condition and follow-up for at least 24 months. Self reported smoking status outcomes for the LHS were biochemically validated and follow-up for this study included 12 and 24 months post baseline. Describing and comparing outcomes and the patterns of smoking of each of these groups over 24 months will provide valuable data in developing and refining counseling assisted smoking cessation treatment of heavy smokers.

Study Objectives

The overall objective of this study is to compare the outcomes and smoking patterns of participants randomly assigned to either a special counseling assisted smoking

intervention (SI) group or to an unassisted usual care (UC) group at 12 and 24 months post baseline in the LHS.

Null hypotheses

Primary Null Hypothesis

H1) There are no differences between the smoking outcomes and smoking patterns of the SI group and the smoking outcomes and smoking patterns of the UC group.

This hypothesis will be tested by an analysis of overall outcome differences between groups and within group by smoking status at 12 and 24 months (12 month and 24 month data points).

In order to more comprehensively describe and compare participant smoking patterns several null hypotheses have been developed for a sub group of those SI and UC participants who report smoking at the 12 month and 24 month data points. The analysis of this sub population is referred to as the smokers only analysis.

Null Hypotheses for Smokers Only

H2) There are no differences between SI and UC smokers for the number of post baseline quit attempts made prior to the 12 month data point and between 12 and 24 month data points.

H3) There are no differences between SI and UC smokers for the post baseline longest time off cigarettes prior to

the 12 month data point and between the 12 and 24 month data points.

H4) There are no differences between SI and UC smokers for the average number of post baseline cigarettes smoked per day prior to the 12 month data point and between the 12 and 24 month data points.

H5) There are no differences between SI smokers and UC smokers for the number of post baseline calendar months in which at least one cigarette was smoked prior to the 12 month data point and between the 12 and 24 month data points.

Rationale for Definitions

Smoking and quitting are fluid processes (Marlatt, Curry & Gordon, 1988) which makes any definition of quit or relapse arbitrary. Although the data in this study will be analyzed by grouping subjects into categories based on smoking status, the categories are only valid for the point in time they are used.

Definitions regarding posttreatment or post quit attempt for the unassisted smoker have also varied somewhat in the literature. For example, the term quit as used by Killen et al. (1988) referred to 48 hours without smoking in their analysis of heavy smokers versus light smokers. Quit or abstinent has often been defined, however, as not smoking for at least seven consecutive days prior to the assessment

of smoking status (Baer, Holt & Lichtenstein, 1986; Davis, Faust and Ordentlich, 1984; Kanzler, Jaffe and Zeidenberg, 1976; Perri, Richards and Schulthesis, 1977). Point prevalence abstinence and continuous abstinence are two ways used in reporting cessation rates. The former refers to smoking status only at the time of the assessment and the latter refers to continuous non-smoking behavior up to and including the time of assessment (Cohen et al., 1989). Somewhat infrequently researchers will use both of these definitions in reporting data. For example, Mermelstein, Cohen, Lichtenstein, Baer & Kamark (1986) when they reported the results of two intervention conditions indicated that at 12 months that the point prevalence abstinence rates were 35.9 % and 32.9% for the two groups and that the continuous abstinence rates at 12 months for the two groups was 17.2% and 23.4% respectively. Unless otherwise specified, however, only point prevalence data is usually reported in the literature (Cohen et al., 1989).

While all these definitions are useful in looking at the process that participants go through as they attempt to achieve long term abstinence from cigarette smoking, none are expansive enough to capture the complexity of smoking patterns that are the focus of this study. Rather, use will be made of multiple definitions to more clearly define and describe smoking as a behavioral process that includes patterns of short term quits and relapses as well as continuous smoking and long term abstinence. In order to

look at smoking patterns for 24 months in addition to outcomes the more conservative continuous abstinence or continuous smoking data will be used in defining sustained non-smokers and continuous smokers at 12 and 24 months. Point prevalence data will be used in defining quit attempts as suggested by Glasgow and Lichtenstein (1987).

Definitions

Participants

SI are those participants who met the medical criteria for having early Chronic Obstructive Pulmonary Disease (COPD), were smokers, were randomized into the Special Intervention group and were provided the Lung Health Study's counseling aided intervention for smoking cessation. SI is synonymous with counseling assisted participant.

UC are those participants who met the medical criteria for having early COPD, were smokers, were randomized into the Usual Care group and were provided with no assistance to quit smoking by the Lung Health Study. These participants were referred back to their usual source of medical care. UC is synonymous with unassisted participant. At the completion of the LHS, UC participants will be offered a counseling assisted smoking cessation intervention.

Smoking Status

Sustained non-smoker is defined as a participant who reported at their 12 month visit that they: 1) had not smoked in the past eight months, 2) were not currently smoking, 3) averaged zero cigarettes per day for the past eight months and had not smoked in the past seven days.

The previous 8 months criterion was used rather than the full 12 months during this first year in order control for any smoking that may have preceded the counseling intervention period that occurred during the first 4 months for SI participants. To be a sustained non-smoker at 24 months a participant had to meet the same non-smoking criteria as outlined at the 12 months visit, but from the 12 month to 24 months data points. This data spanned 12 months rather than the 8 months specified at the 12 month data point. The participant self report data was biochemically verified by either salivary cotinine which detects the presence of nicotine or expired carbon monoxide. Both measures are standard for validating smoking or non-smoking behavior (Hall, Tunstall, Rugg, Jones & Benowitz, 1985). In order to be a sustained non-smoker a participant had to have a cotinine level less than or equal to 20 ng/ml or if using nicotine gum an expired carbon monoxide level of less than 10 ppm at both the 12 month and 24 month data points.

Continuous smoker at 12 months is defined as a participant who reported at the 12 months visit that they: 1) smoked in the past eight months, 2) were currently

smoking, 3) averaged greater than zero cigarettes per day for the past eight months and 4) smoked in the past seven days. To be a continuous smoker at 24 months the participant had to meet the same criteria for smoking as outlined for continuous smokers at the 12 month data point with the exception that the period between 12 and 24 months covered the full 12 month period for the reason previously outlined in the 24 month definition of sustained non-smoker.

Intermittent smoker is defined as a participant who: 1) attended the 12 month and 24 month data points and 2) did not meet the criteria for a sustained non-smoker or a continuous smoker. The intermittent smoker is further defined as a participant who has had at least one relapse, since they had met neither the criteria for sustained non-smoker or continuous smoker.

Additional Definitions

Baseline data is defined as participant smoking history and demographic data collected prior to randomization into the LHS.

Continuous abstinence is defined as reporting non-smoking behavior for the entire period between all data points as well as for the current assessment.

Chronic obstructive pulmonary disease (COPD) is defined as a disease of the lungs and airways that results in obstruction of airflow. Emphysema and chronic bronchitis are the two diseases most commonly referred to as COPD.

Heavy smoker is defined as an SI or UC participant who reported smoking an average equal to or greater than 20 cigarettes per day at baseline prior to randomization into the LHS.

Quit attempt is defined as reporting smoking in the last 12 months and reporting at least one period equal to or greater than 48 hours without smoking at the 12 month or at the 24 month data points.

Relapse is defined, in the most conservative terms, as smoking at least one cigarette in the 8 months prior to the 12 month data point or in the 12 months prior to the 24 month data point and meeting the criteria for intermittent smoker.

Long term abstinence is defined as meeting the criteria for sustained non-smoker at the 24 month data point.

Point prevalence is defined as data reported for a specific point in time. No assumptions are made about behavior prior to that specific point.

Smoker only is a term used in the analysis related to null hypotheses 2-5. It refers to any SI or UC participant who was not a sustained non-smoker at the 12 or 24 month data points.

Smoking pattern is defined in terms of post baseline variables for smokers only in both groups: number of quit attempts of at least 48 hours, longest period of time off cigarettes, number of cigarettes smoked per day and number

of calendar months in which at least one cigarette was smoked.

RELATED LITERATURE REVIEW

Introduction

The Surgeon General's Report (U.S. Public Health Service [USPHS], 1964) ushered in a new era for those who smoke and those providing care to smokers. Smokers, health professionals and counselors have continued to seek effective methods for smoking cessation and maintenance (relapse prevention). In excess of 300,000 deaths in the United States alone are due to cigarette smoking annually (DHHS, 1988).

Many of the health consequences of smoking such as the substantial increases in mortality and morbidity e.g., the prevalence of cancer and cardiovascular disease in smokers, continue to be documented in numerous studies and reports (Benowitz, 1988; Lichtenstein & Brown, 1980; Stokes & Rigotti, 1988; and Department of Health and Human Services [DHHS], 1989). Considering the enormous human and financial costs of smoking related diseases, smoking cessation has received much less attention from practicing counselors, psychologists, and other mental health professionals than the attention given to treatment of other addictive behaviors (Lichtenstein & Brown, 1980).

Unfortunately much of the literature on treatment for smoking cessation points to the poor rate of sustained

maintenance of cessation despite impressive short term quit rates following treatment (Etringer & Lando, 1984; Hunt & Matarazzo, 1973; Lichtenstein & Mermelstein, 1985; Pechachek & Danaher, 1979; Pechacek & McAlister, 1980). Smoking, like other addictive and dependency behaviors, has proven extremely difficult to extinguish as pointed out by the self reports of smokers who indicate a desire to quit but continue to smoke (Kozlowski et al., 1989; Prochaska & DiClementi, 1983a; DHHS, 1988).

A number of studies have pointed out that the relapse rates for those who do manage to quit cigarettes are substantial with the bulk of them reporting rates near 70% within the first year (Brownell, Marlatt, Lichtenstein, and Wilson, 1986; Hunt & Matarazzo, 1970, 1973; Lichtenstein & Mermelstein, 1985; Pechacek & McAlister, 1980). Kozlowski, et al. (1989) also found that for those smokers being treated for alcohol and drug dependency that cigarettes were perceived to be much harder to give up and provide less pleasure than the chemical for which they were being treated. 75% indicated that nicotine was as difficult to give up as the drug for which they were being treated and 57% indicated that nicotine was more difficult to give up than the drug for which they were being treated.

Given the health hazards and the difficulty quitting, research in smoking cessation has been directed at analyzing reasons for smoking and methods for quitting.

Psychological and Counseling Theories for Smoking and Smoking Cessation

The two major thrusts of smoking cessation research to date have been first from a psychobehavioral counseling perspective and more recently from a pharmacological perspective.

Hunt and Matarazzo (1970) were among the forerunners in looking at smoking behavior from the point of view of learning theory. They suggested that much of smoking behavior was due to habit formation and stressed the role of overlearning in maintaining automatic smoking behavior once the behavior was acquired. For a two pack a day smoker they estimated 146,000 puffs from cigarettes per year and many smokers in their study had smoked well over 20 years. Each puff was a unit of reinforcement. They pointed out that no human learning laboratory had ever created a reinforcement schedule to equal the one self administered by the smoker. They did agree that the reasons for acquiring the habit, or primary reinforcers, of smoking were many and varied, but their focus was on the secondary or maintenance reinforcers. They suggested that the secondary stimuli replace the primary reinforcers and produce the same response in situations which are no longer congruent with the situation that originally provided the primary reinforcement, e.g., smokers often go on to smoke for reasons unassociated with pleasure, stress etc. that were primary reinforcers.

Therefore, when comparing smoking with addictions to opiates or alcohol, they suggested that smoking should be more easy to control in terms of quitting but more difficult to maintain complete abstinence due to the greater number of secondary cues for smoking compared to the number of secondary cues for other drugs. They also indicated that the other drugs due to their more powerful pharmacologic effects would be more difficult for the individual to control than nicotine, but that more needed to be learned about the pharmacologic effects of nicotine. They were the first researchers to indicate that the relapse curve for nicotine mirrored a negative and accelerated learning extinction curve where the bulk of relapse occurred in the first few months after quitting. Based on this finding they suggested that booster sessions should be provided to newly quit smokers within the first several months in order to improve abstinence rates over time. They pointed out that most smokers who quit returned to smoking as a function of time just as with any new learned behavior, when the behavior was not regularly reinforced.

In a separate study approximately three years later they constructed relapse curves for heroin, nicotine (smoking) and alcohol use and in comparing the curves found all of the curves similar to each other and similar to a learning extinction curve. The relapse curves for smoking and heroin were almost identical and reflected a relapse rate greater than that for alcohol. They pointed out that

two thirds of the persons who quit smoking returned to smoking within three months (Hunt & Matarazzo, 1973).

Learning theory began to provide an important foundation for smoking cessation counseling. Bandura's (1977) work on learning, self efficacy and expectancy provided a conceptual framework for more formal cognitive behavioral psychological treatment of smoking. He indicated that learning and behavior change were much more than the immediate response of a person to stimuli but also included the efficacy of expectations. This theory proposes that an individual must believe that they can actually be successful in accomplishing the tasks required to create the new behaviors or their willingness to expend energy and persevere in the new behaviors will be limited. If the person fears that a given situation will require coping skills greater than they possess they will more likely avoid that situation and seek a situation where they feel more competent. Further, where differences between actual performances and efficacy expectations did occur it would most likely be in situations where the task requirements were underestimated or overestimated. Therefore, clarity of the task and its requirements is essential if mastery of the task is to be achieved.

In a test of the validity of self efficacy (Bandura, 1977), and its usefulness in smoking cessation, Baer, Holt and Lichtenstein (1986) found that the efficacy ratings of subjects following treatment were significantly related to

posttreatment smoking rate but only somewhat related to abstinence. They concluded that self efficacy was a variable that influenced smoking behavior especially during the posttreatment maintenance phase, but that it was not one of the more powerful variables. Other studies of participants who were in smoking cessation programs have concluded that self efficacy is a predictor of abstinence (Brandon, Tiffany, Obremski & Baker, 1990; Condiotte & Lichtenstein, 1981).

Norcross, Ratzin and Payne (1989) in a study of unassisted quitters found that self efficacy was an important factor in the maintenance of abstinence and reported that successful abstainers expressed higher levels of self efficacy than those who were unsuccessful abstainers. Another study found that self efficacy ratings for those who quit without assistance were predictors of smoking outcomes, but were no better than previous smoking history as a predictor of successful abstinence (Garcia, Schmitz & Doerfler, 1990).

Not all studies support the importance of self efficacy for unassisted quitters, however. Lichtenstein and Cohen (1990) found no significant effect for self efficacy in predicting smoking status in their study of unassisted smoking cessation.

While the results of self efficacy in smoking cessation is mixed, the role of expectancies in therapeutic practice is well established. Rotter's (1972) earlier work while

anticipating many of the concepts of Bandura (1977) described social learning theory as an expectancy theory where the potential for a given behavior to occur was based on the expectancy of the person receiving reinforcement after completing the behavior in a given situation. He then described the applications of the theory in therapy. Because of expectancies, dependent clients were more likely to reject non-directive therapy as readily as independent clients were to reject directive therapy. He further believed that the flexibility of the therapist early in the therapist/client relationship was essential if the needs of the client are to be successfully addressed. He saw the role of the therapist as collaborative and intended to help the client accomplish planned behavior changes, to teach problem solving skills, to actively reinforce the desired behaviors, to help the client understand unrealistic expectations from the past, to model appropriate behaviors and to help the client generalize what is learned to actual life situations in a social environment.

Social learning theory provided much of the basis for cognitive behavioral strategies for smoking cessation (Pechacek & Danaher, 1979). The collaborative role of counselor and patient in behavioral counseling outlined by Rotter (1972) was supported by Russell (1986) in his work on counseling in a medical setting. He advocated that the patient play an active role in assessing the desired changes in given behaviors by monitoring those behaviors along with

the therapist and assessing any needs for adjustment to the behaviors. The focus of therapy was to change unwanted behaviors rather than attempting to change personalities and required that the patient assume the role of expert for his/her own thoughts, relationships and day to day functioning. With this approach the counselor brings his/her overall knowledge of the process of change and helps facilitate change through maintaining focus and direction related to the jointly accepted goals. He pointed out that in a medical setting the goal of behavioral counseling is to slow or arrest the progress of chronic disease. Therefore, when applied to smoking cessation, social learning is a central part of the intervention model.

The enhancement of social support, like self efficacy, has often been included as one of the components in cognitive behavioral smoking cessation programs, but the importance of social support has not been consistently demonstrated (Cohen & Lichtenstein, 1990). Etringer, Gregory, and Lando (1984) found some encouraging trends in group cohesion improving short term cessation success. In this study subjects were randomly assigned to either an enriched or standard cohesiveness group. By increasing cohesiveness to a level above what normally would occur in a group setting for the enriched group, the researchers were able to show significantly greater abstinence rates at three months. However, substantial relapse did occur for both

conditions following three months and the long term effect of the intervention was unclear.

Lichtenstein, Glasgow and Abrams (1986) in their review of five studies that compared cognitive behavioral smoking cessation programs that included social support enhancement components with cognitive programs that did not include the enhanced components found no significant differences in treatment outcomes. They did find significant correlational results that suggested that social support was associated with successful cessation. They concluded that more research was needed before social support was accepted as a significant factor in smoking cessation.

Mermelstein, Cohen, Lichtenstein, Baer and Kamark (1986) found that social support from a partner and general support from others not to smoke helped in the maintenance of non-smoking behavior during the first three months of abstinence but had no significant effect on long term maintenance. Having a social support network that included smokers had a significant negative effect on abstinence and appeared to lead to relapse in the first 12 months.

Lassner (1991) reported similar findings to Lichtenstein et al., (1986). His analysis of eight smoking cessation studies and 21 weight loss studies found no effect for social support for 6 of the smoking studies and 13 of the weight loss studies. Several other studies failed to find social support as a significant predictor of abstinence (Killen et al., 1988; Norcross et al., 1989).

Many of the aforementioned social learning and cognitive behavioral theories have been included in the comprehensive model for smoking behavior change by Prochaska and DiClementi (1983a, 1983b, 1984, 1985) and deserves some discussion in depth. They propose a stages of change model which expands current treatment models for smoking cessation by approaching cessation as a cyclical stage process which includes relapse. They conceived of this model as circular where the client would go through the stages more than once before finally being free of the temptation to return to or to actually relapse to the smoking behavior. The five stages of change eventually identified were precontemplation, contemplation, action, maintenance and relapse. Precontemplation was characterized by the smoker thinking that he/she did not need to change his/her smoking behavior. Contemplation was synonymous with awareness by the smoker that he/she had a behavior that needed to be changed and that a problem did exist. Action was the stage when the smoker made obvious behavioral and environmental changes in order to quit smoking. Maintenance was a continued period of activity in which the smoker attempted to maintain gains made during the action phase and attempted to prevent slipping into relapse. Relapse was the stage that occurred when maintenance strategies failed. Following relapse smokers might return to any of the prior stages. For many smokers going through these stages more than once was necessary before they would finally quit smoking. They

believed that their theory was a significant departure from prior linear theories of behavior change in smoking cessation that took into consideration only those changes in behavior up to and including the initial cessation.

Building on the stages of change approach Cohen et al., (1989) in their analysis of 10 studies of individual's attempting smoking cessation with little or no assistance, reported that quitting was a dynamic process that included cyclical phases of quitting and relapse over an individual's lifetime similar to those suggested by Prochaska and DiClementi (1983a, 1983b, 1984, 1985). Presently, the concept of stages in quitting is widely accepted as an important feature of many cessation programs (Brownell, Glynn et al., 1986; Brownell, Marlatt et al., 1986; Cohen et al., 1989).

Social Learning Smoking Cessation Strategies

Social learning strategies for smoking cessation are broadly divided into two types: aversion and self control. Aversion has included electric shock, covert sensitization (associating smoking with an unpleasant stimulus) and rapid smoking. Rapid smoking is the most common of these strategies and requires that the smoker inhale cigarette smoke in rapid puffs until smoking behavior is so aversive that it is extinguished. Self control strategies require active participation by the smoker in developing and

implementing the treatment plan. The goal is to eliminate smoking behavior by reducing smoking cues (Pechacek & Danaher, 1979).

In a review of seven the state-of-the-art smoking cessation methods Lichtenstein and Brown (1980) concluded that social learning approaches were the most effective when compared to hypnosis, drug therapy, physicians's interventions and community mass media cessation projects. Rapid smoking aversion therapy and multicomponent self control strategies which included client self-management techniques were cited as the social learning approaches with the best outcomes. Due to undesirable side effects and the high costs often associated with aversion therapy which requires clinical supervision, multicomponent programs were found to be more cost effective and less invasive. Multicomponent programs include components for preparation for the quit, the actual quit and maintenance of the new behavior. When using this approach, they found no differences in cessation outcomes between individual or group counseling. Group counseling was found to be more cost effective, however.

Marlatt (1985) also provided a cogent rationale for using social learning principles in his cognitive behavioral approach to treat addictive behaviors. He pointed out that addictive behaviors had often been viewed dichotomously as either somatic or psychological in origin. While the use of any drug results in a somatic experience, the change in

feeling brought on by the chemical was experienced subjectively and cognitively. He concluded that both factors must be included in a treatment model. As drug use increases the individual's perceptual field decreases with a corresponding decrease in non-drug related activity. The chemical also effects the individual's ability to perceive these changes. An internal conflict results from the short term pleasure achieved vs the long term negative consequences which leads to cognitive based defensive reactions. The client is, therefore, blinded to the impact of the distortion by his/her defense mechanisms. Cognitive behavioral therapy teaches the client how their defense mechanisms distort perception and how to take remedial action once aware that the defenses are operating.

Other theorists have also taken social learning theory and applied it directly to the issue of smoking cessation. According to Pechacek and Danaher (1979), social learning theories provide a framework that can include the elements of various smoking cessation models. They suggested that the keys to success in smoking cessation included: that the smoker believe that the treatment will work, that the treatment will result in self efficacy being increased by successful performance, that the client gain specific new skills, that the changes in smoking behavior are seen as the result of learned skills rather than external factors and that personal efficacy is generalized to other behaviors.

Physiology, Pharmacology and Nicotine Gum

The second thrust of smoking cessation research, introduced primarily in the 1980's, has been from a pharmacologic perspective. Recognition by researchers that physiologic changes occur in smokers has led to investigation of the pharmacology of smoking. From this research, nicotine dependence has been shown to closely mirror other drug dependencies in its physiologic impact. Specifically, within the brain there is a bolus effect that occurs in seven seconds when nicotine is inhaled (Cooper & Clayton, 1989). The speed with which the nicotine passes the blood brain barrier is faster than for heroin when heroin is injected intravenously (Schneider, 1987). Somewhat lowered blood pressures, mood changes, stimulation of neuropeptides resulting in changes in pleasure and pain sensations, generally suppressed body weight, memory changes and changes in the effectiveness of some prescribed drug therapies due to the presence of nicotine are some of the physical changes reported in smokers (Benowitz,1988).

The physical effects of nicotine as a basis for smoking was also studied by Sachs (1987) who found that smokers regulated the amount of nicotine they took in despite smoking cigarettes that contained nicotine levels lower or higher than their usual brand. In this study subjects extracted 60% more nicotine from the low yield brands than the levels assigned to the brands by the Federal Trade

Commission and they smoked approximately 25% more of the low yield cigarettes than their usual brand to reach comfortable nicotine levels. The opposite compensation occurred when subjects smoked stronger brands than their usual brand. In both conditions they were able to maintain baseline nicotine blood levels.

Pomerleau, Fertig, Seyler and Jaffe (1988) in a study of the response of neuropeptides to smoking found that the release of neuropeptides was stimulated by smoking and that this release was reinforcing to continued smoking behavior. They went on to indicate that a stimulus that was tied to a cognitive task could often result in continued smoking due to the past improved cognitive functioning such as increased memory that had been experienced during the presence of released nicotine stimulated neuropeptides.

In a comprehensive report, the Surgeon General's Report on Nicotine Addiction (DHHS, 1988) summarized the difficulty faced by those involved in smoking cessation in developing recovery strategies from nicotine addiction. The links between physical factors, psychological factors and the role of overconditioning in the resistance of smoking behavior to successful treatment was pointed out as well as the impossibility of separating out the specific contribution of any one of these factors. The report goes on to indicate that individual differences between smokers including the point the smoker was in his/her smoking history were also significant factors in the smoker's response to treatment.

Because of the frequency of repeating the behaviors involved with smoking such as taking multiple puffs from each cigarette smoked over years of smoking history, overlearning for smoking is greater than for any other drug use. The report further suggested that the role of pharmacology in the addiction to nicotine needed to be included in current smoking cessation treatment programs in addition to the psychological approaches if they were to become more successful than past programs in addressing nicotine addiction. As a result of such findings, separate converging areas of research are providing encouraging insight into both psychologic and physiologic problems of nicotine dependence and treatment options for sustained maintenance of non-smoking behavior.

Pechacek and Danaher pointed out (1979), there were no pharmacological options available to aid in cessation for many years. As a result, smoking cessation programs had addressed only the psychological side of nicotine dependency. The development of nicotine replacement gum (nicotine polacrilex) added an effective method of treatment for the physiological side of this dependency.

Schneider (1987) indicates that nicotine gum has been the primary pharmacologic intervention for treating nicotine dependency in smoking cessation. Prior to the introduction of nicotine gum into the United States in 1985, no effective pharmacologic aid was available in treating cigarette smoking. The gum, developed in Sweden, is an aid in reducing

such withdrawal symptoms as anxiety, irritability, mood changes, inability to concentrate, changes in heart rate, changes in skin temperature and changes in brain wave patterns for those attempting to abstain from cigarettes. Approximately 90% of the nicotine in a piece of nicotine gum can be extracted by the patient in about 20 minutes. The gum produces lower blood nicotine levels, does not have the physically damaging properties of cigarette smoke and delivers a more even level of nicotine in the blood than the peaks and valleys that occur when inhaling tobacco smoke. She goes on to suggest that the slower and more even delivery of nicotine was one of the primary factors necessary for patients to wean themselves from nicotine and points out that instructions on the proper use of the gum were essential to successful treatment. She concluded that the most effective treatment coupled a multicomponent program with the gum.

Fagerstrom (1982) in a study on the effectiveness of nicotine gum compared two groups that received psychological treatment plus either nicotine gum or placebo gum and found that there were significantly higher abstinence rates at six months for the nicotine gum group (63%) vs the placebo gum group (45%). In a review of 12 studies of nicotine gum use Hughes and Miller (1984) found that nicotine gum when linked with a behavioral intervention improved abstinence rates in the short run, but these early improvements in rate at six months tended to decline. By 12 months posttreatment only

three of the 12 studies reported statistically significant differences between groups ($p < .05$.).

Glasgow and Lichtenstein (1987) in their review of 60 behavioral smoking cessation studies found that behavioral skills training when coupled with nicotine gum was more effective than gum only or behavioral skills training only interventions. These findings were supported by the work of Goldstein et al., (1989) when they found that clients who received behavioral skills training plus nicotine gum achieved significantly better six month abstinence rates than clients who received only a health information intervention plus nicotine gum. The results of a number of other studies have also shown enhanced maintenance of non-smoking behavior when a treatment program includes a nicotine replacement therapy such as nicotine gum as well as a cognitive behavioral treatment (Benowitz, 1988; Jarvick & Henningfield, 1990; Lichtenstein & Brown, 1980).

Killen, Fortmann, Newman and Varaday (1990) found similar short term effects for the gum. They reported that a fixed regimen of nicotine gum helped maintain non-smoking behaviors through six months when used alone or with a minimal self guided behavioral program that participants received in the mail. Long term abstinence rates were not significantly better than the placebo or the no gum conditions. They concluded that an intensive cognitive behavioral program was necessary in conjunction with the gum to make a difference in the long term abstinence rates.

Differential responses by participants to nicotine replacement therapy (nicotine gum) has complicated the picture on how to best use this pharmacologic aid in smoking cessation treatment. One study found nicotine gum more effective than placebo in assisting participants maintain abstinence at one year but found no increase in abstinence rates when a behavioral intervention was added to the gum condition (Hall, Tunstall, Ginsberg, Benowitz and Jones, 1987).

Other differential responses to nicotine gum have been reported in the literature. Jarvik and Schneider (1984) found that heavily dependent smokers who used 2 mg nicotine gum were significantly more likely (p= .05) to maintain abstinence than smokers who were lower in nicotine dependence who used 2 mg nicotine gum. No differences were found in abstinence rates for higher vs lower dependent participants in a placebo group. The researchers cautioned against conclusions regarding the usefulness of the gum for lower nicotine dependent participants, however.

Killen et al., (1990) found gender differences in participants response to nicotine gum. Their study included four groups: nicotine gum (ad lib dose), nicotine gum (fixed dose), placebo gum and no gum conditions. Men in the nicotine (fixed dose) gum group were significantly more likely to be abstinent at 12 months posttreatment (p= .05) than men in the other groups. There were no significant

differences in abstinence rates for women across the four conditions.

The search for additional pharmacologic therapies continues with the following studies reporting a number of potentially useful findings that may be important in assisting smokers to achieve cessation in the future. Rose and Hickman's (1987) study indicates that respiratory stimulation was a factor in cessation. They found that much of what smokers refer to as taste when they smoke is actually a stimulation of the airways by an irritant--cigarette smoke. They showed some success using citric acid aerosol to replace the sensation of cigarette smoke.

Clonidine, a hypertension medication, is another pharmacologic aid that has promise. It has been shown to reduce the cravings for tobacco which nicotine gum does not but these effects appear to be gender specific. Significant positive effects on abstinence rates were found for females but no effects on abstinence rates were found for males (Glassman et al., 1988). In a study of cigarette withdrawal symptoms and clonidine Glassman, Stetner and Raizman (1985) found that clonidine quiets the locus ceruleus of the brain like all sedative drugs and suggested that this was the mechanism by which the drug significantly reduced withdrawal symptoms. However, to date clonidine has not been approved for use in smoking cessation (Hughes, 1988).

Several other aids are currently being studied including nicotine nasal sprays, dermal patches, and

aerosols (DHHS, 1989). In at least one smoking cessation study nicotine administered with a transdermal patch was shown, when coupled with behavioral therapy, to result in significantly better abstinence rates for participants than those achieved with behavioral therapy alone (Buchkremer & Minneker 1989). Although the addition of pharmacologic aids and refinements to the social learning based cognitive behavioral therapy approaches has improved quit rates, high rates of relapse continue (Glasgow & Lichtenstein, 1987; Goldstein et al., 1989).

Refining Treatment Approaches: Assisted vs Unassisted Smokers and Heavy vs Light Smokers

Since relapse has continued to be a major problem for many who attempt to quit smoking, it has been suggested that state of the art smoking cessation programs were only effective for a proportion of smokers. Presently, researchers are attempting to refine approaches by investigating both the way smokers go about quitting and investigating the characteristics of smokers especially heavy smokers (Killen, Fortmann, Telch and Newman, 1988).

Investigation comparing methods of quitting have focused on differences between assisted an unassisted quitters. Garcia et al., (1990) in a study of 36 subjects who quit on their own found at four weeks post quit that one (2.7%) subject remained abstinent, two subjects had returned

to baseline levels and the remainder were smoking 33% fewer cigarettes than at baseline. Marlatt et al. (1988) also found that the bulk of self quitters relapsed within a short period (four months) and the point prevalence abstinence rate at 12 months was 13%. Those most likely to remain abstinent at one month were men, lighter smokers, those who had not been involved in a smoking cessation program before, those who did not live with smokers and those having fewer smoking friends. Long term abstinence was characterized by participants subjects who were younger and who had smoked fewer years. They observed that quitting was a fluid process and that participants frequently moved from one smoking status to another over time.

Schachter's (1982) study of those who quit smoking on their own without counseling assistance versus those who quit with the aid of a smoking cessation program found that unassisted smokers were more successful than program assisted smokers in achieving abstinence and that there were no significant differences found in quit rates between light smokers ($\leq$ 15 cigarettes per day) and heavy smokers. He found that most had to make more than one attempt to quit and that most of the literature had reported only the results of a single attempt. As a result he suggested that the view of success for the unassisted smoker had been presented in too negative a light and that the number of successful abstainers increased with successive attempts. He

went on to question the need and the advisability of formal cessation programs.

Cohen, et al. (1989) in a review of the data from ten cessation programs disputed Schachter's original claims regarding quit rates for light and heavy smokers, lack of success of clinic cessation programs and relapse rates. They also disagreed with his definition of light smokers. Their findings indicated that light smokers, defined as smoking 20 or fewer cigarettes per day, were 2.2 times as likely to quit as heavy smokers and that relapse rates were lower for participants in clinic based programs than for self quitters. The MRFIT Study had similar findings and revealed that the highest cessation rates were for those smokers who smoked fewer than 20 cigarettes per day (Ockene, Hymowitz, Sexton & Broste, 1982). Other studies have also defined the cut point for heavy vs light smokers as 20 cigarettes per day (Jarvik & Schneider, 1984; Killen et al., 1988).

Another study on self quitters that included a five year follow up also found that a significant number of self quitters quit easily and stayed quit without going through a clinic program. This data would appear to support Schachter's findings in part. However, the authors did point out that their findings of low relapse rates may have been due to the fact that most of the smokers in their study were not heavy smokers who were highly nicotine dependent since they had few cravings for cigarettes after quitting and reported few problems in remaining abstinent. They differed

with Schachter by pointing out that levels of addiction and individual differences were significant factors in smoking cessation outcome (Carmody, Brischetto, Pierce, Matarazzo, and Connor, 1986). Killen et al., (1988) found that heavy smokers ($\geq$ 25 cigarettes per day) reported more difficulty in quitting and greater withdrawal symptoms than light smokers when suspending smoking without a pharmacologic aid.

These studies taken together point to the need to match treatment approach to smokers' characteristics in order to improve treatment outcomes.

Relapse and Relapse Prevention

Another approach for improving smoking cessation outcomes has been to investigate the circumstances of relapse to smoking and methods of prevention. Results from a number of studies have suggested that smoking relapse was a more profoundly complex set of behaviors than had earlier been anticipated. A review of the relapse curves for heroin, nicotine (smoking), and alcohol use indicated similar curves for all three with the relapse curve for heroin and smoking almost identical (Hunt & Matarazzo, 1973). This finding had been suggested by Hunt and Matarazzo (1970) some years earlier when they compared the smoking relapse curve to a learning extinction curve. Condiotte and Lichtenstein (1981) investigated the validity of Bandura's (1977) theory of self efficacy as it applied to relapse with smokers from two

treatment programs and found that low self efficacy predicted relapse.

Brownell, Marlatt, Lichtenstein and Wilson (1986) in a study of behavior change involving alcoholism, smoking, and obesity found that rates of relapse were similar for each of these addictive behaviors. They believed that behavior change happened in stages and that the motivation to quit could be increased by education about the addiction as well as support and feedback from providers about the participant's physical status and suggested that treatment procedures to prevent relapse should include decision making, cognitive restructuring and coping skills. They went on to conclude that there was a need for even more information on the characteristics and determinants of relapse if intervention strategies were to be more effective.

Circumstances leading to relapse are varied. Brandon, Tiffany, Obremski and Baker (1990) studied the relapse rates of 129 smokers who successfully completed a behavioral counseling plus aversion smoking program for 2 years posttreatment. They found that despite the early successes in abstinence, 88% of those who slipped and smoked one cigarette posttreatment relapsed within the two year period. They defined relapse as returning to smoking for at least three consecutive days. The average time following the first cigarette to return to daily smoking was six weeks and approximately 50% of the initial posttreatment smoking

occurred after drinking alcohol. Most relapse occurred in the first four months and few participants actually used coping responses after having the first cigarette despite specific skill training.

Relapse prevention (RP) theories have synthesized much of the preceding findings and refined them into operational concepts. For example, it has been shown that relapse frequently occurred in the presence of negative emotional states such as anger and depression (Brownell, Glynn et al., 1986; Glassman et al., 1990; Hunt & Matarazzo, 1970, 1982). Positive emotional states and those states that lack either significantly negative or positive affect (e.g., boring situations) may also lead to relapse (Shiffman, Read, Maltese, Rapkin, and Jarvik, 1985).

Marlatt (1985) combined these operational concepts into a more cohesive model, the Relapse Prevention Model (RP) This model includes a coping, self-management model designed to help the individual anticipate and cope with relapse situations and then learn cognitive behavioral coping strategies to replace behaviors previously utilized. The Relapse Prevention Model draws on theories of self efficacy and expectancies and departs from earlier treatment models by incorporating relapse into the model itself. The concept of the abstinence violation effect (AVE) is an additional concept in the model. The AVE occurs as a reaction by the individual to the first use of a problem chemical when he/she violated his/her commitment to complete abstinence.

According to this concept the individual sees any use as a return to old behavior patterns that are inconsistent with their self image as a non-user of the chemical. This dissonance is resolved by changing their personal image to correspond to the behavior of using the chemical. The RP model requires that participants be confronted with the possibility of relapse and, therefore, become aware of the need to specifically prepare for the possibility of temporary slips to the old behaviors in order to minimize the AVE. This is done by identifying a possible number of high risk situations which will lead to relapse and planning specific coping response in advance to deal with them.

Not all researchers support Marlatt's (1985) concept of the abstinence violation effect (AVE). Hall, Havassy and Wasserman (1990) in a study of relapse in individuals who relapsed following treatment for alcohol, opiates or nicotine addiction found that those who did make a commitment to absolute abstinence did significantly better than those who anticipated possible slips.

Other researchers have supported and expanded Marlatt's concepts on relapse, however. Shiffman (1985) pointed out that the idea of certain high risk situations leading to relapse was incomplete since the situations did not by themselves always lead to relapse. It was the perception of the relapse crisis that was critical. Whether an ex-smoker relapses or maintains cessation seems to be less linked to

the high risk situation itself than to the individual's coping response or lack thereof.

It has been shown by Shiffman et al. (1985) that the coping process while seemingly simple was quite complex. They found that improved cessation methods will not improve long term abstinence. They pointed out that relapse prevention (RP) was essential in maintaining abstinence and that RP emphasized a situational focus and coping skills. The client is seen as an active participant who must learn to manage his/her life by developing coping skills and self management skills. Their work also included the notion that the individual not only must recognize that he/she was in a relapse crisis, but must then decide the level of the crisis and choose a coping mechanism that works. They found that alcohol and depression interfered with behavioral coping responses, such as doing substitute activities, but not with the cognitive responses such as reminding oneself of smoking related disease and how hard it was to quit. Therefore, having a wide array of coping strategies, especially cognitive coping strategies, to bring to bear on a given situation was seen as critical to successful avoidance of relapse.

In a later study, Shiffman and Jarvik (1987) found that familiar smoking situations were those situations that most often triggered coping responses and that better coping behavior could be expected during the early period of abstinence when the individual was more vigilant. They went

on to suggest that decreases in coping behaviors over time may have been due not to complacency but rather to decreases in the frequency of temptations to smoke. They concluded that the types of relapse crises that occurred early in abstinence were often tied to withdrawal symptoms and familiar smoking situations while crises late in abstinence were tied to individual circumstances, suggesting that learning coping responses to familiar situations did occur.

In a review of relapse treatment approaches from a stage perspective Brownell, Glynn et al., (1986) advocated that techniques to prevent relapse should be tailored to the individual's stage of behavior change not unlike the concepts presented by Rotter (1972) and those of Prochaska and DiClemente (1983a, 1983b, 1984, 1985). They suggested that relapse prevention strategies needed to be included in the preparation for quitting stage not just in the post quit maintenance stage and pointed out the future research needed to study changes in smoking over time rather than at a given point. Therefore, how to effectively help the relapsed smoker remains an issue in smoking cessation.

Summary

Smoking cessation and relapse continue to generate significant findings both in terms of psychological determinants on the one hand and physiological ones on the other. However, smokers who cannot quit or who frequently

relapse remain at high risk for all the health consequences of smoking. These smokers are generally heavy smokers and comprise an increasing proportion of the shrinking population of smokers. But the literature has yet to provide much insight into the characteristics of the heavy smoker (Killen et al., 1988). Many studies addressing the success of self quitters, those who quit without participating in a formal smoking intervention, have suffered from small sample size, lack of a randomized sample and reliance on self report of smoking status without biochemical validation (Cohen, et al., 1989). Likewise, studies of heavy and light smokers in cognitive behavioral counseling interventions are hampered by inadequate sample size and follow-up periods (Glasgow & Lichtenstein, 1987). Overall, the literature has pointed to the need for research on a large sample of heavy smokers over time.

Comparing the smoking behavior responses of heavy smokers with early chronic obstructive pulmonary disease (COPD) to a state of the art cognitive behavioral counseling intervention with the smoking behavior responses of a like population who were not provided the intervention over 24 months of follow-up is the focus of this study.

SUBJECTS AND METHODS

Introduction

Subjects for this study are participants in the Lung Health Study (LHS). The design and recruitment for the LHS are described in Connett and Benson (in press) and in Connett, Kusek, Bailey, O'Hara and Wu (in press). The Lung Health Study is a multicenter clinical trial funded by the Lung Division of the National Heart Lung and Blood Institute (NHLBI) of the National Institute of Health (NIH) and is designed to examine the effects of an intensive smoking cessation program and the use of an inhaled bronchodialator on the annual rate of decline in lung function over five years. The LHS is a randomized study. Participants are smokers between the ages of 35-59 at entry and have mild to moderate chronic obstructive pulmonary disease (COPD) as measured at three screening visits.

Recruitment and Randomization

There were a total of 10 Lung Health Study Centers selected in the United States and Canada through a competitive proposal process. The center sites are as follows: John Hopkins Medical Center, Baltimore, Maryland; University of Alabama at Birmingham, Birmingham, Alabama;

MetroHealth Medical Center, Cleveland, Ohio; Henry Ford Hospital, Detroit, Michigan; UCLA School of Medicine, Los Angeles, California; University of Pittsburg, Pittsburg, Pennsylvania; Oregon Health Sciences University, Portland, Oregon; Mayo Clinic, Rochester, Minnesota; University of Utah, Salt Lake City, Utah; and University of Manitoba, Winnipeg, Manitoba, Canada.

Recruitment strategies varied across the ten centers and included recruitment through worksites, at public sites such as shopping malls and community events, through direct mail and telephone solicitation, through mass media such as radio, television and newspapers and through referrals from physicians, health organizations, families and friends. Screening visits included both lung function tests (spirometery, response to an inhaled bronchodilator and methacholine challenge) and standardized questionnaires to collect information about tobacco use, respiratory symptoms, demographics and present and past health conditions (See Appendix C & Appendix D).

Exclusion criteria included health conditions which could affect lung function or interfere with a participant's ability to participate in a five year follow-up. Specifically, treatment for any significant mental health disorder or substance abuse within the last 12 months were exclusions. Clinical asthma and regular bronchodilator therapy were also exclusions. Willingness to consider

smoking cessation and to participate in a five year follow-up were key requirements for participation in the LHS.

Those who meet the inclusion criteria and who completed all three screening visits were asked to review and sign the informed consent for participation which was approved separately by the The Committee on Human Research (CHR) at each institution (See Appendix A). Participants were then assigned via a centralized randomization process on a 2 to 1 basis to a Special Intervention (SI) group (counseling assisted) or to a Usual Care (UC) group (unassisted). Half the SI group received active inhalers and half received placebo inhalers. Inhaler assignment was double blind. All SI participants were then asked to participate in the counseling assisted program to stop smoking. Since smoking patterns between counseling assisted and unassisted smokers was the focus of this study rather than the effect of the inhalers, SI participants were treated as one group. UC participants were referred back to their usual source of medical care and no counseling assistance for smoking cessation was offered, but they were asked to return once a year to be interviewed and have their lung function tested. Neither SI participants nor UC participants were paid for their participation in the Lung Health Study.

A total of 5887 participants were randomized into the Lung Health Study over a period of two years. 3923 were randomized into the SI group and 1964 into the UC group. 95% of participants are white (including 0.6% Hispanic), 3.8%

Black, 0.1% Asian 0.19% Native American and 0.2% others. The relative few numbers of ethnic minorities in this study was due to the prevalence of COPD in these populations as well as a reflection of the other medical exclusion criteria. The average age at baseline was 48.4 years. 62.7% of participants are male and 37.3% are female. Education and smoking behavior differed somewhat by gender. 63% of men had more than a high school eduction and 12% had not graduated from high school. 52% of women had more than a high school education and 13% had not graduated from high school. Men smoked an average of 33 cigarettes per day and women smoked an average of 29 cigarettes per day. The overall average is 31.4 cigarettes per day which is well above the generally accepted definition of 20 or greater cigarettes per day to be classified as heavy smokers (Cohen, et al., 1989).

A total of 5395 Lung Health Study participants attended both the first annual (12 month) and second annual (24 month) follow-up visits and are represented in this study.

Procedures

The counseling program for the Lung Health Study was designed by behavioral scientists following state of the art smoking cessation programs for heavy smokers (Schwartz, 1987). The design for the program is described in O'Hara, Grill, Lauger, Rigdon & Connett (1991). The counseling intervention combined a strong physician message to stop

smoking with cognitive behavioral counseling groups and nicotine replacement therapy using nicotine gum (nicotine polacrilex).

Participants assigned to the counseling assisted SI group were first seen by an LHS physician following randomization to review the results of their pulmonary function tests and were strongly urged to stop smoking. The efficacy of physician messages to stop smoking has received attention in the literature and has been found to significantly improve initial quit rates (Cummings, Rubin & Oster, 1989; Janz et al., 1987; Kottke, Brekke, Solberg & Hughes, 1989; Ockene, 1987; Russell, Merriman, Stapleton & Taylor, 1981; Wilson et al., 1988). The purpose of the message was to help overcome resistance by demonstrating personal health risks in the form of lung function test results and diagnosis of chronic lung disease and by a clear emphatic recommendation to quit smoking to prevent future negative health consequences. This combined message coming from a health authority appears to increase the likelihood of quitting and taking advantage of the counseling assistance offered (Katz & Singh, 1986). Other researchers found that by providing feedback on symptoms, pulmonary test results (spirometry) and expired carbon monoxide values in addition to educational intervention to smokers that quit rates were significantly higher than for those who received only an educational intervention (Risser & Belcher, 1990).

Cognitive Behavioral Counseling Program

The cognitive behavioral counseling program consistent with the literature combines behavioral self management techniques such as self monitoring, coping strategies, anxiety management, relaxation and relapse prevention with cognitive techniques such as cognitive replacement strategies, visualization and mental rehearsal of different smoking situations. These techniques were introduced sequentially in an 11 session group program that followed an orientation session over a three month period (See Appendix E). In addition to providing a setting for learning and role modeling, the group also served as a support group for participants. Since lung function is the primary endpoint in the LHS and continuous abstinence is the optimal treatment for protecting lung function by the investigators in the LHS, nearly all of the intervention program was devoted to coping skills and relapse prevention to maintain abstinence.

Quit day occurred at the first session following the orientation session. Quit day was followed by sessions for the next three days of the first week. These sessions were primarily devoted to withdrawal symptoms and coping skills. Two sessions occurred in the second week and were primarily concerned with stress management and relaxation training. The remaining sessions were devoted to additional relapse prevention and lifestyle changes (e.g. weight control and physical activity), as well as reinforcing the aspects of

group support in smoking cessation. Written material designed to guide and instruct participants in self control techniques and to reinforce motivation for abstinence was distributed at each session. The counseling assisted intervention included a total of 11 sessions plus the initial orientation session.

Nicotine Replacement Therapy

Nicotine polacrilex (Nicorette) was offered to all SI participants and its use was strongly encouraged throughout the intervention program. Possible contraindications for Nicorette include: angina pectoris, history of cardiac arrhythmia, heart attack in last six months, other serious cardiac conditions, intermittent claudication, hypertension requiring treatment, active peptic ulcer, pregnancy, nursing, hyperthyroidism, insulin-dependent diabetes, temporo-mandibular joint disease, mouth or throat inflammation or soreness and esophagitis (Physicians' Desk Reference, 1991). Nicorette was provided at no charge to the participants and was dispensed at each session following orientation of the initial program and at two week intervals thereafter for those using nicotine gum.

Detailed instructions for proper use of Nicorette and a demonstration by an LHS counselor or health educator of proper use were provided at the beginning of the program and reviewed at subsequent sessions. The recommended beginning

level of use was 10-12 pieces per day with some allowance for individual dosing differences based on nicotine dependency and/or experienced withdrawal symptoms. Participants were limited to a maximum of 30 pieces per day. Level of gum use and side effects were monitored at each visit. The protocol for Nicorette use followed the standard prescribing instructions which recommends tapering and cessation of gum use after three to six months (Physicians' Desk Reference, 1991). Exceptions were made on a case by case basis for a fairly large number of participants who resisted discontinuing the gum citing fear of relapse to cigarettes. The LHS Steering Committee approved the use of Nicorette for relapse prevention beyond the recommended prescribing instructions and Nicorette was dispensed for as long as necessary for these participants.

Data Collection

Baseline data was collected for both SI and UC at the three screening visits prior to randomization. Baseline data included: results of lung function tests, tobacco use, respiratory symptoms, demographics and present and past health conditions.

Following randomization into the LHS, the following data was collected by structured interview on the annual visit form for both SI participants and UC participants at the 12 month and 24 month follow-up visits: self reported

smoking history and smoking status and a detailed symptom history for the period prior to the annual visit (See Appendix B). Self reported smoking status was biochemically validated by expired carbon monoxide levels with the EC 50 Vitalograph for those participants using nicotine gum or by an analysis of salivary cotinine for those participants not using nicotine gum. Cohen et al.(1989) have reported that retrospective self report data on smoking status collected at 12 month intervals was as reliable as more frequent assessments of smoking status especially when the self report was verified biochemically. Lung function test results were collected with the Spirotech Spirometer.

Statistical Methods

The analysis was done with both the entire SI and UC groups who attended their 12 month and 24 month visits and with a subgroup of smokers only. Since the cell sizes in this study were not equal, the statistical methods chosen had to be appropriate for testing proportions. χ^2 was chosen to test for significant differences in proportions between the SI group and the UC group and for significant differences within the SI group and within the UC group across the three smoking status outcome categories (sustained non-smokers, intermittent smokers and continuous smokers) whenever the data was nominal data. t-test statistics were used in testing for significant differences

between the SI group and the UC group when the data was interval data and only two means were being compared. Analysis of variance (ANOVA) was used to test for significant differences in proportions within the SI group and within the UC group across the three smoking status categories whenever the data was interval data since more than two means were being compared (BMDM Statistical Software Manual, 1990; SAS/STAT Users Guide, 1990). Finally, polytomous logistic regression was used to model the relationships between baseline variables and the three smoking status categories at 12 and 24 months. Polytomous logistic regression analysis was chosen as the statistical test since there were three possible outcomes for smoking status. Regression analysis is only appropriate for dichotomous outcomes (Hosmer & Lemeshow, 1989).

Analysis

The analyses were done comparing baseline demographic and smoking history variables prior to randomization into the LHS for all SI and UC participants to smoking status at 12 and 24 months following randomization into the LHS. Baseline variables included: gender, average number of cigarettes smoked per day, average age started smoking, average number of alcoholic drinks consumed per week, average number of smokers in household, education levels and

spouse/friend support to quit, number of previous quit attempts and longest time quit.

For SI and UC the analysis of smoking status compared the percent within group in each of the three smoking status categories (sustained non-smokers, intermittent smokers and continuous smokers) at 12 and 24 months as well as the differences between groups by smoking status at 12 and 24 months. Polytomous Logistic Regression Analysis was used to identify the more robust variables for SI and UC that predicted smoking status at 12 and 24 months.

For SI and UC who reported any smoking at 12 and 24 months (post baseline) a separate smokers only analysis was used to compare number of quit attempts, longest time quit, average number of cigarettes smoked and average number of calendar months in which at least one cigarette was smoked.

RESULTS

Outcomes

Comparison of Smoking Status at 12 and 24 Months (See Table 1)

Between the SI and UC groups There were significant differences across all smoking status categories at both 12 and 24 months. At 12 months, SI participants were significantly more likely to be sustained non-smokers (χ^2= 466.0, p< .0001), and intermittent smokers (χ^2= 51.9. p< .0001) than UC participants. SI participants were also significantly less likely to be continuous smokers (χ^2= 560.6, p< .0001). Between 12 and 24 months, there was a decline in sustained non-smokers and continuous smokers in both groups and an increase in intermittent smokers for both groups. Despite these changes, the differences between SI and UC across the three smoking status categories remained significant. At 24 months , SI participants continued to be significantly more likely to be sustained non-smokers (χ^2= 67.7, p= .0001) and less likely to be continuous smokers (χ^2= 494.3, p< .0001) than UC participants (See Table 1).

TABLE 1
SI[a] AND UC[b] COMPARISON OF SMOKING STATUS AT
12 AND 24 MONTHS IN PERCENTS

	Sus N.Sm		Interm Sm		Contin Sm	
	12m	24m	12m	24m	12m	24m
SI[1]	29.5	25.1	15.9	26.0	54.6	48.9
UC[2]	4.1	3.5	8.8	16.1	87.1	80.4
χ^2=	466.0	380.6	51.9	67.7	560.6	494.3
p=	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001

[a] N=3592
[b] N=1803

[1] 12 mo (χ^2=23.2, p=<.0001), 24 mo (χ^2=10.9, p<.0001)
[2] 12 mo (χ^2=130.6, p=<.0001), 24 mo (χ^2=102.2,p<.0001)

Baseline Variable Comparisons

Baseline variables are those variables relating to nicotine dependence, smoking history, demographics and other behaviors prior to randomization into the Lung Health Study.

Comparison of Baseline Cigarettes Smoked per Day (Nicotine Dependence) at 12 and 24 Months (See Table 2)

The average number of cigarettes smoked per day at baseline was used as an indicator of nicotine dependence. Significant differences were found for SI participants across smoking categories for the number of cigarettes smoked per day at baseline at 12 months ($F= 17.2$, $p= .0001$) and 24 months ($F= 17.3$, $p=.0001$). SI intermittent smokers' smoked fewer cigarettes per day at baseline than the other two categories at 12 months (26.9 cigarettes/day) and at 24 months (27.6 cigarettes/day). Sustained non-smokers' average cigarettes smoked per day at baseline remained the same at 12 months and 24 months (28.9 cigarettes/day). Continuous smokers' average cigarettes smoked per day at baseline increased slightly from 12 months (30.5/cigarettes/day) to 24 months (30.7 cigarettes/day).

Significant differences were also found for UC participants across smoking categories at 12 months ($F= 26.9$, $p= .0001$) and at 24 months ($F= 26.9$, $p= .0001$). UC sustained non-smokers' average cigarettes smoked per day at baseline were fewer than the other two categories at both 12

TABLE 2
SI[a] AND UC[b] COMPARISON OF BASELINE CIGARETTES SMOKED PER DAY (NICOTINE DEPENDENCE) BY SMOKING STATUS AT 12 AND 24 MONTHS IN AVERAGES

	Sus N.Sm		Interm Sm		Contin Sm	
	12m	24m	12m	24m	12m	24m
SI[1]	28.9	28.9	26.9	27.6	30.5	30.7
UC[2]	20.4	19.6	25.5	26.3	30.2	30.4
t=	-3.95	-3.84	*	*	*	*
p=	.0002	.0002	*	*	*	*

[a] N=3592
[b] N=1803
* Not significant
[1] 12 mo (F=16.7, p=.0001), 24 mo (F=17.3, p=.0001)
[2] 12 mo (F=24.5, p=.0001), 24 mo (F=26.9, p=.0001)

months (20.4 cigarettes/day) and 24 months (19.6 cigarettes/day). Intermittent smokers' average number of cigarettes smoked per day at baseline increased from 12 months (25.5 cigarettes/day) to 24 months (26.3 cigarettes/day). Continuous smokers' average number of cigarettes smoked per day at baseline increased only slightly form 12 months (30.2 cigarettes/day) to 24 months (30.4 cigarettes/day).

Significant between group differences were also found for sustained non-smokers at 12 months (t= -3.95, p= .0002) and 24 months (t= -3.84, p=.0003). No significant between group differences were found for intermittent smokers at 12 months (t= -1.79, p= .1993) and 24 months (t= -1.36, p= .1727) or continuous smokers at 12 months (t= -0.62, p= .5385) and 24 months (t= -0.62, p= .5347)(See Table 2). At 24 months UC sustained non-smokers were significantly more likely to be lighter smokers.

Comparison of Baseline Demographic Variables by Smoking Status at 12 and 24 Months (See Table 3)

Age started smoking.

Differences in the average age started smoking at baseline across the three smoking status categories were not significant for SI participants at 12 months (F= 0.45, p= .6386) or at 24 months (F= 1.04, p= .3538). Significant differences were not found across smoking status categories

TABLE 3
SI[a] AND UC[b] COMPARISON OF BASELINE DEMOGRAPHIC VARIABLES BY SMOKING STATUS AT 12 AND 24 MONTHS IN AVERAGES

		Sus N.Sm		Interm Sm		Contin Sm	
		12m	24m	12m	24m	12m	24m
Age St Sm[1]							
	SI	17.4	17.5	17.6	17.6	17.5	17.4
	UC	18.2	18.3	17.8	17.7	17.6	17.6
	t=	*	*	*	*	*	*
	p=	*	*	*	*	*	*
Sm In House[2]							
	SI	.5	.5	.4	.4	.6	.6
	UC	.4	.3	.4	.4	.5	.5
	t=	*	*	*	*	*	*
	p=	*	*	*	*	*	*
Drinks/Week[3]							
	SI	4.3	4.3	4.1	4.3	4.4	4.4
	UC	3.1	3.0	5.5	4.7	4.3	4.4
	t=	-2.59	-2.47	2.50	*	*	*
	p=	.0110	.0156	.0130	*	*	*

[a] N=3592
[b] N=1803
* Not significant
1 SI 12 and 24 mo (p=not significant)
UC 12 and 24 mo (p=not significant)
2 SI 12 mo (F=3.19, p=.0414), 24 mo (F=3.95, p=.0194)
UC 12 mo (F=3.23, p=0.0398), 24 mo (F=4.46, p=.0117)
3 SI 12 and 24 mo (p=not significant)
UC 12 mo (F=2.54,p=.0050), 24 mo (p=not significant)

for UC participants at 12 months (F= 1.01, p= .3648) or at 24 months (F= 1.25, p=.2870). There were no significant between group differences by smoking category at 12 months (sustained non-smokers, t= 1.76, p= .0790; intermittent smokers, t= 0.34, p= .7347; continuous smokers, t= 0.76, p= .4454) nor at 24 months (sustained non-smokers, t= 1.74, p= .0816; intermittent smokers, t= 0.25, .8022; continuous smokers, t= 1.16, p= .2465).

Smokers in household.

Differences in the number of smokers in the household at baseline across the three smoking categories were significant for SI at 12 months (F= 3.19, p= .0414) and at 24 months (F= 3.95, p=.0194). At 12 months intermittent smokers reported fewer smokers in the household (0.4) than either sustained non-smokers (0.5) or continuous smokers (0.6). The numbers of smokers in the household remained the same for each category at 24 months.

Significant differences were also found for the number of smokers in the household at baseline for UC across the three smoking categories at 12 months (F= 3.23, p= .0398) and at 24 months (F= 4.46, p= .0117). The pattern was somewhat different from the SI pattern at 12 months. Sustained non-smokers and intermittent smokers were equal in the number of smokers in the household at baseline (0.4) with continuous smokers somewhat higher (0.5). At 24 months sustained non-smokers had fewer smokers in the household at

baseline (0.3) when compared to intermittent smokers (0.4) and continuous smokers (0.5).

No significant between group differences were found by smoking status category at 12 months (sustained non-smokers, t= -1.08, p= .2816; intermittent smokers, t= -0.87, p= .3827; continuous smokers, t= -1.63, p= .1025) or at 24 months (sustained non-smokers, t= -1.51, p= .1301; intermittent smokers, t= -0.88, p= .3812; continuous smokers, t= -1.63, p= .1022)(See Table 3).

Alcoholic drinks consumed per week.

For SI participants no significant differences were found for alcoholic drinks consumed per week at baseline across smoking categories at 12 months (F= 0.68, p= .5057) or at 24 months (F= 0.16, p= .8480). For UC participants significant differences were found for alcoholic drinks consumed per week at baseline across smoking categories at 12 months (F= 5.30, p= .0050) but no differences were found at 24 months (F= 2.54, p= .0791).

Between group differences were found for sustained non-smokers at 12 months (t= -2.59, p= .0110) and at 24 months (t= -2.47, p= .0156) and for intermittent smokers at 12 months (t= 2.50, p= .0130). No significant differences were found for intermittent smokers at 24 months (t= 1.16, p= .2452) or for continuous smokers at 12 months (t= -0.43, p= .6672) or at 24 months (t= -0.17, p=.8656)

UC intermittent smokers consumed more drinks per week at baseline at 12 months (5.5 drinks/week) and at 24 months (4.7 drinks/week) than any other category of UC at 12 or 24 months or all three categories of SI at 12 or 24 months (See Table 3).

Comparison of Baseline Education Levels and Spouse/Friend Support at 12 and 24 Months (See Table 4)

Education levels.

For SI significant differences in the levels of education at baseline were found across smoking status categories at 12 months (χ^2= 15.5, p= .004) and at 24 months (χ^2= 17.9, p= .001). For UC no differences in education levels at baseline were found across smoking categories at 12 months (χ^2= 4.85, p= .303) or at 24 months (χ^2= 4.92, p= .296).

No between group differences for education levels by smoking category were found at 12 months for sustained non-smokers (χ^2= 2.31, p= .316); intermittent smokers (χ^2= 1.25, p= .526) or continuous smokers (χ^2= 3.37, p= .185) nor at 24 months for sustained non-smokers (χ^2= 2.49, p= .289); intermittent smokers (χ^2= 0.08, p= .960) and continuous smokers (χ^2= 3.94, p= .140)(See Table 4).

TABLE 4

SI[a] AND UC[b] COMPARISON OF BASELINE EDUCATION LEVELS AND SPOUSE/FRIEND SUPPORT BY SMOKING STATUS AT 12 AND 24 MONTHS IN PERCENTS

		Sus N.Sm		Interm Sm		Contin Sm	
		12m	24m	12m	24m	12m	24m
Education[1]							
SI	LTHS	3.0	2.5	1.9	3.1	7.2	6.4
	HS	8.2	7.1	4.7	7.2	7.5	16.0
	GTHS	18.3	15.0	9.3	15.6	30.0	26.5
UC	LTHS	.6	.4	.8	1.9	10.8	9.8
	HS	.8	.7	2.6	4.4	25.8	24.2
	GTHS	2.7	2.4	5.4	9.8	50.5	40.4
	χ^2=	*	*	*	*	*	*
	p=	*	*	*	*	*	*
Support[2]							
SI	Yes	26.5	22.4	14.2	23.6	49.4	44.1
	No	2.4	2.0	1.3	2.0	4.6	4.3
	Not app.	.6	.6	.4	.5	.6	.5
UC	Yes	3.4	2.9	7.8	14.1	77.6	71.7
	No	.3	.2	.6	1.4	8.1	7.4
	Not app.	.4	.4	.4	.6	1.4	1.3
	χ^2=	14.3	16.6	*	*	*	*
	p=	<.001	<.001	*	*	*	*

[a] N=3592

[b] N=1803

* Not significant

[1] SI 12 mo (χ^2=15.5, p=.004), 24 mo (χ^2=17.9, p=.001)
UC 12 and 24 mo (χ^2=not significant)

[2] SI 12 and 24 mo (χ^2=not significant)
UC 12 mo (χ^2=24.7, p<.001), 24 mo (χ^2=26.6, p<.001)

Spouse/friend support.

For SI no differences were found for spouse/friend support to quit smoking at baseline across smoking categories at 12 months (χ^2= 6.75, p= .149) or at 24 months (χ^2= 7.53, p= .110). For UC differences were found for spouse/friend support to quit smoking at 12 months (χ^2= 24.7, p= <.001) and at 24 months (χ^2= 26.6, p= <.001).

Between group differences were found for sustained non-smokers at 12 months (χ^2= 14.3, p= <.001) and at 24 months (χ^2= 16.6, p= <.001). No between group differences were found at 12 months for intermittent smokers (χ^2=2.35, p= .309) or continuous smokers (χ^2= 2.81, p=.245) nor at 24 months for intermittent smokers (χ^2= 2.71, p= .259) or continuous smokers (χ^2= 1.89, p= .388)(See Table 4).

Comparison of Baseline Previous Quit Attempts and Longest Time Quit at 12 and 24 Months (See Table 5)

Previous quit attempts.

Significant differences were found for SI participants across smoking categories regarding the number of previous quit attempts at baseline at 12 months (χ^2= 16.5, p= .036) and 24 months (χ^2= 23.1, p= .003). Differences across smoking categories were also found for UC participants at 12 months (χ^2= 23.7, p=.003) and at 24 months (χ^2= 36.6, p< .001). In both groups differences were greater at 24 months than at 12 months. Between group differences were found only

TABLE 5
SI[a] AND UC[b] COMPARISON OF BASELINE PREVIOUS QUIT ATTEMPTS AND LONGEST TIME QUIT BY SMOKING STATUS AT 12 AND 24 MONTHS IN PERCENTS

		Sus N.Sm		Interm Sm		Contin Sm	
		12m	24m	12m	24m	12m	24m
Prev Att[1]							
SI	0	3.6	3.1	1.9	2.8	7.2	6.8
	1	6.0	5.2	2.8	4.5	10.9	9.9
	2	5.5	4.5	2.6	4.8	10.7	9.5
	3	5.2	4.6	2.5	4.0	7.8	6.8
	≥4	9.2	7.7	6.1	9.8	18.1	15.9
UC	0	0.2	0.2	0.6	0.8	11.2	11.0
	1	1.1	0.9	1.2	2.6	17.0	15.9
	2	1.1	0.9	2.4	4.3	15.8	14.1
	3	0.6	0.5	1.3	2.6	12.5	11.3
	≥4	1.1	1.0	3.2	5.8	30.6	28.1
	χ^2=	*	*	12.7	16.5	*	*
	p=	*	*	.013	.002	*	*
Long Quit[2]							
SI	0	3.6	3.1	1.9	2.8	7.2	6.8
	> 1 wk	4.1	3.3	2.3	3.8	11.3	10.6
	1-4 wks	4.8	4.1	3.0	4.6	10.7	9.8
	1-6 mos	8.7	7.2	4.8	8.1	14.9	13.1
	7 mos-1 yr	2.9	2.7	1.4	2.3	3.9	3.2
	≥ 1 yr	5.4	4.6	2.5	4.4	6.7	5.5
UC	0	0.2	0.2	0.6	0.8	11.2	11.0
	> 1 wk	0.3	0.3	0.8	1.6	16.5	15.8
	1-4 wks	0.5	0.4	1.8	3.2	16.3	15.0
	1-6 mos	1.7	1.4	2.6	4.8	24.2	22.2
	7 mos-1 yr	0.2	0.2	0.9	1.7	7.7	6.9
	≥ 1 yr	1.2	1.1	2.1	4.0	11.3	9.5
	χ^2=	15.4	13.1	11.4	22.2	*	*
	p=	.009	.022	.044	<.001	*	*

[a] N=3592
[b] N=1803
* Not significant
[1] SI 12 mo (χ^2=16.5, p=.036), 24 mo (χ^2=23.1, p=.003)
UC 12 mo (χ^2=23.7, p=.003), 24 mo (χ^2=36.6, p<.001)
[2] SI 12 mo (χ^2=53.7, p<.001), 24 mo (χ^2=81.1, p<.001)
UC 12 mo (χ^2=52.2, p<.001), 24 mo (χ^2=83.5, p<.001)

for the intermittent smoker category at 12 months (χ^2= 12.7, p= .002). SI intermittent smokers were more likely to make more quit attempts than UC intermittent smokers (See Table 5).

Longest time quit.

Significant differences were found for SI participants across smoking categories for longest time quit at baseline at 12 months (χ^2= 53.7, p< .001) and 24 months (χ^2= 81.1, p< .001). Differences were also found for UC at 12 months (χ^2= 52.2, p< .001) and 24 months (χ^2= 83.5, p< .003). Between group differences were significant for sustained non-smokers at 12 months (χ^2= 15.4, p= .009) and 24 months (χ^2= 13.1, p< .022) and for intermittent smokers at 12 months (χ^2= 11.4, p< .044) and 24 months (χ^2= 22.2, p< .001). No differences between groups were found for continuous smokers at baseline. SI sustained non-smokers and intermittent smokers were more likely to have had longer periods of time off cigarettes that UC sustained non-smokers and intermittent smokers (See Table 5).

Gender Comparisons at 12 and 24 Months (See Table 6)

Significant differences were found between SI male and female participants who were sustained non-smokers at 12 months (χ^2= 10.5, p= .001) and at 24 months (χ^2=12.7, p< .0001) and for continuous smokers at 12 months (χ^2= 17.4, p< .0001) and at 24 months (χ^2= 17.2, p< .0001). SI women were

TABLE 6
SI AND UC GENDER COMPARISONS BY SMOKING STATUS AT 12 AND 24 MONTHS IN PERCENTS

		Sus N.Smok		Interm Sm		Contin Sm	
		12m	24m	12m	24m	12m	24m
SI	Male[a]	31.4	27.1	16.6	26.7	51.9	46.2
	Female[b]	26.4	21.8	14.6	24.9	59.0	53.3
	χ^2=	10.5	12.7	*	*	17.4	17.2
	p=	.001	<.0001	*	*	<.0001	<.0001
UC	Male[c]	3.9	3.4	9.3	16.9	86.8	79.7
	Female[d]	4.4	3.6	7.9	14.7	87.7	81.6
	χ^2=	*	*	*	*	*	*
	p=	*	*	*	*	*	*
Between SI and UC							
	χ^2=	*	*	*	*	8.04	7.46
	p=	*	*	*	*	.005	.006

* Not significant

[a] SI Males (N=2215)
[b] SI Females (N=1377)
[c] UC Males (N=1145)
[d] UC Females (N=658)

less likely than SI men to be sustained non-smokers and more likely to be continuous smokers at both 12 and 24 months. There were no gender differences found for intermittent smokers. For UC no gender differences were found.

Between SI and UC there were significant differences between the proportions of males and females for continuous smokers at 12 months (χ^2= 8.04, p= .005) and at 24 months (χ^2= 7.46, p=.006). No significant differences were found between groups for sustained non-smokers and intermittent smokers at 12 or 24 months (See Table 6).

Polytomous Logistic Regression Analysis (See Tables 7 and 8)

In order to determine which baseline variables predicted one of the three smoking status categories at 12 and 24 months a polytomous logistic regression analysis was used since there were three possible outcomes for smoking status. When baseline variables were entered into the regression model four variables emerged including: average number of cigarettes smoked per day at baseline (cigs/day), gender, average number of alcoholic drinks consumed per week at baseline (drinks/wk), and number of previous quit attempts at baseline (attempts). Differences in predictor variables were found for SI and UC at 12 and 24 months as well as between SI and UC at 12 and 24 months.

Data reported on Table 7 and Table 8 includes the regression coefficient, standard error (in parentheses below

each coefficient), odds ratio (OR), and the 95% confidence interval (95% CI). Interpretations of the coefficients in these models are conditional on all other variables that are present in the model.

SI Model at 12 Months (See Table 7)

At 12 months two predictor variables emerged: average number of cigarettes smoked per day at baseline (cigs/day) and gender. Both were significant when the other variable was present in the model.

Sustained non-smokers vs continuous smokers.

For sustained non-smokers vs continuous smokers the coefficient for cigarettes smoked per day was negative and significant (-0.01039, OR= 0.99, 95% CI= 0.98, 1.00) when gender was included and the coefficient for gender was positive and significant (0.034670, OR= 1.41, 95% CI= 1.21, 1.66) when cigarettes smoked per day was included in the model. That is, those who smoked more were somewhat less likely to be sustained non-smokers vs continuous smokers and men were somewhat more likely to be sustained non-smokers vs continuous smokers.

Intermittent smokers vs continuous smokers.

For intermittent smokers vs continuous smokers the direction was the same as with sustained non-smokers vs continuous smokers. The coefficient for cigarettes smoked

TABLE 7
POLYTOMOUS REGRESSION MODEL FOR SI AND UC AT 12 MONTHS

SI				UC			
Variable	Coeff.	OR	95% CI	Variable	Coeff.	OR	95% CI
Sus N Sm vs. Contin Sm							
Cigs/Day	-0.01039 (0.00283)[a]	0.99	(0.98,1.00)	Cigs/Day	-0.05750 (0.01000)[a]	0.94	(0.93,0.96)
Gender**	0.34670 (0.08040)	1.41	(1.21,1.66)	Drinks/wk**	-0.04018 (0.02810)	0.96	(0.91,1.01)
Interm Sm vs. Contin Sm							
Cigs/day	-0.02176 (0.00368)	0.98	(0.97,0.99)	Cigs/day	-0.02762 (0.00651)	0.97	(0.96,0.99)
Gender	0.34780 (0.10000)	1.41	(1.16,172)	Drinks/wk	0.04018 (0.01400)	1.04	(1.01,1.10)
Sus N. Sm vs. Interm Sm							
Cigs/day	0.01137 (0.00464)	1.01	(1.00,1.02)	Cigs/day	-0.02988 (0.01193)	0.97	(0.95,0.99)
Gender	-0.00110 (0.10975)	1.00	(0.81,1.24)	Drinks/wk	-0.08620 (0.03042)	0.92	(0.86,0.97)

Goodness of Fit χ^2=262.32, d.f.=192, p=.001 Goodness of Fit χ^2=453.18, d.f.=606, p=.999

[a]Standard error of measurement in parentheses below each coefficient

**Variable present in only one model- SI (Gender), UC (Drinks/wk)

per day was negative and significant (-0.2176, OR= 0.98, 95% CI= 0.97, 0.99). and the coefficient for gender was positive and significant (0.34780, OR= 1.41, 95% CI= 1.16, 1.72). Those who smoked more were somewhat less likely to be intermittent smokers vs continuous smokers and men were somewhat more likely to be intermittent smokers vs continuous smokers.

Sustained non-smokers vs intermittent smokers.

For sustained non-smokers vs intermittent smokers a reverse relationship was found. The coefficient for cigarettes smoked per day was positive and significant (0.01137, OR= 1.01, 95% CI= 1.00, 1.02) and the coefficient for gender was negative and significant (-0.00110, OR= 1.00, 95% CI= 0.81, 1.24). Those who smoked more were somewhat more likely to be sustained non-smokers vs intermittent smokers and females were somewhat less likely to be sustained non-smokers vs intermittent smokers.

Goodness of fit.

The χ^2 goodness of fit was significant (χ^2 = 262.32, d.f. 192, p= 0.001) and suggests that this model accounted for a modest amount of the variance in predicting smoking status and that there are probably other unknown factors not included in the model that impact smoking status (See Table 7).

UC Model at 12 Months (See Table 7)

At 12 months two significant baseline predictor variables of smoking status category emerged for UC participants: cigarettes smoked per day and average number of alcoholic drinks consumed per week at baseline (drinks/wk). Both were significant when the other variable was present in the model. Alcoholic drinks consumed per week was a variable that did not emerge at 12 months in the SI model and gender did not emerge as a significant baseline predictor variable for the UC model as it was for SI.

Sustained non-smokers vs continuous smokers.

For sustained non-smokers vs continuous smokers the coefficient for cigarettes smoked per day was negative and significant (-0.05750, OR= 0.94, 95% CI= 0.93, 0.96) when alcoholic drinks per week was included in the model and the coefficient for alcoholic drinks per week was negative and significant (-0.04044, OR= 0.96, 95% CI= 0.91, 1.01) when cigarettes smoked per day was present in the model. That is, those who smoked more were somewhat less likely to be sustained non-smokers vs continuous smokers and those who drank more were somewhat less likely to be sustained non-smokers vs continuous smokers.

Intermittent smokers vs continuous smokers.

For intermittent smokers vs continuous smokers a pattern dissimilar to UC sustained non-smokers vs continuous

smokers emerged. The coefficient for cigarettes smoked per day remained negative and significant (-0.02762, OR= 0.97, 95% CI= 0.96, 0.99) but the coefficient for drinks was no longer negative, but positive and significant (0.04018, OR= 1.04, 95% CI= 1.01, 1.10). Those who smoked more were somewhat less likely to be intermittent smokers rather than continuous smokers but heavier drinkers were somewhat more likely to be intermittent smokers rather than continuous smokers.

Sustained non-smokers vs intermittent smokers.

For sustained non-smokers vs intermittent smokers a pattern similar to UC sustained non-smokers vs continuous smokers emerged. The coefficient for cigarettes smoked per day was negative and significant (-0.02988, OR= 0.97. 95% CI= 0.95, 0.99) and the coefficient for alcoholic drinks consumed per week was also negative and significant (-0.08620, OR= 0.92, 95% CI= 0.86, 0.97). Those who smoked more were somewhat less likely to be sustained non-smokers vs intermittent smokers and those who were heavier drinkers were also somewhat less likely to be sustained non-smokers vs intermittent smokers.

Goodness of fit.

The χ^2 goodness of fit was not significant (χ^2= 453.18, d.f.= 606, p= 0.999) and suggests that this model did account for much of the variance in predicting smoking

status In other words, the variables tested in the model were significant predictor variables for smoking status for UC (See Table 7).

SI Model at 24 Months (See Table 8)

Previous quit attempts at baseline (attempts) emerged as a predictor of smoking status categories in addition to the variables of cigarettes per day and gender that were included in the SI model at 12 months. Each of the three variables was significant when the other two variables were present in the model. Gender appeared to be the most significant variable when cigarettes per day and previous quit attempts were included.

Sustained non-smokers vs continuous smokers.

For sustained non-smokers vs continuous smokers the coefficient for cigarettes per day was negative and significant (-0.01198, OR= 0.99, 95% CI= 0.98, 0.99) when gender and previous quit attempts were included. The coefficient for previous quit attempts was negative and significant (-0.00260, OR= 1.0, 95% CI= 0.94, 1.10) when cigarettes smoked per day and gender were included. The coefficient for gender was positive and significant (0.41120, OR= 1.5, 95% CI= 1.27, 1.79) when cigarettes smoked per day and previous quit attempts were included. Those who smoked more were somewhat less likely to be sustained non-smokers vs continuous smokers, those with a

TABLE 8
POLYTOMOUS REGRESSION MODEL FOR SI AND UC AT 24 MONTHS

SI				UC			
Variable	**Coeff.**	**OR**	**95% CI**	**Variable**	**Coeff.**	**OR**	**95% CI**
Sus N Sm vs. Contin Sm							
Cigs/Day	-0.01198	0.99	(0.98,0.99)	Cigs/Day	-0.06545	0.94	(0.92,0.96)
	(0.00306)[a]				(0.01100)		
Attempts	-0.00260	1.0	(0.94,1.10)	Attempts	-0.02313	0.98	(0.81,1.17)
	(0.02880)				(0.09310)		
Gender**	0.41120	1.5	(1.27,1.79)				
	(0.08710)						
Interm Sm vs. Contin Sm							
Cigs/day	-0.01789	0.98	(0.98,0.99)	Cigs/day	-0.02170	0.98	(0.97,0.99)
	(0.00309)				(0.00492)		
Attempts	0.08198	1.09	(1.02,1.15)	Attempts	0.12320	1.13	(1.03,1.24)
	(0.02890)				(0.04660)		
Gender	0.27030	1.31	(1.11,1.55)				
	(0.08510)						
Sus N. Sm vs. Interm Sm							
Cigs/day	0.00591	1.01	(1.00,1.01)	Cigs/day	-0.04375	0.96	(0.94,0.98)
	(0.00435)				(0.01119)		
Attempts	-0.08458	0.92	(0.86,0.98)	Attempts	-0.14633	0.86	(0.71,1.05)
	(0.03293)				(0.10020)		
Gender	-0.14090	1.16	(0.95,1.40)				
	(0.09944)						

Goodness of Fit χ^2=720.99, d.f.=600, p<.001 Goodness of Fit χ^2=331.36, d.f.=322, p=.348

[a]Standard error of measurement in parentheses below each coefficient

**Variable present in only one model- SI (Gender)

greater number or previous quit attempts were somewhat less likely to be sustained non-smokers vs continuous smokers and males were somewhat more likely than females to be sustained non-smokers than continuous smokers.

Intermittent smokers vs continuous smokers.

For intermittent smokers vs continuous smokers a change in pattern emerged from that of sustained non-smokers vs continuous smokers. The coefficient for cigarettes per day remained negative and significant (-0.01789, OR= 0.98, CI= 0.98, 0.99), the coefficient for previous quit attempts was positive and significant (0.08198, OR= 1.09, 95% CI= 1.02, 1.15) and the coefficient for gender remained positive and significant (0.27030, OR= 1.31, 95% CI= 1.11, 1.55). Those who smoked more were somewhat less likely to be intermittent smokers vs continuous smokers, those who had a greater number of previous quit attempts were somewhat more likely to be intermittent smokers vs continuous smokers and males were somewhat more likely than females to be sustained non-smokers vs continuous smokers.

Sustained non-smokers vs intermittent smokers.

For sustained non-smokers vs intermittent smokers a shift in direction for cigarettes smoked per day for sustained non-smokers emerged. The coefficient for cigarettes smoked per day was positive and significant

(0.00591, OR= 1.01, 95% CI= 1.00, 1.01), the coefficient for previous quit attempts was negative and significant (-0.08458, OR= 0.92, 95% CI= 0.86, 0.98,) and the coefficient for gender was positive and significant (0.14090, OR= 1.16, 95% CI= 0.95, 1.40). Those who smoked more were somewhat more likely to be sustained non-smokers vs intermittent smokers, those who had a greater number of previous quit attempts were less likely to be sustained non-smokers vs intermittent smokers and males were somewhat more likely to be sustained non-smokers vs intermittent smokers than females.

Goodness of fit.

The χ^2 goodness of fit was significant (χ^2= 720.99, d.f. 600, p< 0.001) and suggests that this model, like the 12 month SI model, accounts for only a modest amount of the variance in predicting smoking status and that there are probably other unknown factors that were not included in the model that may significantly impact smoking status for SI (See Table 8).

UC Model at 24 Months (See Table 8)

For UC at 24 months alcoholic drinks per week no longer emerged as a significant predictor variable of smoking status. Previous quit attempts (attempts) was a new variable that did emerge, however, and cigarettes smoked per day remained a significant predictor variable. Each of these two

variables was significant when the other variable was included in the model.

Sustained non-smokers vs continuous smokers.

For sustained non-smokers vs continuous smokers the coefficient for cigarettes smoked per day was negative and significant (-0.06545, OR= 0.94, 95% CI= 0.92, 0.96) when previous quit attempts was included in the model. The coefficient for previous quit attempts was negative and significant (-0.02313, OR= 0.98, 95% CI= 0.81, 1.17) when cigarettes smoked per day was included in the model. Those who smoked more were somewhat less likely to be sustained non-smokers vs continuous smokers and those who had a greater number of previous quit attempts were also somewhat less likely to be sustained non-smokers vs continuous smokers.

Intermittent smokers vs continuous smokers.

For intermittent smokers vs continuous smokers the coefficient for cigarettes smoked per day was negative and significant (-0.02170, OR= 0.98, 95% CI= 0.97, 0.99) and the coefficient for attempts was positive and significant (0.12370, OR= 1.13, 95% CI= 1.03, 1.24). Those who smoked more were somewhat less likely to be intermittent smokers vs continuous smokers and those who had fewer previous quit attempts were somewhat more likely to be intermittent smokers vs continuous smokers.

Sustained non-smokers vs intermittent smokers.

For sustained non-smokers vs intermittent smokers cigarettes smoked per day was negative and significant (-0.04375, OR= 0.96, 95% CI= 0.94, 0.98) and the coefficient for previous quit attempts was negative and significant (-0.14633, OR= 0.86, 95% CI= 0.71, 1.05). Those who smoked more were somewhat less likely to be sustained non-smokers vs intermittent smokers and those who had a greater number of previous quit attempts were somewhat less likely to be sustained non-smokers vs intermittent smokers.

Goodness of fit.

The χ^2 goodness of fit was not significant (χ^2= 331.36, d.f. 322, p= 0.348) and suggests that this model did account for much of the variance in predicting smoking status for UC at 24 months (See Table 8). In other words, the variables tested in the model were significant predictor variables for smoking status for UC.

Summary of Polytomous Logistic Regression Analysis for SI and UC at 12 and 24 Months

Differences in predictor variables were found between SI and UC and within each group at 12 and 24 months. For SI the 12 month predictor variables were cigarettes smoked per day and gender. 24 month variables were cigarettes smoked per day, previous quit attempts and gender. At both 12 and

24 months males were consistently more likely to be sustained non-smokers than females when the other variables were included in the models.

For UC the 12 month predictor variables were cigarettes smoked per day and alcoholic drinks per week. Those who smoked fewer cigarettes and who drank fewer drinks per week were more likely to be sustained non-smokers. At 24 months, alcoholic drinks per week no longer predicted smoking status. Previous quit attempts emerged as a new variable at 24 months.

Cigarettes smoked per day was the only predictor variable that emerged for both SI and UC at 12 and 24 months. This variable showed a consistent pattern of being negative and significant for SI and UC at 12 and 24 months for two out of the three smoking status outcome categories. The exception was SI sustained non-smokers vs intermittent smokers where cigarettes smoked per day was positive and significant for SI at 12 and 24 months. Gender was not a predictor variable for UC at either 12 or 24 months.

Post Baseline Smokers Only Analysis and Tests of Hypotheses (See Tables 9 & 10)

Analysis of smokers only combined SI intermittent smokers and continuous smokers into one group defined as SI smokers. UC participants were similarly combined into a group defined as UC smokers. The smokers only analysis was

conducted to test the hypotheses related to participants who were not sustained non-smokers at 12 or 24 months and to compare post baseline differences in smoking behavior patterns between SI and UC.

SI and UC Comparisons of Smoking Patterns (See Tables 1-10)

Significant between group and within group differences were found at both 12 and 24 months. Support for the decision to reject the primary null hypothesis includes results both in overall outcome differences between SI and UC (See Tables 1-8) and in the subsequent Smokers Only Analysis (See Tables 9 & 10), therefore, a more detailed discussion of this hypothesis will be included at the end of this section.

Null hypothesis H1 (primary null hypothesis): that there are no differences between the smoking outcomes and smoking patterns of the SI group and the smoking outcomes and smoking patterns of the UC group was rejected.

SI and UC Comparison of Number of Post Baseline Quit Attempts (See Table 9)

SI participants were significantly more likely to make greater numbers of quit attempts at 12 months (χ^2= 44.7, p< .0001) and at 24 months (χ^2= 128.2. p< .0001) than UC participants.

Null hypothesis H2: that there are no differences between SI and UC smokers for the number of post baseline

TABLE 9
SI[a] AND UC[b] COMPARISON OF POST BASELINE QUIT ATTEMPTS AND LONGEST TIME OFF CIGARETTES AT 12 AND 24 MONTHS FOR SMOKERS ONLY IN PERCENTS

Quit Attempts		12m	24m
SI	1	47.8	33.6
	2-3	25.6	31.4
	4-5	8.7	11.8
	≥6	17.9	23.2
UC	1	58.3	56.5
	2-3	26.6	27.2
	4-5	5.5	7.8
	≥6	9.6	8.5
	χ^2=	44.7	128.2
	p=	<.0001	<.0001
Time Off Cigs			
SI	48hr-7 da	14.8	35.7
	6-14 da	7.4	10.9
	15 da-1 mo	9.5	11.6
	1-4 mo	31.3	21.4
	≥4 mo	37.0	20.4
UC	48hr-7 da	41.8	45.7
	6-14 da	12.3	9.1
	15 da-1 mo	14.8	11.0
	1-4 mo	19.1	19.7
	≤4 mo	11.9	14.5
	χ^2=	364.2	23.8
	p=	<.0001	<.0001

[a] 12 mo N=2158, 24 mo N=1451
[b] 12 mo N=763, 24 mo N=717

quit attempts made prior to the 12 month data point and between the 12 month and the 24 month data points was rejected (See Table 9).

SI and UC Comparison of Post Baseline Longest Time Off Cigarettes (See Table (Table 9)

SI participants were significantly more likely to have longer periods of time off cigarettes than UC participants at 12 months (χ^2= 364.2, p<. 0001) and at 24 months (χ^2= 23.8, p< .0001).

Null hypothesis H3: that there are no differences between SI and UC smokers for the post baseline longest time off cigarettes prior to the 12 month data point and between the 12 and 24 month data points was rejected (See Table 9).

SI and UC Comparison of Post Baseline Average Number of Cigarettes Smoked per Day (See Table 10)

Smoking data for this variable does not include the first four months following baseline in order to control for the approximate four months of counseling assisted intervention that occurred for SI participants following baseline. SI participants were significantly more likely to smoke fewer cigarettes per day for the 8 months prior to the 12 month data point (t= 25.2, p< .0001) and for the 12 months prior to the 24 month data point (t= 25.3, p< 0001) than UC participants. However, the number of post baseline cigarettes smoked per day for SI increased from

TABLE 10
SI[a] AND UC[b] COMPARISON OF POST BASELINE CIGARETTES SMOKED PER DAY AND CALENDAR MONTHS OF SMOKING AT 12 AND 24 MONTHS* FOR SMOKERS ONLY IN AVERAGES

Cigs/Day	12mo	24mo
SI	15.8	17.2
UC	26.2	24.4
t=	25.2	17.2
p=	<.0001	<.0001
Months Sm*		
SI	5.9	6.1
UC	7.6	7.1
t=	25.7	13.4
p=	<.0001	<.0001

[a] 12mo N=2533, 24mo N=2692

[b] 12mo N=1729, 24mo N=1740

* Months of smoking based on the number of months out of a possible 8 months at both the 12 and 24 month data point.

15.8 cigarettes smoked per day at 12 months to 17.2 cigarettes smoked per day at 24 months while for UC the number decreased from 26.2 cigarettes smoked per day to 24.2 cigarettes smoked per day during the same time period.

Null hypothesis H4: that there are no differences between SI and UC smokers for the average number of post baseline cigarettes smoked per day at the 12 month and between the 12 and 24 month data points was rejected (See Table 10).

SI and UC Comparisons of Post Baseline Number of Calendar Months Smoking (See Table 10)

Smoking data for this variable does not include the first four months following baseline in order to control for the approximate four months of counseling assisted intervention that occurred for SI participants following baseline. In order to have comparable data for each of the two years the first four months following the 12 month data point were not included in the analysis at 24 months. SI participants were much less likely to have smoked during any calendar months than UC participants at the 12 month data point ($t= 25.7$, $p< .0001$). For SI there was some increase in the number of months smoking from the 12 month (5.9 months smoking) to the 24 month data points (6.1 months smoking), but for UC there was a decrease in the number of months smoking from the 12 month (7.6 months smoking) to the 24 month data points (7.1 months smoking). Despite this trend,

SI participants remained more likely to smoke during fewer calendar months than UC participants (t= 13.4, p< .0001).

Null hypothesis H5: that there are no differences between SI and UC smokers for the number of post baseline calendar months in which at least one cigarette was smoked at the 12 month and between the 12 and 24 month data points was rejected (See Table 10).

The Primary Null Hypothesis (Tables 1-10)

The primary null hypothesis H1: that there are no differences between smoking outcomes and smoking patterns for the SI group and smoking outcomes and smoking patterns for the UC group was rejected. Smoking outcomes and smoking patterns have been shown to be significantly different between the SI and UC groups. Outcome measures regarding smoking status at 24 months indicated that differences between the SI and UC groups by smoking status categories were all at p< .0001 (See Table 1).

Differences within and between the SI and UC groups by smoking status were found for a number of demographic and smoking history variables. Alcoholic drinks consumed per week (drinks) was significant for UC but not SI. Nicotine dependence as measured by cigarettes smoked per day at baseline differed not only within group by smoking status, but between groups as well (See Table 2). Differences in the number of quit attempts at baseline were significant within group for both SI and UC at 24 months (See Table 5). Gender

differences at 12 and 24 months were significant for SI but not for UC (See Table 6). Polytomous Logistic Regression Analysis of baseline variables also supported between group differences as to predictor variables of smoking status at 12 and 24 months (See Tables 7 & 8).

Additional evidence from the Smokers Only Analysis indicated that all null hypotheses for smokers only were rejected (See Tables 9 & 10).

Summary of Results

In summary, all null hypotheses were rejected. SI participants were significantly more likely to achieve long term abstinence from smoking at 24 months than UC participants. Those SI participants who were smokers (intermittent smokers and continuous smokers) were significantly more likely post baseline to: 1) make more quit attempts, 2) have longer periods of time off cigarettes, 3) smoke fewer cigarettes per day and 4) smoke during fewer calendar months than UC participants who were smokers. SI men were significantly more likely to be sustained non-smokers than SI women. No significant differences were found between UC women and UC men with regards to smoking status categories.

Predictor variables for smoking status categories that emerged from the polytomous logistic regression analysis supported the differences found between SI and UC from the

analysis on the individual variables. The average cigarettes smoked per day at baseline (cigs/day) was the only variable that predicted smoking status category for both groups at 12 and 24 months and, therefore, was a predictor of long term abstinence. Prior attempts to quit smoking at baseline (attempts) was also a predictor of long term abstinence for both groups but only at the 24 month data point. Based on the analysis chosen, the significance of gender varied slightly. χ^2 analysis of the proportions of males and females by smoking status category indicated that males were more likely to be sustained non-smokers and females were more likely to be continuous smokers at 12 and 24 months. No gender differences were found for SI intermittent smokers at 12 or 24 months. The polytomous regression analysis generally supported the findings from the χ^2 analysis but added gender as a significant predictor variable with the SI intermittent smoker group at 12 and 24 months as well. Gender was a predictor of long term abstinence for SI only.

DISCUSSION

Overview

Overall, counseling assisted SI participants quit smoking and maintained long term abstinence with greater frequency than the UC participants who received no assistance from the Lung Health Study (LHS). This suggests that the counseling assisted smoking intervention had a significant effect in increasing quit rates and long term abstinence rates and also supports the importance of social learning theory (Bandura, 1977; Rotter 1977) as a foundation for successful smoking cessation interventions with heavy smokers. The counseling intervention was a state-of-the-art cognitive behavioral intervention that emphasized the development of coping strategies, self monitoring, self management, cognitive replacement strategies and relapse prevention.

Within the SI group 29.5% were sustained non-smokers at 12 months. For the UC group the percentage of sustained non-smokers at 12 months was 4.1% and was consistent with the 0.5% to 5.5% reported elsewhere in the literature (Lichtenstein & Cohen, 1990). There is little in the literature that describes biochemically validated sustained non-smoking rates beyond 12 months and less still that describes the behavior of heavy smokers for any period

greater than 12 months (Glasgow & Lichtenstein, 1987). By spanning 24 months this study adds important biochemically validated data on smoking outcomes and smoking patterns for heavy smokers. At 24 months sustained non-smoker rates were 25.1% for SI and 3.5% for UC. SI participants not only quit smoking in proportionately greater numbers, but were able to maintain their non-smoking behavior at a rate approximately equal with the UC sustained non-smokers at 24 months despite being heavier smokers (28.9 cigarettes per day) compared to UC (19.6 cigarettes per day).

The high level of long term abstinence for SI is quite encouraging for heavy smokers and is a somewhat different finding than Glasgow and Lichtenstein (1987) reported in their analysis of 60 behavioral smoking cessation studies where they found that the data from follow-ups of two to six years suggested that cessation programs were less successful for heavy smokers (20 or more cigarettes per day). This finding holds for the UC sustained non-smokers who were lighter smokers, but did not hold for the SI group. This suggests that participating in the SI group itself helps to improve success for many smokers.

While the counseling aided SI participants' sustained non-smoking rates were increased by the smoking cessation intervention, the maintenance of the high long term abstinence rate was a somewhat surprising finding based on earlier research (Glasgow & Lichtenstein, 1987). These data indicate that while there was some decline in sustained non-

smoking rates for both groups from 12 months to 24 months, relapse was proportionately no greater for SI than for UC. The percentage for sustained non-smokers for SI declined from 29.5% to 25.1% and UC declined from 4.1% to 3.5%. This is roughly a 15% decline in the percentage of sustained non-smokers for both groups. It appears that the effect of the counseling aided intervention was to encourage more SI participants to quit who would not have quit. However, one might expect that a much higher relapse rate would occur over time for SI as has been reported in other studies (Brandon, Tiffany, Obremski & Baker, 1990). The continued use of nicotine gum may explain part of this long term maintenance in addition to the beneficial aspects of the counseling intervention including regular contacts.

Several demographic variables did not distinguish SI participants from UC participants. Generally, both groups started smoking at about age 17, had similar education levels and about the same number of other smokers in their households. Where differences were found between SI and UC they were frequently between the sustained non-smokers for each group. More often there were differences across smoking categories within each group. This indicates that demographics play more of a role in predicting abstinence than the ability to try to quit.

Social support has been hypothesized as having a positive effect on quit rates and abstinence, but the literature has been mixed regarding its relative importance

(Mermelstein, et al., 1986). The findings in this study were also mixed. Spouse/friend support to quit smoking did not make a difference in SI smoking status categories but did make a difference for UC. Differences in spouse/friend support across the three smoking status categories for UC were significant ($p < .001$) at 12 and 24 months. Additionally, the only differences between the two groups were found for sustained non-smokers with SI reporting proportionately more spouse/friend support to quit smoking at baseline. It may be that the involvement of spouse/friends in going through the group counseling intervention process reinforced support for SI participants thereby leveling out differences which were found across the three smoking status categories for unassisted UC participants. In any event, social support appears to be a factor for smokers who quit without assistance.

Analysis of smoking history variables also produced mixed results. When analyzed by smoking category at each data point, counseling assisted SI participants made about the same number of quit attempts at baseline as unassisted UC participants except that SI intermittent smokers made proportionately more attempts to quit than UC intermittent smokers. However, baseline quit attempts appeared as a predictor of smoking status at 24 months for both SI and UC with fewer quit attempts predicting sustained non-smokers, and more attempts predicting intermittent vs continuous smokers.

The literature has been mixed regarding the predictive value of previous quit attempts in determining future smoking status. Some studies have found, similar to this study, that fewer attempts to quit smoking predicted success in quitting (Fiore, et al., 1990). Pederson, Wanklin and Lefcoe (1988) found that for participants with respiratory disease that previous quit attempts was a predictor of short term abstinence but not of long term abstinence. Schachter (1982) found that more previous quit attempts predicted successful abstinence. In a related study, Glasgow, Klesges, Mizes and Pechacek (1985) concluded that demographic variables, smoking pattern variables and gender were predictors of successful abstinence for participants in cessation programs but not for those who quit without assistance from a program.

Longest period quit at baseline across smoking status categories distinguished smoking status categories in similar fashion for both SI and UC. Continuous smokers for both groups behaved similarly in terms of longest period quit, but SI sustained non-smokers and intermittent smokers had somewhat longer quit periods at baseline than UC sustained non-smokers and intermittent smokers at 12 months ($p = .009$) and 24 months ($p = .022$). This finding is supported by the conclusions of Mothersill, McDowell and Rosser (1988) in their study of long term abstinence where they found that the length of previous quit attempts was positively linked to long term abstinence.

The impact of gender on smoking patterns and long term abstinence is more complex. The counseling aided intervention had a differential effect for women. As reported earlier, the percentage of SI women who were sustained non-smokers was greater at 12 (26.4%) and 24 months (21.8%) when compared to the percentage of women who were sustained non-smokers in the UC group at 12 (4.4%) and 24 months (3.6%). However, for SI the percentage of women who were sustained non-smokers at 12 months (26.4%) and 24 months (21.8%) was smaller when compared to the percentage of men at 12 months (31.4%) and 24 months (27.1%). SI women were also more likely to be continuous smokers at 12 months (59.0%) and at 24 months (53.3%) when compared with men at 12 months (51.9%) and 24 months (46.2%). This finding indicated women had a more difficult time remaining abstinent and that they were more likely to remain smokers.

No similar significant differences were found between UC women and UC men by smoking category. This finding supports what has been reported in other studies for unassisted self quitters (Glasgow, Schafer & O'Niel, 1981; Lichtenstein & Cohen, 1990). Overall these findings point the need for gender sensitive smoking cessation materials and counseling strategies and supports the findings of Brownell et al., (1986) who concluded that modifications to cessation programs to address the unique motivations of women should be tried in order to improve cessation rates. Likewise, Swan et al., (1988) found that predisposing

factors to relapse were different for women and at least one study has indicated that physiologic differences between women and men in the way nicotine is processed may contribute to differential cessation rates (Killen, et al., 1990). Any new direction in counseling for women would need to take into account the relationship of nicotine to the physiology of women.

The fact that no differences in smoking status categories between men and women were found in the UC group indicate that men and women do equally well or poorly in becoming sustained non-smokers when left to their own devices, however the numbers of sustained non-smokers are far fewer than the SI.

The dynamic of quitting, relapsing and requiting at 12 and 24 months for SI and the UC participants who either relapsed or continued to smoke proved important in describing smoking pattern differences between the two groups.

As hypothesized SI and UC smokers behaved very differently on all of the smokers only variables. Counseling assisted SI smokers made more quit attempts after baseline and spent more time off cigarettes when they were quit than unassisted UC smokers. SI also smoked fewer cigarettes per day at 12 months (15.8 per day) than UC (26.2 per day) and at 24 months (17.2 per day) compared to UC (24.4 per day). SI smokers had also smoked in fewer months at 12 months (5.9 months) than UC (7.6 months) and at 24 months (6.1 months)

compared to UC (7.1 months). These differences point strongly in the direction of a consistent intervention effect for SI over time that has influenced abstinence through 24 months.

Limitations of This Study

The participants in this study are not representative of the general smoking population. Participants went through several screenings, were diagnosed with mild to moderate lung impairment and agreed to consider smoking cessation if randomized into the counseling assisted SI group. This process is far more likely to ensure a motivated group than might ordinarily be expected. Additionally, ethnic minorities make up less than 6% of the participants in the study. Because of these selection biases, care should be used in generalizing the results of this study to a more diverse population.

A second limitation is the criteria used to define unassisted quitters and how well that definition applies to the UC group. UC participants in this study were motivated to participate in the screenings and attended yearly visits where they recounted their medical and smoking histories and received feedback on carbon monoxide levels and pulmonary function. While this contact does not constitute help in quitting smoking, it does potentially heighten awareness about smoking. Criteria defining unassisted smoking

cessation was outlined in a recent study of unaided smoking cessation by Lichtenstein and Cohen (1990). This definition requires that the smoker initiate and attempt to quit with minimal promotion from health care providers and does not receive face to face counseling or advice apart from unassisted use of self help materials. By this definition the UC group was unassisted. Risser and Belcher (1990) reported that medical information coupled with advice to quit increases quit rates. Although, no advice to quit was given to the UC, they did receive medical information which may be considered assistance to quit. Even so, their 3.5% sustained non-smoker rate at 24 months fell within the range of 0.5% to 5.5% reported for unassisted quitters in the literature (Lichtenstein & Cohen, 1990) and suggests that the LHS had little additional impact on cessation rates for UC.

The precise effect of nicotine gum in modifying smoking and abstinence patterns is unclear. The use of nicotine gum was encouraged as part of the counseling assisted intervention for all SI participants. It has been shown that nicotine gum when used alone produced much poorer abstinence rates than when used in conjunction with a counseling intervention (Hall, et al., 1985; Killen, et al., 1990).

It seems safe to say that nicotine gum had an effect on short term quit rates and this effect has been documented in numerous studies (Benowitz, 1988; Cooper & Clayton, 1989; Fagerstrom, 1982; Goldstein et al., 1989; Glasgow &

Lichtenstein, 1987). The relative contribution to the success of the SI group of participant variables, counseling intervention and nicotine gum to quit is impossible to tell from this study. However, compared to the control group there was clearly a synergistic effect between the gum and the counseling intervention and it is safe to say that the counseling intervention made a significant contribution to the success of the SI group beyond the use of nicotine gum.

Conclusions

Counseling assisted smoking cessation programs in conjunction with nicotine gum can make a significant contribution in helping smokers to quit. A counseling assisted program seems especially helpful for the heavier smoker. While the relative contribution of client variables, program variables and nicotine gum to overall success in smoking cessation cannot be determined in this study, it is clear that heavy smokers who participate in the counseling assisted program are more likely to quit than those who do not. Since heavy smokers are more likely to develop smoking related diseases, providing counseling assisted programs for these smokers is particularly important.

The counseling assisted program also had an effect on smoking rates. SI participants who were not abstinent at 24 months did not return to their former level of smoking. While the health benefit of reduced smoking in this group

remains to be seen, it is clear that participating in the counseling assisted program helps keep them more active in the stages of smoking behavior change which can lead to long term abstinence. In the LHS, they were more likely to attempt quitting and to remain quit for longer periods of time than the UC group. Further research into the patterns of abstinence and smoking for intermittent smokers would add to our knowledge of how they progress through the stages of change and eventually quit.

The counseling assisted program had a different effect for men and women. Women and men in the UC group quit at modest rates, and both were equally likely to quit smoking. Men and women in the SI group quit at significantly higher rates than the UC, however, men were significantly more likely to quit than women. More research into the specific smoking cessation patterns of women is need to increase the benefits of counseling assisted programs for women.

Although, the general trend in smoking nationwide is declining, hundreds of thousands of smokers continue to suffer from the consequences of their addiction (USDHHS, 1989). The LHS demonstrates the contribution counseling assistance can have in helping heavy smokers quit. The skill and training counselors receive in addictions and recovery can easily be expanded to include addiction to smoking. By learning to counsel smokers and by giving smoking cessation the same priority given to other addictions, counselors can

contribute to reducing the significant health and human costs associated with smoking cigarettes.

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APPENDICES

Appendix A: Consent Form

THE OREGON
HEALTH SCIENCES UNIVERSITY
Mailing Address
Lung Health Study 3030 S.W. Moody Avenue, Suite 105 , Portland, Oregon 97201
(503) 225-8267

DCC USE

Date Received :

Form Seq. No.:

Participant ID : ☐-☐☐☐☐-☐-☐☐☐

Date of Exam : ☐☐-☐☐-☐☐
Month Day Year

Participant's name: _____ _____ _____
(Print) First Middle Last

LUNG HEALTH PROGRAM

Consent for Participation in Study

I understand that the tests I have had thus far suggest that my lung function is somewhat impaired.

I understand that the Lung Health Study is planned to be of five years' duration and that all participants in the Program will be expected to attend the clinic once a year for an examination which will include:

(1) measurement of expired carbon monoxide, height, weight and blood pressure,
(2) collection of a saliva specimen,
(3) measurement of lung function,
(4) measurement of response to an inhaled drug (isoproteronol) which opens bronchial airways,
(5) questions regarding my smoking habits, general health, medications and illnesses.

I understand the study will not be a substitute for regular medical care.

I understand that all participants in the study will be carefully studied and observed for five years. Those who agree to participate in the study will be allocated randomly into one of three groups. One-third of the participants ("usual care") will be referred to their regular source of medical care for treatment and advice relating to lung health; but they will be invited to return once each year for the examination described above, at no cost to them.

The remaining two-thirds of the participants ("special intervention") will be enrolled in a free, 12-week, intensive quit smoking program. This program will involve standard counselling techniques in either individual or group settings. Participants in the quit smoking groups may, at their request, also be prescribed nicotine gum. Side effects which may occur from use of nicotine gum include: jaw muscle soreness, hiccups, belching, irritability, anxiousness, difficulty concentrating, dizziness, headaches, insomnia, decreased hunger, mouth or throat soreness, nausea, and indigestion. These side effects are

Schools Clinical Facilities Special Research Division

temporary and clinic staff will watch for them. If any of these occur, nicotine gum use will be reviewed and stopped if necessary.

In addition to the quit-smoking program, the special intervention participants will use an aerosol inhaler 3 times per day for the five-year duration of the study. Half will be randomly assigned to receive aerosol inhalers containing an active bronchodilating drug (ipratroprium bromide) that may reduce lung damage from smoking, while the other half will receive aerosol inhalers containing a placebo (no active drug). This assignment will be done in a double-blind fashion, which means that neither the clinical center staff nor the participant will know whether the participant is getting the drug or the placebo. I understand that some individuals who get the drug may experience side effects, the most common of which is dry mouth. In rare instances, chest discomfort, constipation, nervousness, irritability, mood changes, heat intolerance, blurred vision, glaucoma, palpitations or urinary hesitancy may occur. Physicians and research staff will watch closely for these side effects and, when necessary, stop the medicine and/or treat these symptoms.

Special intervention participants will not be required to pay for the quit-smoking program, the bronchodilator, or the nicotine gum used in the study. Once every four months for the duration of the study, the special intervention participants will also be asked to come to the clinic for some or all of the examinations listed on the first page of this form.

It is not the policy of the Department of Health and Human Services, or any other agency funding the research project in which you are participating to compensate or provide medical treatment for human subjects in the event the research results in physical injury. The Oregon Health Sciences University, as an agency of the State, is covered by the State Liability Fund. If you suffer any injury from the research project, compensation would be available to you only if you establish that the injury occurred through the fault of the University, its officers or employees. If you have further questions, please call Dr. Michael Baird, M.D. at 503-225-8014.

I understand the purpose of this project and the procedures which will be performed. Clinical staff members have answered to my satisfaction all my questions concerning this project, and I understand that I may ask further questions at any time while the Study is in progress.

This project is under the direction of A. Sonia Buist, M.D., Professor of Medicine.

I understand that I am free to withdraw my consent and discontinue my participation in the study at any time. However, I understand my continuing participation is important to the success of this national study of lung health.

This is to certify that I agree to participate in the Lung Health Study.

_____ _____

Date Signature of Participant

I certify that this participant has been given ample opportunity to have his or her questions answered and has freely given consent to participate in the Lung Health Study.

Appendix B: Annual Visit Form

LUNG HEALTH STUDY

SECOND ANNUAL VISIT FORM

Attach ID Label Here

DCC USE

Date Received :

Form Seq. No. :

Participant ID: ☐-☐☐☐☐☐-☐-☐☐☐☐

Date of Visit: ☐☐-☐☐-☐☐ (Month Day Year)

Current Clinic: ☐ Annual Visit: 2

This form is completed at the second annual visit. This form is to be completed based on an interview conducted by a non-intervention staff member certified to administer forms.

1. **Participant's Name:** _____ (Please print) First Middle Last

   Address: _____

   City: _____ **State/Prov.:** _____ **Zip Code/Mail Code:** _____

2. **Telephone:** (☐☐☐) ☐☐☐-☐☐☐☐ (home) (☐☐☐) ☐☐☐-☐☐☐☐ (work)
   Area Code Area Code

3. **Participant's regular physician (or name of HMO if applicable):** DCC USE ☐

   Name: _____ First Middle Last

   Address: _____

   City: _____ **State/Prov.:** _____ **Zip Code/Mail Code:** _____

DATA COLLECTION PROCEDURES

Questions 1 through 6 must be completed prior to conducting the annual visit PF test.

1. When did you last smoke a cigarette? (Check one answer.)
   - 1 ☐ more than one month ago
   - 2 ☐ 15 days to one month ago
   - 3 ☐ 8 to 14 days ago
   - 4 ☐ 2 to 7 days ago
   - 5 ☐ within the past 48 hours → 2. How many hours and minutes ago? ☐☐:☐☐ (Hours Minutes)

3. Expired CO:

   Background: ☐☐☐ ppm Trial 1: ☐☐☐ ppm Trial 2: ☐☐☐ ppm

   Technician's code: ☐☐☐

4. Weight (without shoes): ☐☐☐.☐ kg 5. Standing height (without shoes): ☐☐☐ cm

Before asking the participant to provide a saliva specimen, ask whether he or she has had anything to eat or drink in the past 20 minutes (including water). If yes, delay collecting the specimen until 20 minutes have elapsed.

6. Saliva sample collected: 1 ☐ yes 2 ☐ no → Explain: _____

INTERIM SMOKING HISTORY

1. Have you smoked cigarettes in the past 12 months?

1 ☐ yes → 2. Do you now smoke cigarettes (one or more per week)?

2 ☐ no

CONTINUE WITH QUESTION 10.

1 ☐ yes → 3. On the average, about how many cigarettes do you now smoke per day? (Answer one of the following.)

a. 1 ☐ fewer than one per day

OR

b. ☐☐☐ cigarettes/day

2 ☐ no

Ask the following of all participants answering "yes" to question 1. For participants who are not current smokers, ask regarding smoking habit when they last smoked cigarettes.

4. Do you inhale the cigarette smoke?

1 ☐ not at all
2 ☐ slightly
3 ☐ moderately
4 ☐ deeply

5. What is the full name of your current brand of cigarettes? DCC USE ☐☐☐

_____

6. What type of cigarettes are they?

a. Are they 1 ☐ filter tip or 2 ☐ non-filter tip?
b. Are they 1 ☐ plain or 2 ☐ menthol?
c. Are they 1 ☐ hard pack or 2 ☐ soft pack?
d. Are they 1 ☐ regular size (70 mm),
2 ☐ king size (85 mm),
3 ☐ 100 mm, or
4 ☐ 120 mm?
e. Are they 1 ☐ lights or 2 ☐ ultra lights or 3 ☐ regular?

7. Did you quit smoking (for at least 48 hours) at any time in the past 12 months?

1 ☐ yes

2 ☐ no → CONTINUE WITH QUESTION 10.

8. How many times in the past 12 months did you quit smoking (for at least 48 hours)?

1 ☐ one time
2 ☐ 2-3 times
3 ☐ 4-5 times
4 ☐ 6 or more times

9. What was the longest time you refrained from smoking in the past 12 months?

1 ☐ 48 hours to 7 days
2 ☐ 8 to 14 days
3 ☐ 15 days to one month
4 ☐ more than one month but less than 4 months
5 ☐ more than 4 months

Prepare the participant to answer this question by explaining that you are going to ask about his or her smoking behavior in the past year. Provide the participant with a calendar including months in the past year.

10. On the average, how many cigarettes per day did you smoke during each month of the past year?

[Begin with this month, one year ago. Proceed month by month through last month. Fill in the name of the month in the space between the number and the answer boxes.]
(e.g. If the annual visit is conducted in February, 1989, ask first about cigarettes per day in February 1988. Proceed asking about the months through January, 1989.)

Month		Month	
1 (one year ago):	☐☐☐ cigarettes/day	7 _____	☐☐☐ cigarettes/day
_____	☐☐☐ cigarettes/day	8 _____	☐☐☐ cigarettes/day
3	☐☐☐ cigarettes/day	9 _____	☐☐☐ cigarettes/day
_____	☐☐☐ cigarettes/day	10 _____	☐☐☐ cigarettes/day
5	☐☐☐ cigarettes/day	11 _____	☐☐☐ cigarettes/day
_____	☐☐☐ cigarettes/day	12 (last month): _____	☐☐☐ cigarettes/day

11. Are there other current cigarette smokers in your household?

1 ☐ yes → 12. Do they include:

a. your spouse? 1 ☐ yes 2 ☐ no
b. one or more of your children? 1 ☐ yes 2 ☐ no
c. others? 1 ☐ yes 2 ☐ no

13. Number of current cigarette smokers who live with you, NOT INCLUDING YOURSELF:

☐☐ smokers

2 ☐ no

14. Do you now smoke cigars or cigarillos?

1 ☐ yes → 15. How many cigars or cigarillos do you smoke daily?

1 ☐ less than one
2 ☐ 1 - 2 daily
3 ☐ 3 - 4 daily
4 ☐ 5 - 7 daily
5 ☐ 8 or more daily

2 ☐ no

16. Do you now smoke pipes?

1 ☐ yes → 17. How many bowls of tobacco do you smoke daily?

1 ☐ less than one
2 ☐ 1 - 2 daily
3 ☐ 3 - 4 daily
4 ☐ 5 - 7 daily
5 ☐ 8 or more daily

2 ☐ no

CONTINUE WITH QUESTION 18

18. Do you now use snuff or chewing tobacco?

1 ☐ yes → 19. How often do you use snuff or chewing tobacco?
- 1 ☐ less than once a day
- 2 ☐ 1 - 2 times daily
- 3 ☐ 3 - 4 times daily
- 4 ☐ 5 - 7 times daily
- 5 ☐ 8 or more times daily

2 ☐ no ↓

20. Indicate the extent to which you have been troubled in the past four months by any of the following. (Please indicate SEVERE, MODERATE, MILD, or NOT AT ALL):

	Severe	Moderate	Mild	Not at All
a. Belching	1 ☐	2 ☐	3 ☐	4 ☐
b. Blurring of vision	1 ☐	2 ☐	3 ☐	4 ☐
c. Chest discomfort	1 ☐	2 ☐	3 ☐	4 ☐
d. Constipation	1 ☐	2 ☐	3 ☐	4 ☐
e. Dizziness or lightheadedness	1 ☐	2 ☐	3 ☐	4 ☐
f. Dry mouth	1 ☐	2 ☐	3 ☐	4 ☐
g. Excessive salivation	1 ☐	2 ☐	3 ☐	4 ☐
h. Flatulence	1 ☐	2 ☐	3 ☐	4 ☐
i. Headache	1 ☐	2 ☐	3 ☐	4 ☐
j. Heart palpitation or rapid heart beat	1 ☐	2 ☐	3 ☐	4 ☐
k. Heat intolerance	1 ☐	2 ☐	3 ☐	4 ☐
l. Hiccups	1 ☐	2 ☐	3 ☐	4 ☐
m. Indigestion	1 ☐	2 ☐	3 ☐	4 ☐
n. Insomnia	1 ☐	2 ☐	3 ☐	4 ☐
o. Irritability	1 ☐	2 ☐	3 ☐	4 ☐
p. Jaw muscle ache	1 ☐	2 ☐	3 ☐	4 ☐
q. Loss of appetite	1 ☐	2 ☐	3 ☐	4 ☐
r. Mood changes	1 ☐	2 ☐	3 ☐	4 ☐
s. Vomiting blood	1 ☐	2 ☐	3 ☐	4 ☐
t. Mouth ulcers	1 ☐	2 ☐	3 ☐	4 ☐
u. Nausea or vomiting	1 ☐	2 ☐	3 ☐	4 ☐
v. Nervousness	1 ☐	2 ☐	3 ☐	4 ☐
w. Psychological illness or disturbance	1 ☐	2 ☐	3 ☐	4 ☐
x. Speech difficulties	1 ☐	2 ☐	3 ☐	4 ☐
y. Throat irritation	1 ☐	2 ☐	3 ☐	4 ☐
z. Urinary hesitancy or slowing	1 ☐	2 ☐	3 ☐	4 ☐
aa. Other,	1 ☐	2 ☐	3 ☐	4 ☐

Specify: _____ DCC USE ☐☐☐

ILLNESSES AND MEDICATIONS

NOTE: SI participants reporting serious illness on this page must be brought to the attention of an interventionist.

1. Since your last attended annual visit, have you been told by a physician that you have a peptic ulcer?

1 ☐ yes → 2. Was it confirmed by X-ray or gastroscopy?
1 ☐ yes 2 ☐ no 3 ☐ not sure

2 ☐ no

3. Since your last attended annual visit, have you been told by a physician that you have had any of the following?

		DCC USE
a. Lung cancer	1 ☐ yes 2 ☐ no	
b. Breast cancer	1 ☐ yes 2 ☐ no	
c. Other cancer, specify: _____	1 ☐ yes 2 ☐ no	☐☐☐.☐
d. Heart attack	1 ☐ yes 2 ☐ no	
e. Congestive heart failure (congestive heart disease)	1 ☐ yes 2 ☐ no	
f. Angina	1 ☐ yes 2 ☐ no	
g. Hypertension (high blood pressure)	1 ☐ yes 2 ☐ no	
h. Stroke	1 ☐ yes 2 ☐ no	
i. Glaucoma	1 ☐ yes 2 ☐ no	
j. Diabetes	1 ☐ yes 2 ☐ no	

SI Participants Only:
For new occurrences of these 3 conditions (since last visit) please have interventionist complete Form 86 and Form 87.

4. Have you undergone any of the following since your last attended annual visit?

		DCC USE
a. Coronary artery bypass	1 ☐ yes 2 ☐ no	
b. Coronary angioplasty	1 ☐ yes 2 ☐ no	
c. Installation of cardiac pacemaker	1 ☐ yes 2 ☐ no	
d. Surgery for lung cancer	1 ☐ yes 2 ☐ no	
e. Surgery for breast cancer	1 ☐ yes 2 ☐ no	
f. Other major surgery involving your chest, specify: _____	1 ☐ yes 2 ☐ no	☐☐☐.☐
g. Serious injury to your chest	1 ☐ yes 2 ☐ no	
h. Radiation treatment for any cancer	1 ☐ yes 2 ☐ no	
i. Other major surgery, specify: _____	1 ☐ yes 2 ☐ no	☐☐☐.☐

5. Have you been hospitalized since your last attended annual visit?*

1 ☐ yes →
6. Specify number of times hospitalized since your last attended annual visit?*
☐☐ times
7. Were you hospitalized for major chest surgery? 1 ☐ yes 2 ☐ no
8. Describe the reasons for hospitalization:
_____
_____

Complete Form 81, obtaining information on all hospital admissions since the last attended annual visit.*

DCC USE ☐☐☐.☐
DCC USE ☐☐☐.☐

2 ☐ no

CONTINUE WITH QUESTION 9.

* If no annual visits have been attended since randomization, ask "since randomization into this study

9 During the past 12 months*, have you seen or talked to a private physician because of conditions that affect your lungs or respiratory tract?

1 ☐ yes 2 ☐ no → GO TO QUESTION 10.

Check YES or NO for each. If YES, enter the number of times in the past 12 months* you consulted a doctor for the reason given.

a. Bronchitis	1 ☐ yes	2 ☐ no	☐☐ times
b. Pneumonia	1 ☐ yes	2 ☐ no	☐☐ times
c. Pleurisy	1 ☐ yes	2 ☐ no	☐☐ times
d. Emphysema	1 ☐ yes	2 ☐ no	☐☐ times
e. Tuberculosis	1 ☐ yes	2 ☐ no	☐☐ times
f. Asthma	1 ☐ yes	2 ☐ no	☐☐ times
g. Head cold	1 ☐ yes	2 ☐ no	☐☐ times
h. Influenza (flu)	1 ☐ yes	2 ☐ no	☐☐ times
i. Chest cold	1 ☐ yes	2 ☐ no	☐☐ times
j. Sore throat	1 ☐ yes	2 ☐ no	☐☐ times
k. Chest pain	1 ☐ yes	2 ☐ no	☐☐ times
l. Allergies affecting respiratory tract (including hay fever)	1 ☐ yes	2 ☐ no	☐☐ times
m. Lung cancer	1 ☐ yes	2 ☐ no	☐☐ times
n. Pulmonary embolism	1 ☐ yes	2 ☐ no	☐☐ times
o. Other respiratory illness (specify): _____	1 ☐ yes	2 ☐ no	☐☐ times

DCC USE ☐☐☐.☐

10 In the past 12 months* were you kept in bed for all or most of the day because of respiratory illness?

1 ☐ yes 2 ☐ no → GO TO QUESTION 11.

Check YES or NO for each. If YES, enter the number of days in the past 12 months* you were kept in bed for all or most of the day, for the reason given.

a. Bronchitis	1 ☐ yes	2 ☐ no	☐☐ days
b. Pneumonia	1 ☐ yes	2 ☐ no	☐☐ days
c. Pleurisy	1 ☐ yes	2 ☐ no	☐☐ days
d. Emphysema	1 ☐ yes	2 ☐ no	☐☐ days
e. Tuberculosis	1 ☐ yes	2 ☐ no	☐☐ days
f. Asthma	1 ☐ yes	2 ☐ no	☐☐ days

* Ask regarding occurrences in the past 12 months OR since the last attended annual visit, whichever is more recent.

g. Head cold 1 ☐ yes 2 ☐ no ☐☐ days

h. Influenza (flu) 1 ☐ yes 2 ☐ no ☐☐ days

i. Chest cold 1 ☐ yes 2 ☐ no ☐☐ days

j. Sore throat 1 ☐ yes 2 ☐ no ☐☐ days

k. Chest pain 1 ☐ yes 2 ☐ no ☐☐ days

l. Allergies affecting respiratory tract (including hay fever) 1 ☐ yes 2 ☐ no ☐☐ days

m. Lung cancer 1 ☐ yes 2 ☐ no ☐☐ days

n. Pulmonary embolism 1 ☐ yes 2 ☐ no ☐☐ days

o. Other respiratory illness (specify): 1 ☐ yes 2 ☐ no ☐☐ days

DCC USE ☐☐☐.☐

_____

The following questions are best answered by examining pill bottles or drug containers brought in by the participant. If no containers have been brought in, ask the participant to recall the names of drugs taken in the past month and in the past year, but not in the past month. Refer to the Drug List in Appendix 7-B of the M.O.P. to classify drugs.

11. Have you taken any prescription medications in the past 12 months*?

1 ☐ yes 2 ☐ no → **GO TO QUESTION 18.**

[Note: names of prescribed aerosol inhalers are recorded in question 13, other drugs (not included below) in question 17.]

12. Have any of the following drugs been taken by the participant in the past 12 months*?

	Yes, within past month	Within past year, but not in past month	No
a. MDI: theophylline or other xanthines	1 ☐	2 ☐	
b. Other MDI prescribed bronchodilators in tablet form	1 ☐	2 ☐	
c. Beta-blockers	1 ☐	2 ☐	3 ☐
d. Calcium channel blockers	1 ☐	2 ☐	3 ☐
e. Ventolin	1 ☐	2 ☐	
f. Systemic or inhaled corticosteroids	1 ☐	2 ☐	
g. Nitroglycerin or other nitrates (for angina)	1 ☐	2 ☐	3 ☐
h. Digitalis	1 ☐	2 ☐	3 ☐
i. Anticoagulants	1 ☐	2 ☐	
j. Antiarrhythmics	1 ☐	2 ☐	
k. Anticancer drugs (chemotherapy)	1 ☐	2 ☐	3 ☐

For SI participants: The LHS physician and the intervention director must be notified if any of the above are currently being taken.

* Ask regarding drugs used in the past 12 months OR since the last attended annual visit, whichever is more recent

13. Are you now using an aerosol inhaler prescribed by a physician? (For SI participants, do NOT include the LHS-assigned inhaler.)

1 ☐ yes → Specify drug(s): _____ DCC USE ☐☐☐

_____ DCC USE ☐☐☐

2 ☐ no

14. About how often do you use an aerosol inhaler?

1 ☐ 3 or more times a day
2 ☐ 2 times a day
3 ☐ once a day
4 ☐ one or more times per week
5 ☐ less than once a week

15. How many puffs per time? ☐ puffs

16. Have you used an aerosol inhaler prescribed by a physician in the past 12 months*? (For SI participants, do NOT include the LHS-assigned inhaler.)

1 ☐ yes 2 ☐ no

17. Have you taken any other prescription drugs (not mentioned above) in the past month?

1 ☐ yes → Specify drug(s): _____ DCC USE ☐☐☐

_____ DCC USE ☐☐☐

_____ DCC USE ☐☐☐

2 ☐ no

18. In the past month, have you taken any non-prescription medications such as Bronkaid Mist, Primatene Mist, Bronkaid Tablets, Primatene Tablets, Bronko-Tabs, Asthma-Haler, Asthma-Nefrin, or Medi-Haler for chest congestion, wheezing, asthma or other lower respiratory problem?

1 ☐ yes → Specify medication: _____ DCC USE ☐☐☐

2 ☐ no

19. Do you drink alcoholic beverages (beer, liquor, or wine)?

1 ☐ yes →

20. How many days per week, on the average, do you drink alcoholic beverages? (Answer one of the following.)

a. 1 ☐ less than one day per week OR b. ☐ days per week

21. On days that you drink alcohol, how many drinks do you have, on the average?

☐☐ drinks per day

2 ☐ no

CONTINUE WITH QUESTION 22.

* Ask regarding prescribed aerosol inhalers used in the past 12 months OR since the last attended annual visit, whichever is more recent.

22. Have you used chewing tobacco or snuff in the past 24 hours? 1 ☐ yes 2 ☐ no

23. Have you used nicotine gum in the past 24 hours? 1 ☐ yes 2 ☐ no

24. Was an appointment scheduled with the participant for the next follow-up visit?

1 ☐ yes → 25. Date scheduled: ☐☐-☐☐-☐☐ (Month Day Year)

2 ☐ no

ID Code ☐☐☐

26. Interviewer: _____ (Name)

ID Code ☐☐☐

27. Clinic Coordinator: _____ (Name)

NOTE: Information obtained on LHS forms must be based on an interview at an LHS clinic if possible. It is permissible to obtain this information by a telephone interview ONLY IF:

a) The participant ABSOLUTELY REFUSES to come in to the clinic, or

b) The participant CANNOT come to the clinic because of serious illness or inability to travel.

In ONLY SPECIAL CASES may the information be obtained by an interview with someone other than the participant.

28. Was the information on this form obtained by:

1 ☐ an interview conducted during clinic visit?

2 ☐ telephone interview with the participant?

3 ☐ an interview with the participant conducted at a non-clinic site (i.e., participant's home or work place)?

4 ☐ proxy due to special circumstances?

Section 11.4.3. of the M.O.P. should be consulted for details of these special circumstances.

COMPLETE MISSED VISIT FORM 65. Explain why the participant did not come in to the clinic:

_____

_____

_____

_____

_____

Appendix C: Third Screen Examination Form

LUNG HEALTH STUDY

THIRD SCREEN EXAMINATION FORM

Attach ID Label Here

DCC USE

Date Received :

Form Seq. No.:

Participant ID : ☐-☐☐☐☐☐-☐-☐☐☐☐

Date of Exam : ☐☐-☐☐-☐☐ (Month Day Year)

This examination must be completed no less than 10, and no more than 90 days from the date of the second screen examination.

Participant's name: _____
(Print) First Middle Last

i. Has a consent form for the Third Screen Visit been signed by the screenee?

1☐ yes 2☐ no → **STOP: The screenee must sign the Third Screen consent form before continuing with this visit.**

Carbon monoxide measurement is optional at this visit.

1. Expired Carbon Monoxide

   a. Estimated time since last cigarette: ☐☐:☐☐:☐☐ (Days Hours Minutes)

   b. Background CO: ☐☐☐ ppm

   c. Technician's Code: ☐☐☐

   d. Trial 1 results: ☐☐☐ ppm

   e. Trial 2 results: ☐☐☐ ppm

---

2. Birthdate: ☐☐-☐☐-☐☐ (Month Day Year)

3. Name, address, phone number of two friends or relatives who do not live with you, but who will probably always know how to contact you.

   a. Name: _____

   Address: _____
   Street No. Apt. No.

   City: _____ State/Province: _____

   Zip Code/Mail Code: _____

   ☐☐☐-☐☐☐-☐☐☐☐ (Home) Area code

   ☐☐☐-☐☐☐-☐☐☐☐ (Work) Area code

   b. Name: _____

   Address: _____
   Street No. Apt. No.

   City: _____ State/Province: _____

   Zip Code/Mail Code: _____

   ☐☐☐-☐☐☐-☐☐☐☐ (Home) Area code

   ☐☐☐-☐☐☐-☐☐☐☐ (Work) Area code

MEDICAL EXCLUSION CRITERIA

4. Have you seen a physician for health reasons since the last screening visit?

1☐ yes → 5. We are going to ask you some questions on medical problems that you may have now or may have had in the past. Some of these conditions have effects on lung function and could interfere with your participation in the study.
[Questions to be asked by a trained interviewer. EXC denotes mandatory EXCLUSION.]

2☐ no

Have you ever been told by a doctor that you have had -:

a. Lung cancer 1☐ yes → EXC 2☐ no

b. Other cancer 1☐ yes 2☐ no

Specify type, site: _____ DCC USE ☐☐☐.☐

Result: 1☐ → EXC 2☐ Eligible Physician's initials: ☐☐☐

c. Heart attack within the past two years (myocardial infarction, coronary occlusion, coronary thrombosis) 1☐ yes → EXC 2☐ no

d. Angina 1☐ yes → EXC 2☐ no

e. Heart failure (congestive heart failure or congestive heart disease) 1☐ yes → EXC 2☐ no

f. Stroke within the past two years 1☐ yes → EXC 2☐ no

g. Renal failure (kidney failure) 1☐ yes → EXC 2☐ no

h. Cirrhosis or other serious chronic liver disease 1☐ yes → EXC 2☐ no

i. Diabetes requiring insulin injection or pump 1☐ yes → EXC 2☐ no

j. Pulmonary aneurism (blood vessel in lung) 1☐ yes → EXC 2☐ no

k. Chronic nervous system disease (such as multiple sclerosis, myasthenia gravis, Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis) 1☐ yes → EXC 2☐ no

l. Narrow angle glaucoma (increased pressure within the eye) 1☐ yes → EXC 2☐ no

m. Other major disease (including psychological illness) 1☐ yes 2☐ no

Specify type, site: _____ DCC USE ☐☐☐.☐

Result: 1☐ → EXC 2☐ Eligible Physician's initials: ☐☐☐

n. Are you taking medicine for active tuberculosis? 1☐ yes → EXC 2☐ no

o. Have you ever had major surgery involving opening your chest cavity? 1☐ yes → EXC 2☐ no

For female participants, go to question 6.

For male participants, go to question 9.

6. (If female) Are you pregnant? 1☐ yes → EXC 2☐ no

7. (If female) Are you nursing? 1☐ yes → EXC 2☐ no

8. (If female) Do you intend to become pregnant in the next five years? 1☐ yes or probably → EXC 2☐ no or not sure

If possible, the following questions should be answered by examining pill bottles or other drug containers that the participant has brought in.

9. Have you started taking any prescription drugs since the last visit? (If unsure as to when started, answer yes.)

1☐ yes → 10.
2☐ no

Names of drugs taken by the participant are compared to names on the DRUG EXCLUSION LIST to determine the drug category. Prescription drugs not on the list are recorded in the box following item l.

Have any of the following drugs been taken by the participant in the past month?
[EXC denotes mandatory EXCLUSION]

	Has taken In past month	Has NOT taken In past month
a. MD prescribed inhaled bronchodilators	1☐ yes → EXC	2☐ no
b. MD prescribed theophylline or other xanthines	1☐ yes → EXC	2☐ no
c. Other MD prescribed bronchodilators	1☐ yes → EXC	2☐ no
d. Beta-blockers	1☐ yes → EXC	2☐ no
e. Insulin	1☐ yes → EXC	2☐ no
f. Systemic or inhaled corticosteroids	1☐ yes → EXC	2☐ no
g. Antipsychotic drugs	1☐ yes → EXC	2☐ no
h. Nitroglycerine (for angina)	1☐ yes → EXC	2☐ no
i. Digitalis (for heart disease)	1☐ yes → EXC	2☐ no
j. Anticoagulants (for blood clots)	1☐ yes → EXC	2☐ no
k. Antiarrhythmics (for heart rhythm disorders)	1☐ yes → EXC	2☐ no
l. Other MD prescribed medications	1☐ yes	2☐ no

DCC USE
Specify: _____ ☐☐☐

DCC USE
Specify: _____ ☐☐☐

Result: 1☐ → EXC 2☐ Eligible Physician's initials: ☐☐☐

Explain: (If the screenee is taking a drug on the DRUG EXCLUSION LIST, but is classified as eligible, please explain.)

DCC USE
_____ ☐
_____

11. Have you ever had an allergic reaction to atropine? 1☐ yes → EXC 2☐ no

12. Have you ever had an allergic reaction to bromine or bromide medications? 1☐ yes → EXC 2☐ no

13. In the past three months, have you had a peptic ulcer which was confirmed by x-ray or gastroscopy?

1☐ yes 2☐ no

To obtain the following answer, the interviewer must refer to the participant's second screen form (Form 20). Do not directly ask the participant this question.

14. Was the participant's second diastolic blood pressure measurement at Second Screen over 95 mm Hg?

1☐ yes →

2☐ no

15. Resting seated blood pressure measurement (mm Hg).

The participant must be quiet and remain in a seated position five minutes before and during the measurements. During the measurement of blood pressure there should be no change in the position of the participant.

	First Measurement	Second Measurement
Systolic:	☐☐☐	☐☐☐
Diastolic:	☐☐☐	☐☐☐

EXCLUDE IF SECOND MEASUREMENT SBP > 160 OR SECOND MEASUREMENT DBP > 95

16. Is the spouse (or other household member) of this person a randomized participant in the Lung Health Study?

1☐ yes → EXC

2☐ no

17. Discretionary exclusion: Is there any reason other than those already noted on this form for which this person should be excluded from the trial?

1☐ yes → EXC

Specify: _____ DCC USE ☐☐☐

2☐ no

SUMMARY

1. Is this participant eligible to continue the Third Screen examination?

1☐ yes 2☐ no

2. Primary Interviewer: _____ ID Code ☐☐☐
Name or Initials

3. Clinic Coordinator: _____ ID Code ☐☐☐
Name or Initials

Appendix D: Third Screen Questionnaire

LUNG HEALTH STUDY
THIRD SCREEN QUESTIONNAIRE

Attach ID Label Here

DCC USE

Date Received :

Form Seq. No.:

Participant ID: ☐-☐☐☐☐☐-☐-☐☐☐☐

Date of Exam: ☐☐-☐☐-☐☐
Month Day Year

Participant's name: _____
(Print) First Middle Last

DEMOGRAPHIC INFORMATION

1. What is your marital status?

   1 ☐ never married
   2 ☐ married
   3 ☐ widowed
   4 ☐ separated
   5 ☐ divorced

2. What is the highest grade completed in school?

   1 ☐ eighth grade or less
   2 ☐ trade school or business school instead of high school
   3 ☐ some high school
   4 ☐ high school graduate
   5 ☐ trade school or business school after graduating from high school
   6 ☐ some college
   7 ☐ received bachelor's degree
   8 ☐ graduate or professional program toward the bachelor's degree
   9 ☐ graduate or professional degree,
   (Specify): _____

3. Father's surname (last name): _____
(Print)

4. Do you consider yourself: 1 ☐ Hispanic or 2 ☐ non-Hispanic?

SYMPTOM HISTORY

These questions pertain mainly to your chest. Please answer YES or NO if possible. [If you are in doubt about whether your answer is YES or NO, answer NO.]

COUGH

1a. Do you usually have a cough? (Count a cough with first smoke or on first going out-of-doors. Exclude clearing of throat.) [If NO, skip to 1c.] 1 ☐ yes 2 ☐ no

b. Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week? 1 ☐ yes 2 ☐ no

c. Do you usually cough at all on getting up, or first thing in the morning? 1 ☐ yes 2 ☐ no

d. Do you usually cough at all during the rest of the day or at night? 1 ☐ yes 2 ☐ no

If YES to any of the above (1a, b, c, d), answer the following. If NO to all, skip to question 2a.

e. Do you usually cough like this on most days for 3 consecutive months or more during the year? 1 ☐ yes 2 ☐ no

f. For how many years have you had this cough? ☐☐ years

PHLEGM

2a. Do you usually bring up phlegm from your chest? (Count phlegm with the first smoke or on first going out-of-doors. Exclude phlegm from the nose. Count swallowed phlegm.) [If NO, skip to 2c.] 1 ☐ yes 2 ☐ no

b. Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? 1 ☐ yes 2 ☐ no

c. Do you usually bring up phlegm at all on getting up, or first thing in the morning? 1 ☐ yes 2 ☐ no

d. Do you usually bring up phlegm at all during the rest of the day or at night? 1 ☐ yes 2 ☐ no

If YES to any of the above (2a, b, c, d), answer the following. If NO to all, skip to question 3a.

e. Do you usually bring up phlegm like this on most days for 3 consecutive months or more during the year? 1 ☐ yes 2 ☐ no

f. For how many years have you had trouble with phlegm? ☐☐ years

EPISODES OF COUGH AND PHLEGM

3a. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year? 1 ☐ yes 2 ☐ no
*(For persons who usually have cough and/or phlegm)

If YES to 3a:

b. For how long have you had at least 1 such episode per year? ☐☐ years

WHEEZING

4a. Does your chest ever sound wheezy or whistling:

1. when you have a cold? 1 ☐ yes 2 ☐ no
2. occasionally apart from colds? 1 ☐ yes 2 ☐ no
3. most days or night? 1 ☐ yes 2 ☐ no

If YES to any of above in 4a:

b. For how many years has this been present? ☐☐ years

5a. Have you ever had an attack of wheezing that has made you feel short of breath? 1 ☐ yes 2 ☐ no

If YES to 5a:

b. How old were you when you had your first such attack? ☐☐ years

c. Have you had 2 or more such episodes? 1 ☐ yes 2 ☐ no

d. Have you ever required medicine or treatment for the(se) attack(s)? 1 ☐ yes 2 ☐ no

BREATHLESSNESS

6. Is the participant disabled from walking by any condition other than heart or lung disease? If YES, please describe and proceed to question 8a. 1 ☐ yes 2 ☐ no

   Nature of condition(s): _____

   _____

7a. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill? 1 ☐ yes 2 ☐ no

If YES to 7a:

b. Do you have to walk slower than people of your age on the level because of breathlessness? 1 ☐ yes 2 ☐ no

c. Do you ever have to stop for breath when walking at your own pace on the level? 1 ☐ yes 2 ☐ no

d. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level? 1 ☐ yes 2 ☐ no

e. Are you too breathless to leave the house or breathless on dressing or undressing? 1 ☐ yes 2 ☐ no

f. For how many years have you been this short of breath? ☐☐ years

CHEST COLDS AND CHEST ILLNESSES

8a. How often do you get colds?

1 ☐ never
2 ☐ once a year
3 ☐ 2-4 times per year
4 ☐ 5 or more times per year

b. If you get a cold, does it usually go to your chest? ("Usually" means more than 1/2 the time.) 1 ☐ yes 2 ☐ no 3 ☐ I don't get colds

9a. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed? 1 ☐ yes 2 ☐ no

If YES to 9a:

b. Did you produce phlegm with any of these chest illnesses? 1 ☐ yes 2 ☐ no

c. In the last 3 years, how many such illnesses, with (increased) phlegm, did you have which lasted a week or more? ☐☐ No. of illnesses

PAST ILLNESSES

10. Did you have any lung trouble before the age of 16? 1 ☐ yes 2 ☐ no

11. Have you ever had any of the following?

a. Attacks of bronchitis 1 ☐ yes 2 ☐ no

If YES to 11a:

1) Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

2) At what age was your first attack? ☐☐ years

b. Pneumonia (include bronchopneumonia) 1 ☐ yes 2 ☐ no

If YES to 11b:

1) Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

2) At what age did you first have it? ☐☐ years

c. Hay Fever 1 ☐ yes 2 ☐ no

If YES to 11c:

1) Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

2) At what age did it start? ☐☐ years

12a. Have you ever had Chronic Bronchitis? 1 ☐ yes 2 ☐ no

If YES to 12a:

b. Do you still have it? 1 ☐ yes 2 ☐ no

c. Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

d. At what age did it start? ☐☐ years

13a. Have you ever had Emphysema? 1 ☐ yes 2 ☐ no

If YES to 13a:

b. Do you still have it? 1 ☐ yes 2 ☐ no

c. Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

d. At what age did it start? ☐☐ years

14a. Have you ever had Asthma? 1 ☐ yes 2 ☐ no

If YES to 14a:

b. Do you still have it? 1 ☐ yes 2 ☐ no

c. Was it confirmed by a doctor? 1 ☐ yes 2 ☐ no

d. At what age did it start? ☐☐ years

e. If you no longer have it, at what age did it stop? ☐☐ years

15. Have you ever had:

a. Any other chest illness? 1 ☐ yes 2 ☐ no
If yes, please specify: _____

b. Any chest operations? 1 ☐ yes 2 ☐ no
If yes, please specify: _____

c. Any chest injuries? 1 ☐ yes 2 ☐ no
If yes, please specify: _____

16a. Has a doctor ever told you that you had heart trouble? 1 ☐ yes 2 ☐ no

If YES to 16a:

b. Have you ever had treatment for heart trouble in the past 10 years? 1 ☐ yes 2 ☐ no

17a. Has a doctor ever told you that you had high blood pressure? 1 ☐ yes 2 ☐ no

If YES to 17a:

b. Have you had any treatment for high blood pressure (hypertension) in the past 10 years? 1 ☐ yes 2 ☐ no

OCCUPATIONAL HISTORY

Have you ever worked for 3 months or more at any of the following?

	Check Yes or No for each	*Number of years worked (If less than 1, enter "0")*
1. Hard-rock mining	1 ☐ yes 2 ☐ no	☐☐ years
2. Coal mining	1 ☐ yes 2 ☐ no	☐☐ years
3. Sandblasting	1 ☐ yes 2 ☐ no	☐☐ years
4. Working with asbestos	1 ☐ yes 2 ☐ no	☐☐ years
5. Chemical or plastics manufacturing	1 ☐ yes 2 ☐ no	☐☐ years
6. Flour, feed or grain milling	1 ☐ yes 2 ☐ no	☐☐ years
7. Cotton or jute processing	1 ☐ yes 2 ☐ no	☐☐ years
8. Foundry or steel milling	1 ☐ yes 2 ☐ no	☐☐ years
9. Welding	1 ☐ yes 2 ☐ no	☐☐ years
10. Fire fighting	1 ☐ yes 2 ☐ no	☐☐ years
11. Other jobs involving regular exposure to dust or fumes	1 ☐ yes 2 ☐ no	

Describe: a. _____ DCC USE ☐☐☐ ☐☐ years

_____

_____

b. _____ DCC USE ☐☐☐ ☐☐ years

_____

_____

12. In your present job, are you regularly exposed to:

a. dust 1 ☐ yes 2 ☐ no
b. fumes 1 ☐ yes 2 ☐ no

13. Do you usually wear a mask or respirator at your present work?

1 ☐ yes 2 ☐ no

14. What has been your usual occupation or job -- the one you have worked at the longest? DCC USE ☐☐☐

a. Job or occupation: _____

b. Number of years employed in this occupation: ☐☐ years

c. Position or job title: _____

d. Business, field, or industry: _____

15. What is your current or most recent job?

DCC USE ☐☐☐

a. Job or occupation: _____

b. Number of years employed in this occupation: ☐☐ years

c. Position or job title: _____

d. Business, field, or industry: _____

e. Are you still employed at this job?

1 ☐ yes, full time _____

2 ☐ yes, part time _____

3 ☐ no

f. If not working at this job, at what age did you last work at it?

☐☐ years of age

SMOKING HISTORY

1. Do you now smoke cigarettes?

1 ☐ yes

2 ☐ no → 2. How long has it been since you last smoked cigarettes? (check one)

1 ☐ one week or less
2 ☐ more than a week but less than a month
3 ☐ one to two months
4 ☐ more than two months

3. At what age did you first become a daily cigarette smoker? ☐☐ years

4. On the average, about how many cigarettes do you now smoke a day? ☐☐☐ cigarettes/day

5. Do you inhale the cigarette smoke?

1 ☐ not applicable (not currently a cigarette smoker)
2 ☐ not at all
3 ☐ slightly
4 ☐ moderately
5 ☐ deeply

DCC USE ☐☐☐

6. What is the full name of your current brand of cigarettes? _____

7. What type of cigarettes are they?

a. [redacted]
b. Are they 1 ☐ plain or 2 ☐ menthol?
c. [redacted]
d. Are they 1 ☐ regular size (70 mm),
2 ☐ king size (85 mm),
3 ☐ 100 mm, or
4 ☐ 120 mm?
e. [redacted]

8. On the average, of the entire time you smoked, how many cigarettes did you smoke per day?

☐☐☐ cigarettes/day

9. Have you ever made a serious attempt to quit smoking (that is, given up smoking cigarettes for at least 24 hours)?

1 ☐ yes → 10. How many times have you made a serious attempt to quit smoking?

1 ☐ one time
2 ☐ two times
3 ☐ three times
4 ☐ four or more times

11. The last time you stopped, was it:

1 ☐ extremely difficult
2 ☐ difficult
3 ☐ easy

12. What was the longest period of time you ever stayed off cigarettes?

1 ☐ less than 1 week
2 ☐ 1-4 weeks
3 ☐ 1-6 months
4 ☐ 7 months to 1 year
5 ☐ over 1 year

2 ☐ no

13. Do you smoke cigars or cigarillos?

1 ☐ yes → 14. How many cigars or cigarillos do you smoke daily?

1 ☐ less than one
2 ☐ 1-2 daily
3 ☐ 3-4 daily
4 ☐ 5-7 daily
5 ☐ 8 or more daily

2 ☐ no

15. Do you smoke pipes?

1 ☐ yes → 16. How many bowls of tobacco do you smoke daily?

1 ☐ less than one
2 ☐ 1-2 daily
3 ☐ 3-4 daily
4 ☐ 5-7 daily
5 ☐ 8 or more daily

2 ☐ no

17. Do you use snuff or chewing tobacco?

1 ☐ yes → 18. How often do you use snuff or chewing tobacco?

1 ☐ less than once a day
2 ☐ 1-2 times daily
3 ☐ 3-4 times daily
4 ☐ 5-7 times daily
5 ☐ 8 or more times daily

2 ☐ no

19. Have you ever used nicotine gum (Nicorette)?

1 ☐ yes → 20. Do you currently use nicotine gum?
1 ☐ yes 2 ☐ no

21. (If yes) How many pieces of nicotine gum do you use per day?

☐☐ pieces/day

22. When did you last use nicotine gum?

1 ☐ within past month
2 ☐ more than a month ago

2 ☐ no ↓

23. Are there other cigarette smokers in your household?

1 ☐ yes → 24. Do they include:

a. your spouse? 1 ☐ yes 2 ☐ no
b. one or more of your children? 1 ☐ yes 2 ☐ no
c. others? 1 ☐ yes 2 ☐ no

25. Total number of cigarette smokers who live with you, NOT INCLUDING YOURSELF:

☐☐ smokers

2 ☐ no ↓

26. Would your spouse (or closest friend, if not married) like you to give up smoking?

1 ☐ yes
2 ☐ not sure
3 ☐ probably doesn't care
4 ☐ no
5 ☐ not applicable

GENERAL HEALTH QUESTIONS

1. Has anyone in your immediate family (parent, brother, sister, or child) been told by a physician that he or she has asthma, hay fever, chronic bronchitis, emphysema, or lung cancer?

1 ☐ yes → 2. Please specify (check NO if unknown):

	Asthma		Hay fever		Chronic Bronchitis		Emphysema		Lung Cancer	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Mother	1 ☐	2 ☐			1 ☐	2 ☐			1 ☐	2 ☐
Father	1 ☐	2 ☐			1 ☐	2 ☐			1 ☐	2 ☐
Sibling(s)	1 ☐	2 ☐			1 ☐	2 ☐			1 ☐	2 ☐
Child(ren)	1 ☐	2 ☐			1 ☐	2 ☐			1 ☐	2 ☐

2 ☐ no ↓

3. During the past 12 months, have you seen or talked to a private physician because of respiratory illness?

1 ☐ yes 2 ☐ no

4. Check YES or NO for each. If YES, enter the number of times in the past 12 months you consulted a doctor for the reason given.

a. Bronchitis	1 ☐ yes 2 ☐ no	☐☐ times
b. Pneumonia	1 ☐ yes 2 ☐ no	☐☐ times
c. Pleurisy	1 ☐ yes 2 ☐ no	☐☐ times
d. Emphysema	1 ☐ yes 2 ☐ no	☐☐ times
e. Tuberculosis	1 ☐ yes 2 ☐ no	☐☐ times
f. Asthma	1 ☐ yes 2 ☐ no	☐☐ times
g. Head cold	1 ☐ yes 2 ☐ no	☐☐ times
h. Influenza (flu)	1 ☐ yes 2 ☐ no	☐☐ times
i. Chest cold	1 ☐ yes 2 ☐ no	☐☐ times
j. Sore throat	1 ☐ yes 2 ☐ no	☐☐ times
k. Chest pain	1 ☐ yes 2 ☐ no	☐☐ times
l. Allergies affecting respiration, incl. breathing, hay fever	1 ☐ yes 2 ☐ no	☐☐ times
m. Other respiratory illness, specify: _____	1 ☐ yes 2 ☐ no	☐☐ times

5. Have you been hospitalized during the past 12 months?

1 ☐ yes → 6. Specify the number of times hospitalized in the past year: ☐☐ times

2 ☐ no

7. Describe reasons for the hospitalization(s):

_____

_____

_____

DCC USE

☐☐☐.☐

☐☐☐.☐

☐☐☐.☐

8. During the past 12 months, were you kept in bed for all or most of the day because of respiratory illness?

1 ☐ yes 2 ☐ no

9. Check YES or NO for each. If YES, enter the number of days in the past 12 months you were kept in bed for all or most of the day, for the reason given.

a. Bronchitis	1 ☐ yes 2 ☐ no	☐☐ days
b. Pneumonia	1 ☐ yes 2 ☐ no	☐☐ days
c. Pleurisy	1 ☐ yes 2 ☐ no	☐☐ days
d. Emphysema	1 ☐ yes 2 ☐ no	☐☐ days
e. Tuberculosis	1 ☐ yes 2 ☐ no	☐☐ days
f. Asthma	1 ☐ yes 2 ☐ no	☐☐ days
g. Head cold	1 ☐ yes 2 ☐ no	☐☐ days
h. Influenza (flu)	1 ☐ yes 2 ☐ no	☐☐ days
i. Chest cold	1 ☐ yes 2 ☐ no	☐☐ days
j. Sore throat	1 ☐ yes 2 ☐ no	☐☐ days
k. Chest pain	1 ☐ yes 2 ☐ no	☐☐ days
l. Allergies affecting respiratory tract (hay fever)	1 ☐ yes 2 ☐ no	☐☐ days
m. Other respiratory illness, specify: _____	1 ☐ yes 2 ☐ no	☐☐ days

10. Indicate the extent to which you have been troubled in the past 3 months by any of the following: (Please indicate SEVERE, MILD, or NOT AT ALL.)

	Severe	*Mild*	*Not at All*
a) Belching	1 ☐	2 ☐	3 ☐
b) Blurring of vision	1 ☐	2 ☐	3 ☐
c) Chest discomfort	1 ☐	2 ☐	3 ☐
d) Constipation	1 ☐	2 ☐	3 ☐
e) Dizziness or lightheadedness	1 ☐	2 ☐	3 ☐
f) Dry mouth	1 ☐	2 ☐	3 ☐
g) Excessive salivation	1 ☐	2 ☐	3 ☐
h) Heartburn	1 ☐	2 ☐	3 ☐
i) Headache	1 ☐	2 ☐	3 ☐
j) Heart palpitation or rapid heart beat	1 ☐	2 ☐	3 ☐

		Severe	Mild	Not at All
k)	Heat intolerance	1 ☐	2 ☐	3 ☐
l)	Hiccups	1 ☐	2 ☐	3 ☐
m)	Indigestion	1 ☐	2 ☐	3 ☐
n)	Insomnia	1 ☐	2 ☐	3 ☐
o)	Irritability	1 ☐	2 ☐	3 ☐
p)	Jaw muscle ache	1 ☐	2 ☐	3 ☐
q)	Loss of appetite	1 ☐	2 ☐	3 ☐
r)	Mood changes	1 ☐	2 ☐	3 ☐
s)	Mouth irritation	1 ☐	2 ☐	3 ☐
t)	Mouth ulcers	1 ☐	2 ☐	3 ☐
u)	Nausea or vomiting	1 ☐	2 ☐	3 ☐
v)	Nervousness	1 ☐	2 ☐	3 ☐
w)	Psychological illness or disturbance	1 ☐	2 ☐	3 ☐
x)	Speech difficulties	1 ☐	2 ☐	3 ☐
y)	Tooth irritation	1 ☐	2 ☐	3 ☐
z)	Urinary hesitancy or slowing	1 ☐	2 ☐	3 ☐
aa)	Other, Specify: _____	1 ☐	2 ☐	3 ☐

DCC USE ☐☐☐

11. Interviewer: _____ ID Code ☐☐☐
Name

12. Clinic coordinator: _____ ID Code ☐☐☐
Name

Appendix E: Schedule of Group Intervention Sessions

8.2.3.10. Schedule of Group Intervention Sessions

The following are session outlines for the intensive intervention group sessions. It is generally understood that individual centers will choose to provide additional materials in the sessions and/or modify existing handouts. Session topics, such as Coping With Tension, Relaxation Training, and Weight Control may be rearranged to respond to specific group needs. The following are guidelines for group programs that are to be adhered to across centers:

- Quit day is scheduled for the initial session after Orientation.
- Sessions 1, 2, 3 and 4 are to be scheduled on consecutive days.
- Eleven sessions are scheduled for each group. Cancellations are not acceptable - if only one group member can attend, the group meeting dates should be maintained.

1) Sessions 1-4: INITIAL CESSATION WEEK

These four consecutive sessions are designed to provide participants with coping strategies for use during initial smoking cessation when withdrawal symptoms are strongest. Additionally, daily monitoring of nicotine gum and inhaler use will establish compliance early in the Trial.

a) Session 1: QUIT DAY

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review homework assigned at the orientation meeting.

Discussion and small group activities: Review of smoking cessation program, schedule and content; instructions for gum use, demonstration of chewing techniques, and distribution of gum.

Review strategies for preventing and eliminating urges to smoke; substitution activities; discard smoking paraphernalia.

Demonstration: Instructions for inhaler use; demonstration of proper use; individual monitoring of each participant to ensure that proper methods are used.

Assignments & Review: Measures review, homework assignments, self-monitoring form use.

MATERIALS: (See Appendix 8-B, Session 1 materials)

Slides: Using Nicotine Gum; Using Inhaler.

Handouts: Preventing Cigarette Urges; Eliminating Cigarette Urges; Instructions for Using Nicotine Gum; Instructions for Using Inhaler.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

b) Session 2: COPING STRATEGIES TO PREVENT RELAPSE: COGNITIVE TECHNIQUES

ACTIVITIES:

Measures: Expired CO; weight; withdrawal symptom checklist; record of gum and bronchodilator use; distribution of gum; homework check.

Discussion and small group activities: Brief presentation followed by discussion on family support and/or buddy system, with suggestions for support that are most effective for smoking cessation.

Discussion of cognitive coping strategies for dealing with the changes accompanying smoking cessation; using positive self-statements; imagery, relaxation exercises.

Assignments & Review: Measures review, homework assignments.

MATERIALS:

Slides: Smoking Slogans, Cigarette Advertising.

Handouts: "Understanding Cigarette Urges"

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

c) Session 3: HEALTH BENEFITS OF QUITTING; SELF-REWARDS

ACTIVITIES:

Measures: Expired CO; weight; withdrawal symptom checklist; record of gum and bronchodilator use; distribution of gum; homework check.

Discussion and small group activities: Short lecture - Benefits of Quitting Smoking, immediate, longterm and life-saving benefits from quitting cigarettes.

Complete worksheet on self-rewards for changing the smoking habit.

Assignments & Review: Measures review, homework assignments.

MATERIALS:

Handouts: Quitting Games; Risks of Smoking, Benefits of Quitting; Self-rewards.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

d) Session 4: MAINTAINING NON-SMOKING

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum; homework check.

Discussion and small group activities: A brief review of "Why People Relapse"; complete worksheet on high risk situations.

Short lecture on behavioral and cognitive techniques for preventing relapse to smoking.

Complete a self-assessment of coping skills.

MATERIALS:

Slides: Relapse Slides

Handouts: High Risk Situations; List of Coping Responses

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

2) Sessions 5-11: MAINTAINING SMOKING CESSATION

These sessions are scheduled as follows:

i) Week 2 (Sessions 5 and 6).

ii) Weeks 3,4 (Sessions 7,8, held weekly).

iii) Weeks 6,8,12 (Sessions 9,10,11)

Sessions 5 to 11 will provide the participant with strategies for remaining abstinent from cigarettes long term. Carbon monoxide measurements collected at these meetings are used to provide participants with evidence of immediate benefits from smoking cessation.

a) Session 5: COPING WITH TENSION

ACTIVITIES:

Measures: Collect expired CO; weight; withdrawal symptom checklist; record of gum and bronchodilator use; distribution of gum.

Discussion and small group activities: Group discussion; coping techniques which have been effective in high risk situations and continuing problem situations.

Assignments & Review: Monitor coping strategies for one week; practice using coping self-statements.

MATERIALS:

Handouts: Five Stress Coping Strategies; Coping Skills Self-Assessment; Examples of Coping Self-Statements.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

b) Session 6: WEIGHT CONTROL

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum; homework check.

Discussion and small group activities: Review high risk situations for smoking and discuss coping strategies that were used most often in those situations.

Introduce topic of weight control by asking each individual to calculate any weight changes since stopping smoking.

Review calorie counts from different types of restaurants and suggestions for eating calorie conscious meals.

Assignments & Review: Assignment is to complete a 3 day food record.

MATERIALS:

Handouts: Eating Out Wisely; Food Record Forms; Energy Intake.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

c) Session 7: RELAXATION TRAINING

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum.

Discussion and small group activities: Discussion and review of coping skills that have been useful and practiced by group members to curb any withdrawal symptoms that might have occurred.

Practice relaxation techniques (shortened forms) - quieting response and smokeless inhalation.

Assignments & Review: Listen to relaxation recording and practice techniques.

MATERIALS:

Handouts: Quieting Response

Audiotapes: American Lung Association, Smoking Cessation Program, Relaxation Recording.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

d) Session 8: SPOUSE & SOCIAL SUPPORT

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum; homework check.

Discussion and small group activities: Discussion of sources of support to aid in maintaining non-smoking status (group - friends, assigned buddy, family members) and prior experience with support in smoking cessation efforts.

List specific helpful and hindering behaviors for social support in changing the smoking habit.

Assignments & Review: Identify and complete form for partner support.

MATERIALS:

Handouts: Partner Support; Contracting With Yourself

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

e) Session 9: RELAPSE PREVENTION: SLIPS, LAPSES, AND RELAPSES

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum.

Discussion and small group activities: Short presentation on the 5 major types of relapse situations (Shiffman, Read & Jarvik): alcohol; withdrawal; positive and negative affect; social situations; relaxing situations at home (after dinner).

Discussion of behavioral (things you might do) coping responses and cognitive (things you might think) responses.

Outline firstline strategies for coping with temptations to smoke: avoidance, escape, distraction and delay.

Assignments & Review: Assignment for the next week is to identify high risk or situations in which you are tempted to smoke and to identify the coping responses used in those situations.

MATERIALS:

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

f) Session 10: POSITIVE BENEFITS OF BEING A NON-SMOKER

ACTIVITIES:

Measures: Expired CO; weight; withdrawal symptom checklist; record of gum and bronchodilator use; distribution of gum; homework review.

Discussion and small group activities: Discussion of tapering activities for nicotine chewing gum.

Complete checklist on "Reasons to Continue Smoking" and "Reasons for Quitting Smoking".

Make a list of reasons that participants have named comparing the benefits of quitting with reasons for continuing to smoke.

A short presentation is made on the health benefits to the pulmonary and cardiovascular system.

MATERIALS:

Handouts: Reasons for Quitting Smoking vs Reasons for Continuing to Smoke.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)

g) Session 11: PHYSICAL ACTIVITY + GROUP CELEBRATION

ACTIVITIES:

Measures: Expired CO; weight; checklist for withdrawal symptoms; review gum and inhaler use; distribution of gum.

Discussion and small group activities: Review food records and discuss activities that have been substituted for smoking and eating.

Short presentation on the role of exercise/physical activity as a coping response for cigarette urges and tension reduction. Guidelines are given for individuals who have not previously been involved in exercise programs.

A checklist of physical activity preferences is completed and an activity guide distributed.

A group celebration can include food, balloons, awards, picture of group to go into newsletter, visit from other Trial personnel to congratulate the group.

MATERIALS:

Handouts: What Can Exercise Do; Further Exercise Guidelines; Personal Activity Checklist; Physical Activity Benefits Chart.

Forms: Intervention Visit Form (I-01)
Intervention Contact Log (Form 222)