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AUGMENTING TOBACCO CESSATION TREATMENT OUTCOMES WITH
TELEPHONE-DELIVERED INTERVENTIONS

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iii

DEDICATION

The dissertation is dedicated to my husband and son, to the men and women of the United States military, to the victims of September 11th and to my mother whose spirit sustained me.

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I would like to express my gratitude to Dr. Rosanne Harrigan who has always been available and ready to assist me throughout this long process. She has served as a guiding light and a source of strength. Mentoring and advising me has not always been easy, nevertheless she maintained her faith in my abilities to complete this study. Her guidance was indispensable.

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ABSTRACT

Tobacco use is a serious public health problem impacting both the length and quality of life. Cigarette smoking significantly depletes American health care resources while also lowering the national state of the military readiness. In the United States, one out of every five deaths is associated with tobacco use, and many of these deaths involve a loss of 20 to 25 years of life. In light of the tremendous financial and social impacts of nicotine dependence and the limited success rates demonstrated by current interventions (the majority of cessation attempts are largely unsuccessful), an intensive approach to treatment is warranted.

The purpose of this study was to examine the enhancement of a telephone-delivered intervention administered by a nurse added to a multi-component smoking cessation program to augment abstinence and harm reduction and decrease smoking relapse. This was done by selecting a sample of sixty individuals, who were then blocked by the pharmacological aid of their choice (bupropion or transdermal patch) and then randomly assigned to one of two groups: usual care alone, as provided in the smoking cessation program, or usual care plus the weekly nurse delivered telephone intervention ("treatment" group).

With the *intention-to-treat* principle as the study denominator, there was no statistical significance found in the difference between point-prevalence abstinences, continuous abstinences, or the number of cigarettes smoked after ten weeks of treatment for the two groups. However, the treatment group had a

higher frequency of abstinence, suggesting potential clinical value. Moods described by the participants prior to smoking relapse were correlated with the average number of days relapsed weekly, which resulted in the finding that relapse is positively strongly correlated with loneliness ($r=.87$) and uneasiness ($r=.86$).

Conclusions: Although the nurse telephone delivered interventions were not shown to be statistically significant their potential clinical value warrants further investigation. Further investigation should focus on their value in sustaining abstinence by tailoring interventions to mood.

TABLE OF CONTENTS

Dedication.....	iv
Acknowledgement.....	v
Abstract.....	vi
List of Tables.....	xi
List of Figures.....	xii
Chapter 1: Introduction and Statement of the Problem.....	1
Purpose of the Study.....	2
Research Questions.....	2
Theoretical Framework.....	5
Assumptions of This Study.....	8
Definition of Terms.....	9
Value of the Study.....	11
Chapter 2: Literature Review.....	12
Tobacco: A Public Health Problem.....	12
Health Benefits of Tobacco Cessation.....	13
Smoking Harm Reduction.....	14
Nicotine Dependence Treatment.....	15
Interventions, Abstinence, and Relapse.....	18
Models and Concepts of Health Behavior Change.....	22
The Evolution of Telephone Delivered Interventions.....	24
Summary.....	26

Chapter 3: Methods and Procedures.....	28
Research Design.....	28
Screening and Randomization Procedure.....	28
Measures.....	32
The Smoking Cessation Program.....	40
Delivery of the Therapeutic Interventions.....	43
Delivery of the Experimental Intervention.....	43
Ethical Issues and Risks.....	44
Statistical Analysis of the Data.....	45
Chapter 4: Results.....	47
Sample.....	47
Study Attrition.....	48
Demographic Characteristics.....	48
Smoking Characteristics	49
Reliability of Measures.....	52
Results: Objective 1	53
Results: Objective 2	55
Summary.....	57
Chapter 5: Discussion.....	58
Objective 1 and Its Research Questions.....	58
Objective 2 and Its Research Questions.....	63
Limitations of the Present Study.....	67
Conclusions.....	69

Implications for Theory and Practice.....	70
Recommendations for Future Research.....	71
Appendix A: Literature Reviews of Interventions Delivered by Multiple Devices.....	102
Appendix B: Review of Evidence of Smoking Cessation Using Telephone-delivered Interventions.....	103
Appendix C: Tripler Army Medical Center Consent Form.....	104
Appendix D: University of Hawaii at Manoa Consent Form.....	109
Appendix E: Approval from Committee on Human Subjects, University of Hawaii at Manoa	111
Appendix F: Approval from Committee on Human Subjects, Tripler Army Medical Center Subjects.....	113
Appendix G: Study Screening Questions.....	115
Appendix H: Demographic Interview	116
Appendix I: Smoking History Questionnaire.....	117
Appendix J: Fagerstrom Test of Nicotine Dependence (FTND).....	119
Appendix K: Nicotine Withdrawal Questionnaire.....	120
Appendix L: Profile of Mood States—Short Form.....	121
Appendix M: Codes for SUDs.....	123
Appendix N: Follow-up Phone Call Questionnaire Form.....	124
Appendix O: Telephone-delivered Interventions Algorithm.....	126
Appendix P: Protocol and Frequency of TDI's.....	127
References.....	130

LIST OF TABLES

<u>Tables</u>	<u>Page</u>
1. Statistical Analyses for Descriptive Variables.....	73
2. Statistical Analyses for Research Questions.....	74
3. Demographic Characteristics.....	77
4. Smoking Characteristics of Participants.....	78
5. Comparison of Study Outcomes.....	79
6. Comparison of Demographic Characteristics.....	80
7. Comparison of Groups by Selected Smoking Characteristics.....	81
8. Comparison of Groups by Previously Experienced Withdrawals.....	83
9. Summary of the SUDs Preceding Relapses.....	84
10. Correlates of the SUDs.....	85
11. Reasons for Relapses to Smoking.....	86

LIST OF FIGURES

<u>Figure</u>	<u>Page</u>
1. Marlatt and Gordon's Model of the Relapse Process.....	88
2. Interaction of Relapse Prevention Model.....	89
3. Study Timeline.....	90
4. Link between Research Questions and Measures Used.....	91
5. Flow and Comparison of Groups.....	92
6. Study Attrition of Participants.....	93
7. Withdrawal Frequencies-Cravings.....	94
8. Withdrawal Frequencies-Increased Appetite.....	95
9. Withdrawal Frequencies- Depressed Mood.....	96
10. Withdrawal Frequencies-Anxiety.....	97
11. Withdrawal Frequencies- Difficulty Concentrating.....	98
12. Withdrawal Frequencies-Irritable, Angry and Frustrated.....	99
13. Withdrawal Frequencies Restlessness.....	100
14. Withdrawal Frequencies- Difficulty Sleeping.....	101

CHAPTER 1

INTRODUCTION AND STATEMENT OF THE PROBLEM

Tobacco use is a serious public health problem that significantly depletes American health-care resources and lowers the national state of military readiness.(1) Although notable advances have been made in the treatment of nicotine dependence, the majority of cessation attempts are largely unsuccessful: 35-75% of smokers relapse before completion of the most advanced behavioral and pharmacological interventions, and few cessation programs achieve long-term abstinence rates (one year or longer).(2-4) Improved cessation outcomes await the development of more comprehensive treatments to adequately manage this health problem. Behavioral components of tobacco cessation programs have typically provided short-term interventions and minimal, if any, long-term follow-up treatment. Intra-program interventions—that is, interventions between weekly smoking cessation treatments—have not been investigated. In addition, outcome measures have focused almost exclusively on abstinence alone; few studies have looked at relapse duration or harm reduction. This study evaluates the impact of a telephone-delivered intervention (TDI) between sessions of the Tripler Smoking Cessation Program to prevent relapse to smoking and enhance the smoking cessation treatment offered. The aim of this study is to determine the impact of the TDI on smoking behavior after completion of a multi-component smoking cessation program.

PURPOSE OF THE STUDY

The health hazards of smoking (5) and the high relapse rate after smoking cessation programs (6) present the need to impact smoking behavior with improved treatment. Telephone-delivered interventions have been used in nonmilitary-based facilities to evaluate smoking cessation outcomes and as adjunct therapy. The varying degrees of success they have achieved in enhancing the effectiveness of smoking cessation programs warrants further investigation and holds promise for enhanced therapy application. Thus, the purpose of this study was to examine a TDI enhancement to a multi-component smoking cessation program in a military setting and compare results with those of a multi-component smoking cessation program alone.

RESEARCH QUESTIONS

Research Objective 1

This tobacco cessation study sought to determine whether participants who received TDIs after enrollment in a smoking cessation treatment program had more changes in their smoking behavior than participants who did not receive TDIs (usual care). The following questions were investigated during the 10 weeks of the smoking cessation program:

1. In point-prevalence abstinence, is there a difference between treatment (TDI) and control (usual care) groups at end of program?
2. In continuous abstinence, is there a difference between treatment (TDI) and control (usual care) groups at end of program?

3. In the mean number of cigarettes smoked per day, is there a difference between the treatment (TDI) and control (usual care) groups?
4. In the mean number of days relapsed to smoking, is there a difference between treatment (TDI) and control (usual care) groups at end of program?
5. In selected demographic characteristics and selected smoking characteristics, are there differences between the treatment and control groups?
 - a. The selected demographic characteristics are: age, gender, ethnic group, marital status, military status, service branch, and military rank.
 - b. The selected smoking characteristics are: motivation, initial exhaled carbon monoxide, pharmacological aid, initial number of cigarettes per day, age of initiation to smoking, smoking status of spouse, weekly use of alcohol, smoking status of mother, smoking status of father, FTND total score, withdrawal (individual and total scores), POM-SF total score.

Research Hypothesis 1 and Expected Results

TDIs have had various degrees of success as adjunct therapy in enhancing abstinence from smoking. Therefore, over the 10 weeks of the smoking cessation program, participants receiving a weekly TDI were expected to demonstrate significantly higher levels of point-prevalence abstinence and continuous abstinence, and a decrease in the number of days of relapse. For

those who were still smoking at end of program, it was hypothesized that fewer cigarettes would be consumed at 10 weeks than at baseline.

Research Objective 2

This tobacco cessation study sought to describe mood states and their relationship to abstinent periods and relapse episodes for those individuals in the treatment group and the perceived reasons for smoking relapse of all the participants. Over the 10 weeks of the Tripler Smoking Cessation Program, these questions were investigated:

1. What are the mood states that precede smoking relapse episodes and smoke-free periods?
2. Are there patterns of mood state that are associated with relapse and periods of abstinence?
3. What are the perceived reasons for smoking relapse reported by participants?

Research Hypothesis 2 and Expected Results

In 1996, 83% of the participants of the Tripler Tobacco Cessation Program were reported to have relapsed to smoking within one year of finishing the program. Relapse is mediated by the ability to cope with negative affective experiences. Therefore, it was expected that the majority of participants' relapse episodes would be preceded by moods that were more negative than during smoke-free status.

THEORETICAL FRAMEWORK

Marlatt and Gordon's cognitive-behavioral model of the relapse process served as the foundation for this study. Marlatt's relapse prevention model (Figure 1) was developed in the late 1970s.(7) The term "relapse prevention" became well known during the 1980s as an explanation of the relapse process that was based on empiricism (8) and cognitive social-learning theory, with associated treatment implications. A precursor to Marlatt's approach was Bandura's development of the self-efficacy theory in 1977.(9) Bandura differentiated between the acquisition of behavior change (i.e., quitting smoking) and the maintenance of behavior change (i.e., remaining abstinent). Influenced by this theory and his own finding of a high relapse rate in his study of treated alcoholics, Marlatt was led to focus on attempting to understand the relapse process, and he subsequently developed a model of the relapse process along with procedures to prevent relapse from occurring. The resulting relapse prevention model is evidence based. It was originally formulated as a possible explanation for data obtained in treatment outcome studies. The prevention model consists of a well-formulated and testable set of hypotheses about factors that determine the likelihood of relapse, and research has been underway for several years testing various aspects of the model.(10)

Marlatt's model categorized the emotional, environmental, and interpersonal characteristics of relapse-inducing situations that were described by participants in his studies; he called these characteristics "immediate determinants of relapse." Several types of high-risk situations fall into these

categories. They are: 1) negative emotional states during situations that involve another person or groups of people (for example, an argument with a family member), 2) social pressures (direct and indirect persuasion), and 3) positive emotional states (such as a celebration). Other immediate determinants of relapse in the model are coping skills, outcome expectancies, and the “abstinence violation effect,” which is explained below in greater detail. Marlatt’s model includes not only these immediate determinants of relapse, but also other less obvious ones he called “covert antecedents,” which can contribute to relapsing to the “substance using behavior” (such as alcohol, cocaine, tobacco, etc.). These covert antecedents are high-risk situations that are less obvious because they refer to lifestyle factors, urges, and cravings. For example, a stressful lifestyle or cognitive factor such as immediate gratification (urges and cravings) can serve as a “trap” by increasing a person’s vulnerability to relapse through increased exposure to the high-risk situation and decreasing motivation to resist relapse.

In the model, “relapse” is defined as a violation of a self-imposed rule or set of rules governing the rate, or pattern, of a selected target behavior, while “lapse” is a single instance of violation of the rule.⁽¹¹⁾ Thus, when a violation of these rules (a lapse) occurs, an “abstinence violation effect” can also occur—feelings of shame, hopelessness, helplessness, and self-depreciation, and low self-efficacy. The abstinence violation effect can undermine relapse prevention. This model proposes specific and global interventions that help the individual self-manage. Specific interventions center around helping the client identify

specific high-risk situations, enhancing the client's skills for coping with those situations, increasing the client's self-efficacy, eliminating myths regarding the substance's effects, managing lapses, and restructuring the client's perceptions of the relapse process in order to help minimize the chances for relapse. Global self-managing strategies consist of balancing the client's lifestyle and helping him or her develop positive addictions, employing stimulus-control and urge-management techniques, and developing relapse road maps.

Studies that include research on nicotine addiction have provided theoretical and practical support for Marlatt's relapse prevention model.(11-13) Several studies have evaluated the reliability, predictive validity, and efficacy of the model. Lowman's study, funded by the National Institute on Alcohol Abuse and Alcoholism, evaluated the reliability of raters' categorizing high-risk situations using Marlatt's taxonomy and assessed the predictability of future relapse based on prior situation.(14) Although the results on the inter-rater reliability and predictive validity were found to be modest, these studies provided good support for other aspects of Marlatt's model. For instance, the study found that exposure to a specific high-risk situation did not predict relapse but rather indicated the manner in which people coped with the situation.(15) Most relapse episodes were found to occur along with negative emotional states, a finding that has been replicated by other studies.(13,16,17) Also, support was found for the role of the abstinence violation effect as a predictor of full relapse.(15) Various literature reviews and meta-analyses explore the effectiveness of treatments applying Marlatt's model.(11, 18,19) Their findings can be summarized as supportive of the

practical application of the model to reduce the frequency of relapse episodes, as well as the intensity of the relapse in persons undergoing alcohol treatment. These studies compared the relapse rates in persons before and after treatment, and also compared persons receiving treatment with control groups receiving no treatment. There was no association with higher abstinence when compared to other treatment approaches. Combining relapse prevention with medications to treat alcoholism led to improved outcomes in one study.(11)

Although the model seems to be applicable to many addictive behaviors, caution must be taken when applying the results of the model to tobacco cessation because the bulk of the evidence of its applicability has been in alcohol treatment. Nevertheless, Marlatt's model has been tested in nicotine addiction,(20,21) in one case yielding successful smoking cessation in individuals that gained competency dealing with high-risk situations.(6) The tested applicability of this model has been limited to studies using face-to-face treatment modalities, and it has yet to be tested using other methods of delivery. In the present study, the telephone-delivered intervention was guided by Marlatt's model of relapse prevention to test its applicability in achieving higher smoking cessation rates at the end of a structured program.

ASSUMPTIONS OF THIS STUDY

This study was carried out based on the following assumptions:

1. Participants are in Prochaska's Stage of Action from the beginning of the smoking cessation program (inclusion criteria ≥ 5 in motivation scale).

2. Participants completed questionnaires and answered questions during the TDIs to the best of their knowledge.
3. Psychologists administered the program according to the *Tripler Tobacco Cessation Program Manual*.

DEFINITION OF TERMS

1. **Abstinence:** refraining from smoking in the last seven days, in accordance with the National Heart, Lung and Blood Institute guidelines.(22)
2. **Advanced-practice nurse:** a registered nurse whose education includes a master's degree and formal training and experience in smoking cessation counseling, and who, in this case, delivered the TDIs.
3. **Change in cigarette consumption:** the ratio of number of cigarettes smoked at a given time point compared to cigarettes smoked at the start of the study.
4. **Continuous abstinence:** refraining from smoking since target quit date (TQD) until the 10-week end point of the study, verified by carbon monoxide breath analyzer (Vitalograph Breath CO[®]).
5. **Continuous smoker:** a person who has smoked for at least seven consecutive days prior to assessment one week after the end of the smoking cessation program.(23)
6. **Control group (also "usual care"):** participants in the Tripler Tobacco Cessation Program (which includes pharmacological and psychological therapy) who did not receive TDIs.

7. Evaluation telephone call: the telephone interview conducted at the end of the 10-week program for the purpose of obtaining information about smoking behavior from all the participants.
8. Lapse: a single episode of cigarette smoking (even a puff), also known as a lapse.(22)
9. Licensed psychologist: a licensed clinical psychologist who has training and experience in cognitive behavioral therapy and smoking cessation group therapy.
10. Mood state: frame of mind prior to relapse, coded in the style of subjective units of discomfort scores (SUDs).
11. Non-smoker: participant who has not smoked since target quit date (TQD).
12. Point-prevalence abstinence: a measure, at end of study, of the incidence of successful abstinence for the preceding week, verified by carbon monoxide breath analyzer (Vitalograph Breath CO[®]).
13. Relapse: a return to smoking after at least a 24-hour period of abstinence.
14. Relapser: a person who has experienced smoking relapses.
15. Target quit date (TDQ): The date chosen by the participant as the goal by which time he/she will stop smoking (usually set within two weeks of starting the program).
16. Telephone-delivered intervention (TDI): a telephone call to participants in the treatment group by an advanced-practice nurse for the purpose of

discussing smoking behavior and providing smoking cessation support guided by social cognitive theory.

17. Treatment group (high intensity): participants in the Tripler Tobacco Cessation program who additionally received once-weekly TDIs for the duration of the 10-week program.

VALUE OF THE STUDY

This study provides knowledge about the effects of a multi-component smoking cessation therapy enhanced by TDIs. The health hazards of smoking are well known, and the prevalence of relapse among people who attempt to quit smoking makes the development of effective treatments imperative. Telephone-delivered interventions have been delivered by various types of providers (nurses, trained counselors, etc.) and have been used as an adjunct to enhance smoking cessation, but the varying degrees of success these interventions have achieved warrants further investigation. Furthermore, studies of smoking cessation programs conducted in military settings and incorporating telephone counseling have not been reported in the professional literature. This study tested the impact of an intensive program incorporating TDIs on a military population, utilizing providers from two disciplines (nursing and psychology). The study contributes to the field of smoking cessation research and therapy by providing evidence for the potential benefits of augmenting smoking cessation treatment in structured smoking cessation programs with telephone-delivered interventions in a military population.

CHAPTER 2

LITERATURE REVIEW

TOBACCO: A PUBLIC HEALTH PROBLEM

Tobacco use is a serious public health problem that has rapidly become the leading cause of preventable death throughout the world.(24,25) In the United States, one out of every five deaths is associated with tobacco use, and many of these deaths involve a loss of 20 to 25 years of life. The American Lung Association estimates that smoking-related diseases claim 430,700 American lives each year, and an additional 50,000 deaths are attributed to the effects of passive smoking. The total of tobacco-related deaths is astounding: it surpasses all deaths from AIDS, automobile accidents, murder, suicide, illegal drugs, and alcohol combined.(26,27) The devastating impacts of tobacco use affect both men and women, and although the incidence of tobacco-related fatality is higher in men, approximately 1,500 young women begin smoking in the United States every day. Tobacco use also carries a severe economic toll: Americans spend an estimated \$97.2 billion annually on tobacco-related health-care costs and lost productivity. The problem is so serious that organizations of health professionals have adopted guidelines recommending that their member practitioners provide assessment and treatment for all of their patients who smoke.(28,29)

Additionally, the American Nurses Association and the American Medical Association have published position statements regarding the hazards of smoking.(30-32)

HEALTH BENEFITS OF TOBACCO CESSATION

Tobacco cessation has been shown to be associated with substantial health benefits, including decreased risks of developing cancer, heart attack, stroke, and chronic lung disease.(29) Yet despite the facts that the majority of smokers wish to quit and nearly half of all smokers (military and civilian) attempt to quit each year, over one-quarter of American adults continue to smoke.(26, 27) Unfortunately, most cessation attempts are unsuccessful: most smokers relapse within the first three days. Of those remaining, only 14% abstain from tobacco use for a full month,(26) and less than 5% of those who quit "cold turkey" report abstinence a year later.

These figures, as well as new scientific evidence, highlight the fact that nicotine is a psychoactive and highly addictive substance that stimulates the pleasure centers of the brain.(33) Dependency is precipitated via neurophysiological adaptation and, to a certain extent, genetic predisposition.(34) Withdrawal has been associated with impaired brain functioning, including alterations in concentration, mood, and appetite, and craving sensations may be experienced for decades after the last cigarette is smoked. In addition, nicotine withdrawal may provoke major depressive episodes for some smokers, particularly those with a history of major depressive disorder.(35) Hence, tobacco cessation requires much more than adequate motivation and strong willpower.

SMOKING HARM REDUCTION

The recognition of smoking reduction as an outcome of attempted smoking cessation has generated controversy among health-care professionals. While opponents fear that reduction of smoking will not lead to cessation, there is mounting evidence to argue for smoking reduction as a goal in itself. One trial demonstrated that smoking reduction may promote smoking cessation by allowing smokers to take control of their smoking gradually.(36) Other studies suggest that, by suppressing smoking behavior, nicotine treatment that reduces smoking levels still benefits the smoker. Other studies, whose primary aim was cessation, found unexpected benefits from reduction. For example, in a lung health study, 60% of the participants reduced rather than stopped smoking, and 39% of these reduced their smoking by at least 50%.(37) Likewise, the Community Intervention Trial for smoking cessation (COMMIT), an analysis of 1,410 people who smoked both at baseline and at two-year follow up, reported a reduction in cigarette use. The COMMIT study, which involved participants in 22 U.S. cities, reported that at two years 17% of participants had decreased their smoking by 5-25%, 15% of participants by 24-49%, and 8% of participants by at least 50%. The reduction in smoking seen at two years did not undermine the effects of cessation at a later date. The ability of smokers to reduce their smoking was associated with future smoking cessation.(38) In a recent study testing the effectiveness of the oral nicotine inhaler, it was found that 10% of the participants who were unwilling or unable to stop smoking at baseline were abstinent at two years. All these outcomes give support to the argument that smoking reduction

needs to be considered as an intermediary goal in the pursuit of abstinence, at least in some cases.(39)

NICOTINE DEPENDENCE TREATMENT

Many significant advances have been made in the treatment of nicotine dependence over the past 10 to 15 years, as heightened public and scientific awareness have precipitated the development of several effective behavioral and pharmacological interventions.(28,35,40,41) Behavioral interventions are a key component of successful tobacco cessation programs because they help smokers to achieve abstinence rates (10-25%) that are significantly higher than rates for programs that omit this aspect (8-10%). Behavioral interventions tend to be most effective when they (a) are provided by multiple clinicians; (b) employ individual or group counseling formats as opposed to self-help formats; (c) involve intensive (i.e., >10 minutes) as opposed to minimal (i.e., <3 minutes) contact; (d) are greater than eight weeks in duration; and (e) involve aversive smoking techniques, emotional and social support, and training in coping skills, relapse prevention, and stress management.(28,40)

Nicotine Replacement Therapy

Nicotine replacement therapies (NRT) (including nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine transdermal patch) represent another effective component of tobacco cessation efforts, particularly for smokers who are nicotine dependent and less motivated to quit.(41,42) These non-carcinogenic, pharmacological interventions are known to alleviate many of the

symptoms of nicotine withdrawal, including craving, anxiety, inability to concentrate, depressed mood, restlessness, decreased heart rate, increased appetite, and drowsiness. Similar to behavioral interventions, nicotine replacement therapies have been shown to be 1.5 to 2.5 times more likely to help smokers achieve abstinence than are unassisted interventions,(41,43) a success rate that compares to that of behavioral interventions. The nicotine transdermal patch has been reported to have an effect size of 5% (CI 4-7%) for moderate to heavy smokers receiving intensive behavioral support.(44)

Other Pharmacological Smoking Cessation Aids

Antidepressant therapies have become an increasingly researched and effective pharmacological approach for treating nicotine dependence.

Nortriptyline, a tricyclic antidepressant with adrenergic activity, and bupropion, an atypical antidepressant with dopaminergic and adrenergic activity, have both been shown to double cessation rates, independent of smokers' histories of major depression.(45-47) These medications are believed to activate the mesolimbic dopamine reinforcement pathways that are a common neurophysiological substrate of many addictive compounds such as nicotine.(35, 48) Fluoxetine, a selective serotonin reuptake inhibitor, has been shown to be selectively efficacious for smokers who demonstrate either histories or baseline symptoms of depression, thereby suggesting that its efficacy is directly related to its serotonin-mediated antidepressant effect.(49-51) Of all the antidepressants, bupropion is the one approved by the FDA for smoking cessation therapy.

Bupropion, at 300mg/day sustained-release form, has been reported to have an

effect size of 9% (CI 5-14%) in moderate to heavy smokers receiving intensive behavioral treatment. It is not yet clear whether bupropion is more effective than NRT.(44) One randomized placebo-controlled trial found a higher one-year sustained-abstinence rate with bupropion than a transdermal patch in the context of a behavioral support package.(52)

Cognitive Behavioral Therapy

Coping deficits are one of the major reasons cited for relapse(53, 54) and thus also the reason that cognitive-behavioral coping-skills treatment is employed in tobacco cessation treatment.(45,55) Cognitive behavioral therapy (CBT) is based on social learning theory.(56) The underlying assumption is that learning processes play an important role in the development and continuation of the use of a substance. In other words, individuals begin to use tobacco, at least in part, because they learn to do so—and the same learning processes that precipitated smoking can be used to help individuals stop or reduce their use of tobacco products.(55-58) CBT assists patients to “recognize, avoid, and cope”: recognize the situations in which they are most likely to use tobacco products, avoid these situations when appropriate, and cope more effectively with these situations.

Cognitive behavioral therapy has two critical components: functional analysis and skills training. Functional analysis is the identification of the patient’s thoughts, feelings, and circumstances before and after the act of using tobacco and is done in the early sessions. This analysis assesses the determinants of high-risk situations that are likely to lead to using tobacco and provides insights into some of the reasons the individual may be using tobacco (for example, to cope with

interpersonal difficulties).(59) This study incorporates cognitive behavioral approaches during the tobacco cessation sessions and also during the telephone-delivered interventions.

Combination Therapies

Smoking cessation researchers are increasingly discovering that combinations of psychosocial and pharmacological interventions optimize clinical outcomes. These intervention strategies are designed to enhance smokers' coping skills while simultaneously alleviating their symptoms of nicotine withdrawal. Intensive counseling plus nicotine gum or patch,(29) combined nicotine patch and nicotine gum,(3,60,61) brief therapy plus bupropion,(47) cognitive behavioral therapy plus nortriptyline,(45) supportive therapy plus combined fluoxetine and nicotine inhaler,(51) supportive therapy plus combined nicotine patch and inhaler,(51) and brief therapy plus combined bupropion and nicotine patch (52) have all been shown to produce higher cessation rates than the individual therapeutic components alone. Preliminary clinical and laboratory studies have demonstrated that the combined use of multiple pharmacological agents is relatively safe and does not appear to increase adverse effects or the potential for abuse.(62,63) These treatments may be on the horizon of smoking cessation treatment.

INTERVENTIONS, ABSTINENCE AND RELAPSE

Notwithstanding these significant advances in the treatment of nicotine dependence, smoking cessation studies for the most part have proven long-term

abstinence to be an elusive goal. Historically, few smoking cessation programs have achieved long-term abstinence rates (i.e., one year or longer) of greater than 35%.^(45,52,64) However, evaluations of smoking cessation outcomes that are based solely upon lapse-free point-prevalence abstinence rates may tend to veil some of the effectiveness of tobacco cessation interventions. Although the ultimate goal of treatment is lifelong abstinence, most smokers attempt to quit several times over the course of many years before permanently giving up cigarettes.⁽⁴³⁾ Since abstinence is an ideal but unrealistic therapeutic goal for the majority of smokers who attempt cessation, it is in fact a narrow measure of treatment outcome that will generate conservative estimates of treatment success. Ironically, little attention has been given to evaluating whether cessation interventions lead to long-term reductions in cigarette consumption and nicotine intake,⁽²⁴⁾ even though these outcomes are directly related to the probability of experiencing tobacco-related health difficulties.⁽⁴²⁾

By shifting the evaluative focus from static measurements of smoking abstinence to continuous quantifications of cigarette consumption, researchers will reach a better understanding of the extent to which smoking cessation interventions reduce the risks of experiencing serious health disorders (cancer, pulmonary disease, cardiovascular disease, complications during pregnancy), providing an opportunity to directly evaluate the relationship between reduced smoking and tobacco-related morbidity and mortality.⁽²⁵⁾ They will also better understand the factors that precipitate smoking relapse and that moderate the length and intensity of smoking relapse. Follow-up counseling that focuses on

smoking reduction as well as abstinence is more likely to enhance self-efficacy and encourage smokers to employ positive coping strategies to avert future relapse events.

Whether evaluated in terms of abstinence or reduction, improved smoking cessation outcomes require treatments that are more precisely tailored to the needs and clinical characteristics of smokers who are slow to reestablish or who fail to reestablish abstinence after periods of relapse. Although few prospective studies have examined the relationship between smokers' clinical characteristics, the factors that trigger relapse, and smoking behavior, many theoreticians and researchers believe that the management of negative mood is an important factor contributing to the initiation of smoking, the development of nicotine dependence, and the inability to abstain from smoking.(65-68) Indeed, sadness, depression, anxiety, low self-esteem, anger, and a history of a psychiatric disorder are all predictive of failed smoking cessation attempts.(35,51,65,66,69-72) Irrespective of psychiatric history or baseline affective status, 35-75% of smokers will relapse before the completion of even the most advanced behavioral and pharmacological cessation therapies.(45,47,51,52,73) In addition, no cessation programs have been able to achieve point-prevalence abstinence rates that do not continuously decline over time.(64) Thus, while it is relatively clear that current and historical disturbances in mood are risk factors for smoking relapse, it would appear that current smoking cessation interventions are not sufficiently capable of providing short-term or long-term protection against these risk factors, and/or there exist other unaccounted-for risk factors that are

responsible for a significant amount of the variation in smoking cessation outcomes.(25) Improved outcomes may therefore await the development of more effective behavioral interventions and clarification of the unknown risk factors for relapse.

In order to clarify and evaluate the various risk factors that contribute to smoking relapse, future cessation studies will need to incorporate continuous assessments of smokers' affective status, withdrawal symptoms, cigarette consumption, and attributed causes of relapse. The provision of this information would require smokers to report the information on a weekly basis. Telephone interviews may be an efficient way to collect the information. Participant cooperation may be assured by properly educating smokers of the potential benefits that they may experience as a result of their participation (i.e., a greater likelihood of long-term abstinence) and by explaining that the assessment process is an integral and required component of their treatment.

The addition of an intensive follow-up methodology to standard behavioral modification and supportive therapy may be a key factor in achieving improved smoking cessation outcomes. Traditionally, smoking cessation programs have adopted therapeutic goals that are defined solely in terms of smoking abstinence. Hence, behavioral interventions have usually been confined in both time and scope, and follow-up evaluations have been performed relatively infrequently. A more comprehensive smoking cessation therapy might adopt therapeutic goals that are more closely aligned with the reality of cessation outcomes. These behavioral regimes would extend beyond the boundaries of traditional smoking

cessation treatments and would likely incorporate relapse counseling between weekly group-therapy sessions that focus on minimizing the frequency, duration, and severity of smokers' relapse episodes, in addition to achieving absolute smoking abstinence. These follow-up treatments could be provided weekly via telephone, focusing on evaluations of smokers' affective status, cigarette consumption, and unique relapse vulnerabilities. The cost-effectiveness of TDIs is well known; further, research has demonstrated that behavioral and supportive therapies for smoking cessation may be conducted effectively without face-to-face contact.(74)

MODELS AND CONCEPTS OF HEALTH BEHAVIOR CHANGE

Several models and concepts of health behavior change are frequently used as a basis for interventions. Since patients are currently more involved in managing their health than in times past, the challenge for health-care providers is to motivate, educate, and assist people in adhering to healthy behaviors.(75, 76) Models serve as a framework for understanding behaviors and help in identifying factors that assist people to change unhealthy behaviors. These factors can be used to develop and evaluate interventions that will promote change.(77)

In the literature on behavioral change interventions, cognitive behavioral theories are reported most frequently as the model guiding interventions.(78) Cognitive behavioral theories focus on the individual level and use two key concepts: 1) behavior as mediated through cognition, and 2) knowledge that is

necessary but not sufficient to produce behavior change. Inherent in these two concepts are intrapersonal factors such as an individual's knowledge, beliefs, motivation, attitudes, developmental history, experiences, skills, self-concept, and behavior. Some examples of cognitive behavioral theories are: the Health Belief Model (HBM), Prochaska's Transtheoretical Model (TM), and the Theory of Reasoned Action/Theory of Planned Behavior (TRA).(79,80) The Health Belief Model (HBM) focuses on the interactions between values and beliefs about health and the influence of these on choices of behavior. Prochaska's Transtheoretical Model (TM) refers to change as a process composed of stages that mark an individual's readiness to change.(80,81) The Theory of Reasoned Action (TRA) focuses on an individual's intention to perform a behavior. This theory provides a framework to study attitudes toward behaviors. The individual's intention to perform a behavior is a combination of attitude toward performing the behavior and subjective norm. The individual's attitude toward the behavior includes: behavioral belief, evaluations of behavioral outcome, subjective norm, normative beliefs, and the motivation to comply.(80)

Social cognitive theory incorporates interpersonal and intrapersonal factors. Interpersonal factors are defined as: reciprocal determinism (behavior change that results from interaction between individual and environment), observational learning (belief of behavior based on observing others) and reinforcement (responses to the person's behavior that increase or decrease chances of recurrence). Intrapersonal factors are: behavioral capability (knowledge and skills that influence behavior), expectations (beliefs about likely

results of action), and self-efficacy (confidence in ability to take action and persist in action). The concepts incorporated in social-cognitive theory are similar to HBM and TRA in that benefits of a behavior must outweigh the cost if change is to occur, and the person must have a sense of empowerment (defined as the individual's ability to cope with situations and perceived sense of control over them).(9,82) Figure 2 demonstrates how these theories interact with Marlatt and Gordon's model of the relapse process, which forms the theoretical basis for this study. Readiness, intentions, cognition and knowledge, values, and interpersonal and intrapersonal factors collectively and/or individually are inherent in the relapse prevention process.

THE EVOLUTION OF TELEPHONE-DELIVERED INTERVENTIONS

Widespread use of telephone and computer technologies has emerged in the past decade. Appendix A presents a review of the literature on interventions delivered by multiple devices, ranging from computer communications to telephone counseling. Although the telephone is the oldest of these technologies, its role as a tool for behavioral change had not been the focus of study until the advent of telehealth, in the past two decades. Cost-containing advantages have driven the proliferation of TDIs, which have expanded to telephone network and transtelephonic communications, all of which facilitate the delivery of health-care from a distance.(83) Appendix B presents findings from major papers published on the use of TDIs with smoking cessation interventions. When used as the sole intervention, TDIs have had limited success.(84,85) It is plausible that the limited

duration of telephone contact is insufficient to bring about change in a significant amount of persons. However, telephone counseling accompanied by multi-component therapy of a single behavior, coupled with highly motivated individuals, may have greater success in relapse prevention for smokers: TDIs have been reported as effective in diabetes, cholesterol, and weight management.(85-87)

TDIs employed to promote smoking cessation have been more extensively studied than with other health-risk behaviors, though the studies have yielded mixed results.(74,88-90) Telephone-delivered interventions have been categorized as either reactive or proactive in nature. Reactive TDIs in the form of helplines for smokers have been reported to increase rates of smoking cessation, but use of the helplines has been low and they have required media campaigns to generate callers.(91,92) Proactive TDIs, which are prearranged telephone calls to smokers, have been used to supplement written self-help materials and have consistently enhanced smokers' receptivity to self-help cessation approaches.(93-97)

The effectiveness of nicotine replacement therapy has been enhanced by proactive TDIs.(90,98-100) Proactive TDIs have resulted in higher rates of abstinence than self-help materials alone and also have increased the likelihood of resumed abstinence in relapsed smokers.(93-96) Multiple and frequent calls may have a greater effect,(90,101) though the effect of the call erodes over time regardless of frequency. Booster calls have been effective in recycling relapsers.(94) Hospitalized patients that have received multiple TDIs following

discharge have consistently improved cessation rates over usual care both in the short term and at twelve-month follow-up.(4,102-105)

Despite the varying successes of TDIs as relapse prevention enhancers, their use for smoking cessation in the military population is limited, for reasons unknown.(106) There is a need for further study given that the health and economic implications of tobacco use within the United States Department of Defense (DoD) are quite severe. Military personnel smoke at approximately the same rate as the civilian population (i.e., 30-35%),(26,107,108) and in 1995, smoking-related health disorders accounted for 16% of all deaths and approximately 10% of all hospital bed days within the DoD health-care system. The direct health-care costs associated with the treatment of these smoking-related disorders was estimated at \$584 million, and lost productivity due to hospitalization and smoking breaks was valued at an additional \$346 million. A significant portion of DoD health-care resources is spent caring for preventable disease, therein highlighting the importance of military programs that are targeted toward preventing the initiation of smoking and encouraging smoking cessation.(26) With specific regard to the strategic concerns of the DoD, the results of the proposed study could translate into significant reductions in overall health-care costs and lost active-duty time for military personnel.

SUMMARY

Tobacco use in any form causes health problems, and a global consensus shows that it is the leading cause of preventable death throughout the world.

Cigarettes (the most common form of tobacco use) are used by military personnel and constitute a drain on the economic and the human resources of the United States Armed Forces. Multiple methods are available to assist smokers in quitting smoking. Among those methods, cognitive behavioral and pharmacological aids have achieved modest results, but are insufficient to achieve cessation for most smokers. Telephone counseling has been employed in a variety of settings by multiple providers but has seldom been the focus of research in nursing literature, particularly as an enhancement to a structured smoking cessation program that uses both pharmacological and psychological therapies.

Evidence of the efficacy of telephone counseling in nonmilitary settings is inconclusive at best, though further research has been encouraged by authors of previous studies. The method merits testing in a military health-care facility, where continued telephone contact may be more feasible than in a civilian setting and where higher smoking cessation rates continue to be a goal.

CHAPTER 3

METHODS AND PROCEDURES

This chapter describes the research design, study population and recruitment of the sample, study procedures, and setting. The experimental *intervention tested in the study is explained through descriptions of the questionnaires and measurement scales and of the data analysis by which the research questions were answered and study hypothesis tested.*

RESEARCH DESIGN

An experimental design was used to evaluate the impact of a telephone delivered intervention (TDI) added to an established tobacco cessation program for smokers eligible to receive health-care at Tripler Army Medical Center. The program used a cognitive behavioral approach with added pharmacotherapy. Eligible subjects were program participants who consented to participate in the study. The participants were randomly allocated to one of two groups: a) the treatment group (receiving standard program treatment plus weekly TDIs) or b) the control group (receiving standard program treatment only, without TDIs).

SCREENING AND RANDOMIZATION PROCEDURE

Recruitment and Screening

The participants were 60 provider-referred and self-referred smokers within the Pacific Region Department of Defense health-care system that

attended the Tripler Tobacco Cessation Program as part of a larger ongoing investigation. The larger study will consist of 120 participants, including 60 from this study, that will be followed for 34 weeks and is estimated to conclude in 2003. Potential participants were screened using questions found in Appendix G and were chosen based on the following eligibility criteria: they 1) were at least 18 years of age, 2) reported smoking at least 10 cigarettes per day, 3) expressed motivation to stop smoking by selecting >5 on a scale of 1 (least motivation) to 10 (most), and 4) indicated availability and willingness to adhere to the protocol requirements. Participants were excluded for the following reasons: 1) if their healthcare provider had not approved the pharmacological smoking cessation aid; 2) if they had a history of seizures; 3) if there was any history of eating disorder, panic disorder, psychosis, or bipolar disorder; 4) if they were currently experiencing a major depressive episode; 5) if they were pregnant or lactating; and 6) if there was current use of any nicotine replacement therapy, psychotropic medication, or tobacco product other than cigarettes.

The 60 participants were recruited from the Tripler Tobacco Cessation Program during six program orientation sessions, conducted monthly from October 2001 to May 2002. The recruitment procedure began with a presentation by the investigator to all individuals attending each orientation session. At the end of each session, interested individuals were interviewed and screened by the investigator using the screening questionnaire (Appendix G). As part of the interview process, the investigator obtained a measurement of their exhaled carbon monoxide using the Vitalograph Breath CO[®]. Individuals with exhaled

carbon monoxide measurements of >10 parts per million (ppm) and that met the inclusion and exclusion criteria were then invited to participate in the study.

In accordance with the requirements of the University of Hawaii at Manoa and the Tripler Army Medical Center Institutional Review Boards, an explanation of the nature of the study was followed by a briefing on participant responsibilities and rights as human research subjects, and those who wished to participate were presented with the consent forms from Tripler and University of Hawaii at Manoa. After reading and signing the informed consent form, participants were asked to provide a telephone number where they could be reached for delivery of the TDIs. Following the study's protocol for assessing selected smoking history variables, level of nicotine dependence, and previous experience with withdrawals and mood states during the past week, all qualifying participants then were asked to complete the following four baseline questionnaires: 1) the Smoking History Questionnaire (Appendix I); 2) the Fagerstrom Test for Nicotine Dependence (Appendix J); 3) the Nicotine Withdrawal Questionnaire (Appendix K); and 4) the Profile of Mood Disturbances (Appendix L).

The first treatment session was scheduled for two weeks following the orientation session at which the participants had been recruited. In the first week following orientation (designated as week 0 on the timeline; see Figure 3), all the participants received a telephone call from the investigator for the purpose of boosting their motivation and collecting the following information during the telephone call: demographics, selected smoking variables from the Smoking History Questionnaire, and choice of pharmacological aid. Program staff also

program's conclusion, participants from both groups received a telephone call to collect endpoint data (smoking cessation outcomes).

During the treatment group's initial calls (made in week 0, prior to the first treatment session), participants were informed that they had been selected to receive a weekly telephone call. Consequently, they expected to receive a telephone call from a nurse once a week and, as informed by the investigator upon orientation, they were aware that the phone call would vary in frequency and content, focusing exclusively on smoking behavior and mood state experienced during the previous week.

A chronological description of the measures used for screening and describing each participant and for recording and verifying the smoking outcomes is presented below. Their respective timeline was presented earlier in this section.

MEASURES

1. Study Screening Questions (Appendix G)

Potential participants were screened using these 12 questions during the orientation sessions, when recruitment occurred. Of the 180 people screened, only 60 were eligible to be participants in this study. Only the motivation score (question three) for those individuals who were recruited for the study was retained for analysis. Motivation was rated on a scale of one to 10, with one meaning lowest motivation and 10 meaning highest motivation. Participants with motivation scores greater than five were retained for the study. The results of the

questions were deleted from the analysis to comply with the University of Hawaii at Manoa ethical review committee requirements to protect the participants' confidentiality.

2. Demographic Interview (Appendix H)

During the first telephone interview (week 0), data was collected concerning age, ethnicity, gender, marital status, military status, service branch, and military rank. This information was later analyzed and tabled to describe the sample.

3. Smoking History Questionnaire (Appendix I)

This questionnaire was administered to all potential participants during the orientation session. It has been used for several years in assessing smoking history by the Tripler Tobacco Cessation Program and is consistent with the National Institute of Drug Abuse recommendations for developing questionnaires for smoking adults.(109)

During the initial telephone call (week 0), selected items from the smoking questionnaire were further discussed with each study participant. These items were: 1) When did you smoke your first cigarette? 6) Does your spouse or significant other smoke? 8) Does, or did your father smoke? 9) Does, or did your mother smoke? 10) Do you drink alcoholic beverages? 16) Why do you smoke? and 17) Do you want to stop? If so, why? The results from this discussion with each participant yielded variables that were included in the data analysis based on their association with variables that inhibited smoking cessation as reported in smoking cessation literature.(15,110) Further information on items 1, 6, 8, 9, and

10 was obtained during the initial telephone call (week 0) to form the following variables for analysis: age of initiation to smoking, smoking status of spouse, weekly use of alcohol, mother's smoking status (current or former smoker), and father's smoking status (current or former smoker). Responses to the remaining items will be analyzed at a later date, as part of a larger, more comprehensive study.

4. Fagerstrom Test for Nicotine Dependence (FTND) (Appendix J)

The FTND is a 6-item instrument with moderate reliability that is commonly used in smoking cessation studies to measure perceived nicotine dependence. This questionnaire has been widely used in smoking cessation literature to detect heaviness of smoking. Scores range from 0 to 10, with higher scores correlating with heavier levels of smoking. The FTND is scored in the following manner: a score of 0 to 2 indicates low dependence; 3 to 5, medium dependence; 6 to 7, high dependence; and 8 to 10, high dependence. A cut score of 6 points or greater in the FTND was used to determine a strong likelihood for addiction to cigarettes.(111)

The FTND has been reported in two previous studies to have an internal consistency, with a coefficient alpha of 0.66 and 0.70.(112,113) In spite of its low internal consistency, this test is widely used because its scores are highly correlated with plasma cotinine levels ($p < 0.005$). Cotinine is a measure of tobacco smoke exposure and the major metabolite of nicotine.(113-116) The total score of this instrument was used to measure participants' nicotine

dependence at the start of treatment. This measurement has been published and is in public domain.(113)

5. Nicotine Withdrawal Questionnaire (Appendix K)

The Nicotine Withdrawal Symptom Questionnaire is designed to measure desire to smoke by compiling ratings on cravings, increased appetite, depressed mood, anxiety, difficulty concentrating, irritability, anger and frustration, restlessness, and difficulty sleeping. Each symptom was derived from the DSM-IV and was scored as none (0), slight (1), mild (2), moderate (3), or severe (4). *Withdrawal symptoms scaling has been used in other smoking cessation studies,(117) although reliabilities have not been reported.(117-119) In this study, the withdrawal symptoms scales were administered to describe the participants' previous experience with withdrawals of cravings. Both the total score and each individual symptom were used as variables to describe the participants' past experience with cessation and withdrawal.*

6. Profile of Mood States—Short Form (POMS-SF) (Appendix L)

The short form of the Profile of Mood States is an assessment of transient (past week), distinct mood states by self-report using an adjective checklist. With the author's permission, this study used the 30-item POMS-SF instead of the 65-item form in order to minimize patient burden. The 30-item form was provided by McNair (120) and is based on a 37-item version reduced from the original 65-item form.(121) The items load onto six subscales: tension, depression, anger, fatigue, vigor, and confusion. Items are answered on a five-point scale, ranging from 0 ("not at all") to 4 ("extremely"). The total POMS score, which is calculated

with the vigor subscale items subtracted from the total of the other items, offers an index of total negative mood disturbance. Internal consistency is supported by Cronbach's alpha values, which range from 0.76 to 0.95 (difference between samples). The POMS-SF has been found to have convergent validity with other measures of global psychological distress.(122,123) Total higher mood disturbance score (TMD) signifies higher mood disturbances.(120) The SF-POMS has been used previously with healthy adult college students (120) and has established psychometric properties similar to the original POMS.(124) In this study, the Profile of Mood States total score was used to measure negative mood experienced in the past week by the participants. The individual 30 items were used as the global scores for the Subjective Units of Distress (SUDs) during the telephone-delivered intervention.

7. Subjective Units of Distress (SUDs) (Appendix M)

Subjective Units of Distress were used weekly during each TDI to measure the moods experienced during periods of smoking relapse and periods of abstinence. The adjectives that describe the moods included in the SUD coding are drawn from the Profile of Mood States—Short Form (POMS-SF). Adjectives from the vigor scale (*lively, active, energetic, efficient, full of pep*) were interpreted as positive moods. The remaining adjectives included in the *anxiety, confusion, depression, fatigue, and tension* scales were interpreted as negative moods. Each adjective was counted as a Subjective Unit of Distress and was coded from one to 10, with 10 signifying the greatest mood intensity. During each weekly TDI, participants were asked to select

SUDs to retrospectively describe moods experienced during the days prior to smoking relapse and during their periods of abstinence. The SUDs scale in this study was used to measure mood states, and its application in this study varies from the POMS-SF in frequency (once weekly), time of administration (during the TDI), and scaling (1-10). The POMS-SF was administered only once to each participant upon enrollment, and it was used as a descriptive measure of the mood state of each participant during the previous week.

8. Number of days relapsed during the 10-week program

The number of days each participant spent smoking (at least one puff in 24 hours) during the 10-week smoking cessation program defines the variable used in correlating average weekly scores for each SUD reported by that individual.

9. Carbon Monoxide Breath Analysis

Carbon monoxide breath analysis was performed using a Vitalograph Breath CO[®] at the orientation session and within a week after the end of the program. Carbon monoxide (CO) is produced by three methods only: cooking (the least significant), diesel exhaust, and tobacco smoke (the most significant).(125-127) The affinity of CO for hemoglobin is approximately 210 times that of oxygen.(127) The combination of CO and hemoglobin is known as carboxyhemoglobin (COHb). The amount of CO in end-expired alveolar air after holding one's breath is in equilibrium with COHb in the blood.(127-129) Carbon monoxide has a half-life of four to six hours, is a product of combustion, and is a

major constituent of inhaled cigarette smoke that, when measured, can be used as a reliable and valid indicator of exposure to cigarette smoking.(130)

The Vitalograph Breath CO[®] (Vitalograph USA, Lenexa, Kansas) was used to measure the carbon monoxide in a single breath of expired air (carbon monoxide). The Vitalograph Breath CO[®] has a range of 0-500 parts per million (ppm) with a drift of less than 2% at constant temperatures. The digital display on the monitor (ppm) is accurate within 2% after monthly calibration. The obtained value is displayed on the front panel of the Vitalograph Breath CO[®], and is calibrated every six months by a check of the carbon-monoxide ppm-meter zero-adjustment and verified against a standard carbon-monoxide gas sample of 50 ppm. Jarvis, Russell, and Saloojee (127,131) have described this method as a fast, accurate, and noninvasive way to quantify the amount of carbon monoxide in end-expiratory alveolar air, which provides an indirect measure of carboxyhemoglobin in the blood. Studies in their laboratory indicated a strong correlation (0.98) between expired-air carbon monoxide and a venous sample of carboxyhemoglobin in smokers.

Readings have been highly correlated with reported tobacco use (99.3% positive correlation).(106) Further, carbon-monoxide breath analysis is widely used and widely accepted as a method of verification in tobacco cessation studies.(104,127,131-134) The level of end-expired carbon monoxide (EECO) can provide an accurate, noninvasive, indirect measurement of COHb. For this study, the CO breath analyzer (Vitalograph Breath CO[®]) was used. Based on a previous smoking cessation study with adult participants,(135) an exhaled CO

level at less than 8 ppm was established as the basis for confirming abstinence in this study when combined with a self-report of not smoking in the previous seven days. The measure of exhaled CO was chosen taking into account that the average smoker (smoking one pack a day) has exhaled carbon monoxide averaging 25 to 35 ppm. A heavy smoker can have a COHb level of 8% and exhaled CO of 48 ppm.(127,131) The Vitalograph Breath CO[®] was used on all participants as part of the inclusion criteria and for group comparison. Self-reported seven-day abstinence periods were verified using this instrument. Calibration was maintained monthly by Tripler Smoking Cessation Program.

10. Follow-up Phone Call Questionnaire Form (Appendix N)

Within a week of completion of the smoking cessation program, the Follow-up Phone Call Questionnaire Form (Appendix N) was used during a final telephone interview with all reachable participants of both treatment and control groups. This questionnaire has been used previously by the Tripler Tobacco Cessation program to assess the program's effectiveness. Four variables derived from this form were: 1) abstinence from smoking in the last seven days, 2) continuous abstinences, 3) number of relapses during the program, 4) number of cigarettes being smoked per day (if smoking within the last seven days). These measures were selected for their alignment with the outcomes-verification used in smoking cessation literature and research. In addition, the "reasons for relapse" statements listed in this form were rated by participants on a scale of one (not important) to five (extremely important). These reasons-for-relapse statements were used in a previous study and offer a basis for comparison to the present

study.(106) The links between the research questions, measures, questionnaire items, and statistical tests are shown as a diagram in Figure 4.

The remainder of the responses to this questionnaire were not analyzed for this study, but will be analyzed as part of a larger study.

THE SMOKING CESSATION PROGRAM

The Tripler Smoking Cessation Program consisted of a manualized smoking cessation program that combined cognitive behavioral therapy, education, and pharmacological aids in 10 weekly sessions that were one hour in length and conducted in a group format. A clinical psychologist with extensive experience in smoking cessation treatment led the group. In the first 15 to 30 minutes of each session the educational component was delivered, followed by the cognitive behavioral therapy component. The pharmacological aid was provided (without cost) to the participant at the end of each session. Participants were expected to attend at least five of the sessions to be included in the analysis.

Interventions Used in the Program

Below are the interventions or strategies that were delivered during each of the smoking cessation sessions to each individual in the group, in accordance with the manual. All sessions began with setting the agenda for the session.

Session 1: The Triangle of Nicotine Addiction: Physiologic, Psychologic and Environmental

Session 2: Discussing, reviewing, and reformulating the patient's goals for treatment of nicotine dependence.

Session 3: Discussion of tobacco use and craving.

Session 4: Exploring positive and negative consequences of tobacco use.

Session 5: Discussing advantages of an abstinence goal; exploring the patient's ambivalence about abstinence.

Session 6: Meeting resistance with exploration and a problem-solving approach; supporting patient efforts.

Session 7: Assessing level of family support; explaining the distinction between a slip and a relapse.

Session 8: Exploring self-help involvement as a coping skill; identifying means of self-reinforcement for abstinence.

Session 9: Exploring discrepancies between a patient's stated goals and actions, when applicable.

Session 10: Eliciting concerns about tobacco use and consequences.

Self Selection of Pharmacological Aids

As part of the standard Tripler Tobacco Cessation Program, at the end of each cognitive behavioral session participants from both control and treatment groups were provided with a seven-day supply of either bupropion or nicotine replacement therapy (transdermal patch), which they self-administered at home beginning on the first day of week one. (Previous clearance from their health-care provider is a requirement for receiving the pharmacological intervention in the program.) The participants who chose bupropion self-administered 150 mg of bupropion once a day for three days and twice a day after the third day and continued this regime for the rest of

the 10 weeks. Those who chose NRT self-administered transdermal patches daily (21 mg for the first six weeks, 14 mg for weeks seven and eight, and 7 mg for weeks nine and ten). Each week, when the participants returned for the group session, they received the next week's supply of either bupropion or NRT. Program staff monitored the participants weekly for adverse medication effects, checking for elevations in blood pressure, complaints of nausea and insomnia, and changes in weight and appetite. The licensed psychologist leading the weekly group sessions monitored the participants for activation of manic episodes, seizures, and suicide tendencies.

Psychological Therapies

This study engaged all participants in a course of educational and cognitive behavioral therapy. According to the manual, these interventions were provided consistently by the licensed clinical psychologist in the form of one-hour weekly group meetings, which were designed to help participants a) understand the physical and psychological benefits that accompany smoking cessation and a transition to a healthier lifestyle; b) identify the cognitive, emotional, motivational, and experiential factors that are most likely to precipitate relapse; c) restructure the self-defeating cognitions that accompany relapse and inhibit recovery; and d) develop effective coping strategies to maintain abstinence and minimize the duration and severity of future relapse events.

Additionally, participants in the treatment group received an individualized weekly TDI that, in concept and protocol, was based on the cognitive behavioral model of the relapse process.(7) The control group did not receive the TDI. Both

treatment and control groups were asked to come to TAMC psychology services for carbon-monoxide breath analysis within the week following the conclusion of smoking cessation program (10th session). Participants who preferred or were unable to return to the clinic were contacted by the advanced-practice nurse within a week after the 10th session, to obtain the exhaled carbonmonoxide reading at their home or worksite.

DELIVERY OF THE THERAPEUTIC INTERVENTIONS

All participants in the study were expected to attend the 10-week course of cognitive behavioral therapy accompanied by a self-selected pharmacological smoking cessation aid. All study participants were encouraged to set target quitting dates (TQD) during the second week of therapy. Participants in the experimental group were provided with a weekly TDI beginning during the first week of their smoking cessation program. As shown in Figure 5, participants assigned to the control group did not receive TDIs. The content of the call followed the prescribed protocol in Appendices O and P.

DELIVERY OF THE EXPERIMENTAL INTERVENTION

The advanced-practice nurse scheduled one telephone-delivered intervention per week per treatment-group member. Both quantitative and qualitative data were collected during the calls, following the prescribed protocol. (See Appendices O and P.) The advanced-practice nurse referred to information

gathered during the TDIs to assist her counseling in subsequent TDIs. Both experimental and control groups received a final evaluative call within a week of program completion for the purpose of obtaining self-reported smoking status that could be verified by the Vitalograph Breath CO[®], which was scheduled for the same week. The TDI served as both a mechanism for support and for monitoring changes in smoking behavior, and for data collection purposes.

ETHICAL ISSUES AND RISKS

To protect the rights of eligible participants for this study, the following measures were taken. These were: a) using informed consent; b) ensuring confidentiality; and c) proceeding through formal ethical review processes.

The informed consent was obtained prior to the collection of any data (Appendix C, D). Potential participants were given a full verbal and written explanation of the study by the investigator. The study was presented during the group orientation sessions as one designed to potentially increase their chances of success in quitting smoking. Potential participants were assured that their participation was voluntary and that each would have an equal chance to be selected to receive the telephone calls. All side effects regarding medications were fully explained by the psychologist leading the weekly group sessions.

In assuring potential participants that participation was voluntary, it was made clear that there were no known hazards to participating in receiving the phone call (there have been no reports of untoward effects from telephone counseling in the professional literature), that they could withdraw from the study at any time,

that their questions would be answered, and that they would be referred to the psychologist leading the group sessions for other conversational topics other than their smoking behavior. Also, they were informed that there were no costs associated with participating other than a 15- to 20-minutes/week time involvement and a trip to the psychology department to use the Vitalograph Breath CO[®] for measurement of exhaled carbon monoxide.

All information was treated with anonymity and confidentiality. All data were kept confidential through use of participant numbers and all raw data were stored in a locked file located in the researcher's office. All raw data will be kept for three years and then will be shredded.

The study protocol was presented to the Tripler Army Medical Center Clinical Investigations Scientific Review Panel and deemed of merit to the science. Subsequently, the protocol was presented to two ethical review committees, which also granted their approval: the ethical review committee at the University of Hawaii at Manoa (Appendix E) and the ethical review committee at the Tripler Army Medical Center (Appendix F).

STATISTICAL ANALYSIS OF THE DATA

The data were entered and analyzed using the Statistical Package for the Social Sciences. Prior to determining the main outcome results, the data were cleaned and verified. Table 1 shows the analytical variables and their corresponding descriptors. Table 2 shows the type of analysis used to address each research question. The data were analyzed with the study denominator (30

for treatment and control groups respectively) based on the intention-to-treat principle, as in randomized clinical trials for evaluation of pharmacotherapy for nicotine addiction.(136) Baseline analyses were performed using t-test and chi-square statistical tests to determine the possible differences between the treatment and control groups in terms of demographic and smoking characteristics; these tabulations are listed in tables 3 and 4. All statistical tests were two-sided with an alpha level of .05 to avoid type II error.

According to the protocol, data from all participants enrolled in the study were used in the analysis. Participants who refused the TDI 20% of the time, failed to attend at least five program sessions, could not be reached due to disconnected contact numbers, or dropped out of the study, as well as those stating that they had returned to continuous smoking, were all counted as smokers. Persons who could not be reached after three attempts in one week were also counted as smokers.

CHAPTER 4

RESULTS

SAMPLE

Sixty volunteers who met the inclusion criteria for the study were recruited from six smoking cessation program orientation sessions that occurred between October 2001 and May 2002. Altogether, 180 individuals were screened for eligibility, and of those, 120 did not meet the inclusion criteria, were not interested in participating, or were not willing to adhere to the study protocol. All of these 120 individuals went on to receive usual treatment in the Tripler Tobacco Cessation program, but were not part of the study. The participants that met the inclusion criteria and were willing to follow the protocol (n=60) signed the informed consent form and completed the following baseline measures during the orientation: 1) the Smoking History Questionnaire (Appendix I), 2) the Fagerstrom Test for Nicotine Dependence (Appendix J), 3) the Nicotine Withdrawal Questionnaire (Appendix K), and 4) the Profile of Mood Disturbances (Appendix L). In addition, initial exhaled carbon monoxide was measured in parts per million (ppm) via the Vitalograph®.

After completion of each questionnaire, the investigator reviewed it for missing items and the participant was given an opportunity to provide any missing data, thus minimizing missing data (except for three responses in the Smoking History Questionnaire). During the first call (week 0), demographic data was collected. The rest of the data was systematically collected during the TDI

and during the evaluative telephone interview at the end of the program. This chapter summarizes the analytical results that describe the sample and answer the research questions.

STUDY ATTRITION

Nine individuals altogether, four males in the treatment group (13%) and three males and two female from the control group (17%), were lost to follow-up after three attempted calls to each. These individuals were counted as smokers in the final analysis. Figure 6 illustrates the study's attrition at the end of the program.

DEMOGRAPHIC CHARACTERISTICS

The demographic data collected during the initial telephone call at week 0 was described in terms of frequencies and percentages. The data are reported in full detail in Table 3. The sample pool was composed of 53% (n=32) males and 47% (n=28) females. A higher percentage of males was expected, due to reports that men constitute 59% of the military population, and women 41%.⁽¹³⁷⁾ In age, most of the participants (79%) were under 35: 42% (n=25) were between the ages of 18 and 25, and 37% (n=22) between 26 and 35. Eighteen percent (n=11) were between 36 and 45 years of age, and one participant (3%) fell between the ages of 46 and 55. The largest ethnic group represented in the sample was Caucasians (77%, n=46), aligning closely with Department of Defense (DoD) demographic reports of 79% in the general military population.⁽¹³⁷⁾ African

Americans were overrepresented (13%, n=8) in this group when compared with DoD reports (5%). The percentage of Hispanics, Asian Americans, and Native Americans was 5% (n=3), 3% (n=2), and 2% (n=1) respectively, again closely following trends in the larger population. Married participants were in the majority, composing 52% (n=31) of the sample, followed by singles (42%, n=25) and divorced individuals (7%, n=4).

Three-quarters (75%, n=45) of the participants were active duty, with family members and retirees constituting 25% (n=15) of the total sample. The retiree frequencies were combined with dependent family members because, with exclusion criteria disqualifying persons with illnesses, few retirees were expected to enroll. By far the majority of the participants were members of the Army service branch (69%, n=31), with members of the Navy totaling 18% (n=8), Air Force 9% (n=4), Marine Corps 2% (n=1), and Air Guard 2% (n=1). The participants serving in active duty were all enlisted, with the majority of ranks being E 2 (38%, n=17), E 5 (27%, n=12), and E 4 (22%, n=10). The remaining 13% were comprised of enlisted ranks E 6 (7%, n=3), E 3 (4%, n=2) and E 1 (2% n=1). Attempts were made to recruit officers for the study, but only two volunteered and these did not meet the inclusion criteria.

SMOKING CHARACTERISTICS

The characteristics addressed in the Smoking History Questionnaire were selected in order to gain information about factors commonly associated with increased difficulty in quitting smoking and factors associated with higher levels

of dependence on nicotine, as described in the published literature. Frequencies, percentages, means, and standard deviations were used for analysis, depending on the data characteristics.

The mean of scores for motivation (8.12) is notably higher than five, which was the level of motivation for inclusion into the study. At start of treatment, the sample's mean initial exhaled carbon monoxide measured 16.78 ppm (SD=4.90), indicating the high levels of cigarette consumption reported: 19.57 cigarettes per day. (Research studies have reported carbon monoxide levels of <8 as verifying seven-day abstinences.) Participants began smoking early in life, with the mean age of initiation being 15.8 years and range of values clustered around this mean (SD=2.78). The mean Fagerstrom score of 6.20 matches the level interpreted in smoking cessation studies to signify addiction to cigarettes. Sixty-five percent of the participants selected bupropion as the pharmacological aid of their choice, and over 50% reported using alcohol weekly, having a spouse that smokes, and/or having a father who is either a current or former smoker.

The total withdrawal score described past experiences with nicotine withdrawal according to the diagnostic criteria for addiction described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Individual scores were derived by adding together the score selected by the participant (zero for absent, four for severe) for each of the eight withdrawal symptoms. The maximum possible score was 32, with the minimum being zero. Overall, the participants' previous experiences with withdrawals during smoking cessation

were very similar. For the entire sample, the mean total score was relatively high ($M=22.88$, $SD=5.12$), and a statistical range of four indicated little variability. The frequencies for each withdrawal symptom are presented in bar graph form in figures 7-14. An explanation of each of these figures follows:

Cravings (Figure 7) were experienced as severe by 42% of the participants, and none reported cravings to be absent. Increases in appetite (Figure 8) were reported by 97% of the respondents; all participants reported some degree of depression (Figure 9) and anxiety (Figure 10), primarily in the mild to moderate range. Difficulty concentrating (Figure 11) was reported by most participants as occurring in the moderate to severe range. Experiences of anger (Figure 12) and restlessness (Figure 13) were slight to moderate, while difficulty sleeping (Figure 14) was moderate to severe for more than 35% of the respondents.

In the Smoking History Questionnaire (Appendix I), participants were asked to list their reasons for smoking. The number of responses per participant varied (1 to 5). Their multiple responses were grouped into four categories. These categories, and the corresponding percentage of participants who listed a reason falling within each category, were as follows: 1) assistance with stress management (30%), 2) fitting in social interactions (30%), 3) association with other activities (22%), 4) strong urges (18%).

Multiple reasons were reported for wanting to quit smoking, which was addressed with an open-ended question: "Why do you smoke?" The responses varied (i.e. "my children see me smoking and I don't want them to smoke," "All

my friends smoke," etc.). These statements were organized into five categories, presented here in order of frequency: 1) improvement of overall health, n=60; 2) role modeling for family, n=52; 3) increased endurance during physical training exercises, n=32; 4) financial reasons, n=30; and 5) feelings of being stigmatized at work and in social settings, n=20. Other reasons to quit that did not fit into the above categories were 1) dislike of the habit of smoking, n=2, and 2) need to regain control, n=1. Three participants did not have responses for this item.

RELIABILITY OF MEASURES

Reliability analyses were done using Cronbach alphas (also referred to as coefficient alphas) on three scales: the FTND, the POMS-SF, and the Nicotine Withdrawal Scale. The Cronbach alpha is designed to measure internal consistency and the scale's coefficient is calculated with the SPSS statistical software. In this study, the Cronbach alphas were calculated as follows: FTND (0.58), POMS-SF (0.87), Nicotine Withdrawal Scale (0.56). The POMS-SF reliably exceeded the acceptable 0.70 coefficient alpha. Although the alphas of the FTND and the Nicotine Withdrawal Scale fell below acceptable limits, limited by the small sample size, it must be emphasized that the FTND has been reported to be used in numerous smoking cessation studies and that the withdrawal scale has face validity due to its source, the DSM-IV. The Smoking History Questionnaire and the evaluative telephone interview form have both been used in a retrospective study (106) and are regularly used in the smoking cessation program at Tripler Army Medical Center. The reasons-for-relapse

statements included in the latter form were generated from statements offered by smokers.

RESULTS: OBJECTIVE 1

The first objective of the study was to determine whether participants who received TDIs experienced more changes in their smoking behavior than usual-care participants. Results from main outcome variables drawn from items in the follow-up questionnaire addressing smoking cessation (point-prevalence and continuous abstinence) and harm reduction (initial and current number of cigarettes smoked per day) were analyzed for statistical significance with chi-squares and t-tests, respectively, to answer the research questions. The results for each main outcome are detailed in tables 5 through 8 and summarized below.

The first question in objective 1 addressed differences in point-prevalence abstinence between treatment (TDI) and control groups (usual care) at the 10th week. A higher rate of abstinence was found in the treatment group, although the difference was not statistically significant: 50% of TDI participants reported having abstained from smoking for the previous seven days, while 37% of the control group reported the same (Table 5).

The second question addressed differences in the rate of continuous abstinences (refraining from smoking since the target quit date) between treatment and control groups at 10 weeks. Again, although no statistical significance was found, the treatment group produced a greater percentage of

persons (20%) who reported continuous abstinence since their target quit date than did the control group (7%) (Table 5).

The third question sought to determine if, among those still smoking at 10 weeks, there was a difference between treatment and control groups in the degree to which cigarette consumption had decreased. This question was answered by subtracting the reported figures for cigarette consumption at the end of the program from the consumption rates reported at the beginning. The reduction of cigarette consumption was the same for both groups (14 cigarettes per day). A t-test found no statistically significant difference between the two groups' daily cigarette consumption, both reporting a mean consumption rate of 14 cigarettes per day (Table 5).

The fourth question sought to determine any difference between treatment and control groups' mean number of relapse days as reported at the end of the program in the TDIs (treatment group) and follow-up questionnaire (control group). Only a slight difference was seen between the means of the treatment group and control groups (3.7 vs. 4.3, respectively). The results were not statistically significant (Table 5).

The fifth question was exploratory in nature and sought to determine differences between treatment and control groups in selected demographic and smoking characteristics that may have impacted the outcome at 10 weeks. The selected background demographics and smoking characteristics of the participants (whose assignment to treatment vs. control group was randomized) are presented in tables 6 and 7. Statistical difference ($p > 0.05$) was detected in

two demographic categories: age and years spent smoking. Those receiving TDIs were proportionally a younger group than the control group: 63% and 24%, respectively, were under the age of 25. On average, control-group participants had smoked longer (16 years) than treatment group participants (11 years), a statistical significance of $p=.02$.

Statistically significant differences ($p<.05$) between the two groups' smoking characteristics were also found in the mean scores of two withdrawal symptoms: cravings and difficulty concentrating. The mean scores for reports of cravings (Table 8) were slightly higher in the treatment group than in the control group (3.8 vs. 3.0), while difficulty concentrating (Table 8) was more prevalent in the control group (3.7 vs. 2.53). Reports of other withdrawal symptoms (increased appetite, depressed mood, anxiety, irritability, anger and frustration, restlessness, and difficulty sleeping) were not statistically significant.

RESULTS: OBJECTIVE 2

The second objective of the study was to describe mood states accompanying smoking behavior and determine their relationship to abstinent periods and relapse episodes. The first question addressing this objective inquired as to the particular mood states that precede relapse and abstinent periods for those participants who received the TDIs but experienced relapse ($n=11$). The SUD scores from the POM-SF are detailed in Table 9. During relapse, the most frequently reported SUDs were "tense" (24), "nervous" (24), "discouraged" (22), "anxious" (22), "bad-tempered" (20), and "angry" (20). Their

scores have a wide range, with most falling between one and eight on a scale of 1 to 9.

Only four SUDs were reported as experienced during periods of abstinence. They were, in order of frequency, "lively" (30), "active" (30), "grouchy" (22), and "worn out" (1). During the TDI, individuals reported feeling reluctant to comment on moods experienced during periods of abstinence, often stating that it was difficult for them to discern retrospectively.

The second question in objective 2 sought to determine any correlation between mood states and the duration of relapse. The SUDs that were reported prior to relapse were reported as persisting during the relapse period. The correlation coefficients between each SUD and the average number of days relapsed are shown in Table 10. These correlates were calculated by averaging the weekly scores reported for each SUD and correlating them with the individual's number of days relapsed. Two SUDs ("lonely" and "uneasy") were found to have a strong positive correlation ($r= 0.872, 0.855$, respectively), with the number of relapsed days at the 0.01 confidence level. Three SUDs ("gloomy," "annoyed," and "discouraged") had a strong positive correlation ($r=.778, 0.496$ and 0.492 , respectively), with the relapse duration at the 0.05 confidence level.

The third and last question of objective 2 targeted perceived reasons for smoking relapse, as reported by participants at the end of the program and while receiving the TDIs. These were selected from a list provided during the follow-up telephone call. The selection of the participants for perceived reasons for relapse are presented in Table 11, shown in frequencies and percentages. Twenty-four

participants made selections from the list. Eleven persons in the treatment group and 13 persons in the control group experienced relapse and selected items from the list. Illness in the family was selected as not important by 73% (8) in the treatment group and 50% (8) in the control group. Cigarettes were essential to functioning for nearly half of the participants in both groups, and as high as 62% in the control group found cigarettes necessary to find life worth living. Temptation was found too strong for over 90% of the persons that relapsed for both groups. Also, over 90% found their relapse related to the timing of their smoking cessation attempt. Gaining weight, insufficient social support, and work-related problems were found to be of at least some importance in relation to their smoking relapse.

SUMMARY

This chapter presented the results for each objective in this study. Descriptions of the tables and figures were provided. The reader can refer to the tables and figures mentioned throughout the chapter to review results in greater detail. Discussion of these results and conclusions follows in Chapter 5.

CHAPTER 5

DISCUSSION

In this section, the results related to the questions addressed by this study and their implications for theory and practice are discussed. Directions for future research are also presented, then considered.

Sometimes, in the course of a study, interventions are affected by the qualifications, personality traits, and skills of those who deliver it. The telephone interventions in this study were delivered by an advanced-practice nurse with training in smoking cessation intervention and motivational interviewing skills from University of Massachusetts, University of Arizona, and University of Albuquerque that preceded and coincided with the administration of the intervention. The engaging personality traits of this individual, coupled by her extensive experience as an advanced-practice nurse and tobacco cessation counseling skills, may have affected the outcomes of this study.

OBJECTIVE 1 AND ITS RESEARCH QUESTIONS

The first objective focused on the results of an enhanced intervention (TDI) added to an existing smoking cessation program that used both pharmacological and behavioral methods to assist persons in ceasing or reducing their smoking behavior. It was hypothesized that by the end of the program, more individuals in the group receiving the enhanced intervention would be abstinent or reduce their smoking behavior, evidenced by the number

of cigarettes smoked. The research questions for objective 1 were aimed at obtaining specific outcomes in order to analyze the effectiveness of the enhanced intervention.

The results gathered for question 1 determined that there was no statistically significant difference in the point-prevalence abstinence between treatment (TDI) and control group (usual care) at 10 weeks (end of program). However, point-prevalence abstinence at program end was higher for the control group, verified by exhaled carbon monoxide (<8 ppm) one week later. This finding was consistent with similar studies,(138) suggesting that clinical use of the TDI holds potential in smoking cessation treatment. The absence of statistical significance may have been due to the small sample size; it may also have been affected by factors in the TDI interview that weren't controlled for, such as age and pharmacological aid administration. During the TDI, participants were encouraged by the advanced-practice nurse to reserve a time to use the Vitalograph Breath CO[®]. The measurement of exhaled carbon monoxide served as a verification tool of the self-reported abstinences. Relapsed participants expressed, during the TDI, a wish to not receive the TDI weekly, though they were receptive to receiving the calls less frequently and agreed to continue receiving the calls until the end of the program in order to comply with the study protocol. The participants that remained abstinent at the end of the smoking cessation program reported that the most helpful TDIs were the ones received around their target quit date and the earlier phases of their quitting attempt. Their reports coincide with the recommendations of timing frequent telephone

interventions during the target quit date and in the first few weeks of smoking cessation.(90)

The second question inquired into the difference in continuous abstinence between treatment (TDI) and control group (usual care) at 10 weeks (end of program). The number of individuals that maintained continuous abstinence from smoking since their target quit date was expected to be higher for the treatment group. Although the numbers of continuously abstinent persons were small for both groups, the treatment group contained more continuously abstinent participants (although again, possibly due to the small sample size, the difference was not statistically significant). Caution must be taken in interpreting this finding, because the *continuous abstinence rates* are based strictly on self-reports. Continuous abstinence can be verified with more precise biological markers such as cotinine,(139) but this option was not financially feasible for this study. With adequate funding, future studies would benefit from incorporating measurement of cotinine. Reports of continuous abstinence may also have been affected by the dynamic of the TDI interviews and the background of the advanced-practice nurse.

The third question explored decrease in cigarette consumption at end of program, again comparing between treatment (TDI) and control (usual care) groups. Although a reduction in the mean number of cigarettes smoked daily was expected in the treatment group, no difference was found. Future studies might explore the value of harm reduction as an independent goal in smoking cessation treatment programs, since it may serve as a bridge to abstinence. Currently in

the literature, harm reduction by decreasing cigarette consumption is considered primarily when the ideal goal of continuous abstinence cannot be achieved. New biomarkers are being explored that would validate the benefits of harm reduction by decreasing cigarette consumption.(140) The goal of harm reduction has been approached with the release of various decreased-nicotine products to the market. Although these products promise lower nicotine, they may not be achieving any harm reduction since smokers titrate the nicotine according to their level of addiction; and beyond this, potentially harmful chemicals may be delivered simultaneously, as in the case of “light” cigarettes, which still contain carcinogenic chemicals. By contrast, reduction of cigarette use has not been documented as having any adverse effects.

The fourth question sought a comparison of mean number of days of relapse to smoking between treatment and control groups. The slightly higher mean found for the control group (0.6 days) was neither clinically nor statistically significant. The lack of statistical significance throughout the results of this study diminish its impact on practice, but the increased frequencies in both point-prevalence and continuous abstinence suggest a need to test other types of supportive interventions, such as web-based reinforcement or an interactive TDI arrangement in which the call is initiated by the smoker engaged in the cessation effort.

The last question of objective one explored group differences in demographic and smoking characteristics (common descriptors of smoking addiction) that may have affected outcomes for the TDI intervention. In this

aspect of the study, statistical significance was found with respect to the age of the participants in the two groups. The randomization process did not control for age, and as a result the 18- to 25-year-old category comprised 63% of the treatment group and only 24% of the control group. The rest of the participants ranged from 26 to 55 years old. This finding is of interest because, in a 1996 study at Tripler, the majority of participants in the smoking cessation program were between the ages 26 and 45. Other studies have found that older smokers are more likely to stop smoking than younger smokers.(141) In future studies, randomization for age would avoid age bias, which may have impacted this study.

Another point of interest in the results from this study is the scant number of volunteers from officer ranks; the two who were recruited did not meet the inclusion criteria. This may be explained by reports that officers make up less than one-third of the program census and that the incidence of smoking is low among higher-ranking military personnel. The image of smokers as less fit than nonsmokers may be a factor in officers' enrollment in smoking cessation program enrollment. Low officer enrollment was evident in the previous Tripler study as well,(106) where 120 program charts were retrospectively analyzed and 70 individuals volunteered to answer questions in a follow-up telephone call. In that study's findings, no data were collected from officers. This finding has implications for the planning of workplace smoking cessation programs. It is challenging to develop strategies to attract individuals in executive positions who may be closet smokers and who may not enroll in order to protect their image as

leaders. In the civilian sector, workplace smoking cessation programs may be underutilized, suggesting that a more neutral environment may be more effective (142). The same may be true in a military setting.

OBJECTIVE 2 AND ITS RESEARCH QUESTIONS

The second objective focused on moods experienced by the participants who received the enhanced intervention and the relationship of mood to the occurrence of relapse and abstinence. The first question within this objective sought a description of the mood states that precede smoking relapse episodes and the moods states experienced during smoke-free periods.

There was reluctance among the participants in this study to speak about their moods and details about reasons for relapse to smoking. The population was mostly active-duty military, and one can speculate that constraints regarding the nature of their military work and the timing of the study (which began shortly after September 11th, 2001) may have had an inhibiting effect on participants' reports of mood and reasons for relapse. Most of the SUDs reported during relapse were negative ("tense," "nervous," "discouraged," "anxious," "angry," "bad-tempered," and "grouchy"); positive adjectives were offered by the questionnaire but not selected. Only three moods ("lively," "active," and "grouchy") were reported during periods of abstinence. Of note is the fact that "grouchy" was reported frequently, both during abstinence and preceding relapse, implying that this mood prevails throughout the smoking cessation

process. Interventions and future studies need to incorporate awareness of this mood and address specific coping skills.

The second question further explored negative mood states, in particular the patterns of mood state that correlated to duration of relapse and abstinence. "Lonely," "uneasy," "gloomy," "annoyed," and "discouraged" moods had a strong positive correlation with the number of days relapsed to smoking. However, except for "discouraged," all of these SUDs were infrequently selected but nevertheless associated with the highest number of days of relapse. SUDs selected to describe moods during periods of abstinence were not correlated with number of days of smoking abstinence. Use of SUDs has not been reported in the literature regarding cigarette smoking in relationship to mood. Other novel ideas continue to be explored in an effort to understand the phenomenon of mood,(123), and these, together with the use of SUDs, need to be incorporated in future studies in order to advance our understanding of the effect cigarette smoking has on mood.

The last question of objective 2 asked participants to indicate reasons for relapse. A surprising finding was that "illness in the family" was selected by a majority as unimportant in relapse, while "stress" was selected frequently. The association between stress and smoking is well known,(143, 144) implying that this interview statement may have led participants to disassociate illness and stress. It is plausible, also, that respondents were reluctant to attribute the cause of the smoking behavior to their families. Nevertheless, consideration should be given to clarifying this statement in future studies.

More than half of the participants reported feeling that an important factor in their relapse experiences was the effect that a lack of cigarettes had on their overall functioning. This has global implications for program planning. Program components that address how to function without cigarettes should be included, so that participants can learn skills that will allow them to function without cigarettes.

Strong cravings were deemed an important reason for relapse by more than 90% of persons who experienced relapses. Use of pharmacological interventions was reported during the TDIs as inconsistent for reasons ranging from the interference of field exercises with program attendance to not following instructions for self-administering of medications. Participants with strong cravings have reported ceasing to use coping skills after smoking one or two cigarettes. These findings are open to a number of compatible interpretations. First, the urge to smoke may be a fairly stable phenomenon in individuals who continue to smoke, and second, the type of skills commonly taught in smoking cessation classes may not have a large or immediate impact on reducing the amount of urge experienced by persons that continue to smoke more than one cigarette.

More than the majority of participants attached some importance to the statement "Life is not worth living without cigarettes." This implies that program planning should be alert to the potential for severe reactions to smoking cessation. Reports in the professional literature of depressive reaction to smoking cessation literature should guide program planners in addressing the

need for specialists providing therapy to develop assessment skills that will address these depressive reactions.

With few exceptions, the statement "Temptations to smoke were too strong" held at least some importance for the participants. Program planners should address temptation that can lead to relapse individually with each participant. This was discussed retrospectively with many participants during the TDI, and although it did assist these individuals in recognizing future temptations, relapses might have been prevented if these temptations had been addressed from the start. This can be accomplished perhaps through an assessment of the individual's situation at the beginning of the program.

"The timing was wrong for me" was rated as important by nearly all the participants. Related to this statement were comments made by participants in the treatment group during the TDIs and recorded by the advanced-practice nurse: "This time is very stressful," "My spouse is being deployed," "I can't give up my cigarettes now, maybe later." It is plausible to surmise that world events surrounding the smoking cessation attempt influenced this selection, and may also have impacted study recruitment. This finding implies that the timing of the quitting attempt should be assessed at the beginning of a smoking cessation program. Future research should investigate situational variables regarding timing of a successful quitting attempt.

The statement "I gained too much weight" was selected as a reason for relapse for most of the participants. This implies that attention should be given to combining discussion of diet and exercise. Some programs have included

exercise as part of a multimodal smoking cessation program with successful effects.(145)

Ratings for "I didn't have enough social support" ranged from some importance to extremely important. Participants expressed repeatedly that their spouses and friends smoked, and therefore they lacked the social and home environment they needed to not relapse to smoking. This finding implies that family and social support should be elicited during the administration of the program. Family members and friends should be invited to participate regularly in program sessions to equip them with the skills needed to support the smoker in the quitting process.

Finally, "Too many problems at work" was rated important by about at least half of the relapsed participants. Problems at work may have been underreported since this study occurred in a place related to their work. It must be taken into consideration that work in the military expands to a whole way of life, which is not necessarily the case in the civilian sector.

LIMITATIONS OF THE PRESENT STUDY

This study has some conceptual and methodological limitations. First, the participants were self-selected. Second, there was a 15% attrition rate and attendance at the smoking cessation sessions was not consistent by all the participants. As a consequence, additional attention was given to each participant when the groups were smaller. Although problems with subject recruitment and treatment are ever-present in studies on smoking cessation,(71,

146, 147) it must be noted that the smaller sample size further limits the universality of any findings. Since all the participants who were not reached at the end of the study were counted as smokers, it is impossible to determine whether any benefits were derived by these individuals. Third, the cataclysmic event of September 11th happened during the initial phase of recruitment and was an influential factor throughout the study. Not surprisingly, the program enrollment, attendance, and availability for TDIs became more challenging for most of the participants.

Fourth, some methodological limitations were inherent in the design of the study. These limitations were the following: 1) The study was conducted during the implementation of the smoking cessation therapies delivered by two different psychologists, and the participants were recruited from six different cohorts in order to obtain an acceptable sample size; 2) All data, other than baseline, was obtained through retrospective self-report, with a high response burden expressed by the participants; and 3) The pharmacological aids were self-administered at home by the participants, and inconsistencies in dosage and compliance occurred throughout the study. Specifically, the quality of the responses regarding moods preceding relapse and the treatment issues mentioned earlier in this chapter, not controlled, are major limitations on the interpretation of the data. More immediate methods of reporting moods prior to smoking may yield a better understanding of the influence of TDIs on preventing the relapse and affecting moods related to smoking. Additionally, the follow-up was short-term, and the data from three- to six-months post-treatment might

indicate a need for continued reinforcement, through TDIs, as a method of sustaining the coping skills learned to respond to novel situation.(148)

In summary, there was no statistical significance found in point-prevalence abstinence, continuous abstinence, and the number of cigarettes smoked per day after 10 weeks of treatment. Differences were noted in the frequency of abstinence, with more abstinent participants found in the treatment group (50% vs. 37%), suggesting that this treatment promises some clinical value. The strong correlation between relapse and moods of loneliness and uneasiness, discouragement and gloom, suggests a need for further study with a larger number of subjects.

CONCLUSIONS

This study explored the use of a telephone-delivered intervention to enhance smoking cessation outcomes of a multimodal smoking cessation program. There was no significant statistical difference found between the group receiving the enhanced intervention and the control group. Reasons for the lack of statistical significance include the small sample size of 60 (since a difference in frequency indicates a potential clinical value).

Descriptions of mood were obtained by using SUDs during relapsed times and periods of abstinence. Negative moods were prevalent during relapse periods while positive moods were experienced during periods of abstinence from smoking, with the exception of one negative mood (grouchy) that was constant throughout the smoking cessation experience. Infrequently selected

SUDs (loneliness, uneasiness, gloominess, and annoyance) were highly correlated with higher number of days relapsed, and this requires further investigation.

The cost-benefit ratio of a telephone-delivered intervention needs to be further studied, as well as the lasting benefits beyond the period of the smoking cessation program.

Smoking cessation continues to be a challenge for smokers. Effective, evidence-based methods of delivering interventions using advanced technologies that are available need to be further developed. Identification of effective, evidence-based smoking cessation programs continues to be a national priority. The field of Nursing Science, which focuses on promoting caring and wellness, should continue to focus on resolving this devastating health problem.

IMPLICATIONS FOR THEORY AND PRACTICE

The relapse prevention model has been tested in the substance abuse field and should be similarly examined for its value in smoking cessation. This study advances knowledge regarding the applicability of the relapse prevention model to smoking cessation. The telephone is a handy vehicle for the delivery of an intervention. Involvement in the process that helps smokers break their addiction is the responsibility of all nurses. This study demonstrates how nurses can be involved in a multidisciplinary effort and use the simple technology available to them to help their patients stop smoking.

Because statistical significance was not achieved, there is insufficient evidence to change current practice in the smoking cessation program with the results of this study, although the heightened frequency of smoking cessation in the treatment group suggests a potential clinical value. To my knowledge, intra-program interventions using TDIs have not been published. Therefore, *comparison of this study with other studies is also limited. Correlating relapse with specific moods through use of SUDs has the potential to tailor the delivery of the TDI and thus increase its effectiveness, but this interpretation is limited due to the small number of participants.*

RECOMMENDATIONS FOR FUTURE RESEARCH

The telephone-delivered intervention continues to provide an applicable *alternative to prolonging the smoking cessation therapy of an intensive smoking cessation program. In the literature, there still remain inconsistencies in terminology when referring to delivering therapy or support via telephone. More studies on the timing and frequency of telephone calls are warranted. The concept of harm reduction needs to be further explored.*

A larger sample size is needed for future studies in order to assess small magnitude effects. The frequency of the telephone-delivered interventions needs to be *tailored for efficient and timely contact with the patients at their target quit date. Program planning for smoking cessation should include attention to the timing of the attempt, and development of coping skills that are mood specific, such as loneliness and uneasiness, should be considered when planning a*

smoking cessation program. The design of future investigations should take into consideration the difficulties encountered in recalling mood retrospectively by the participants in this study.

In future studies further questions to be explored are: What are the mood state needs of smokers initiating cessation? Does a combination of participant initiated and investigator initiated calls yield increased cessation rates? What populations are most likely to benefit from the telephone-delivered interventions? What is the potential for reimbursement of telephone-delivered interventions for smoking cessation? What call frequency and length are the most effective? Which approaches (i.e. motivational interviewing or other styles of communication) are most effective during the telephone-delivered interventions? What recruitment strategies can be employed to attract closet smokers? A comprehensive smoking cessation program design including exercise, attention to mood state and coping skills needs to be tested to determine if addressing these concerns can improve outcomes, and if so why and how much.

Table 1 Statistical Analyses for Descriptive Variables

Variables	Type of Analyses
<p>Demographics and Smoking Characteristics of the Sample</p> <ul style="list-style-type: none"> • Gender • Age • Ethnic Group • Marital Status • Military Status • Service Branch • Military Rank • Smoking Characteristics <ul style="list-style-type: none"> ○ Motivation Score ○ Initial Exhaled CO ○ Initial Number of Cigarettes Per Day ○ Age of Initiation to Smoking ○ Total Fagerstrom Score ○ Total Withdrawal Score ○ Total Profile of Mood States Scores ○ Pharmacologic Aid ○ Smoking Status of Spouse ○ Weekly use of alcohol ○ Mother Current or Former Smoker ○ Father Current or Former Smoker ○ Previous experience with withdrawal symptoms 	<ul style="list-style-type: none"> • Frequencies and Percentages/ Means and standard deviations dependent on data characteristics
<ul style="list-style-type: none"> • Description of study attrition 	<ul style="list-style-type: none"> • Frequencies and percentages
<p>Reliabilities of Measures</p> <ul style="list-style-type: none"> • Profile of Mood States • Fagerstrom • Withdrawal scale 	<ul style="list-style-type: none"> • Cronbach Alpha • Cronbach Alpha • Cronbach Alpha

Table 2. Statistical Analyses for Research Questions and Main Outcomes

Research Questions and Main Outcomes	Type of Analyses
<p>Questions for Objective 1:</p> <ul style="list-style-type: none"> • Question 1- Is there a difference in the point prevalence abstinence between treatment (TDI) and control group (usual care) at 10 weeks (end of program)? <ul style="list-style-type: none"> ➤ Measures: number of persons abstinence from smoking in the last seven days at the end of program (10 weeks) • Question 2- Is there a difference in continuous abstinence between treatment (TDI) and control group (usual care) at 10 weeks (end of program)? <ul style="list-style-type: none"> ➤ Measure: number of persons abstinent from smoking since quit date at the end of program (10 weeks) • Question 3- Is there a reduction in the mean number of cigarettes smoked between treatment (TDI) and control group (usual care) at 10 weeks (end of program)? <ul style="list-style-type: none"> ➤ Measure: Mean reduction of cigarettes smoked by persons who continue to smoke at the end of the program (10 weeks) • Question 4: Is there a difference in the mean number of days of relapse to smoking between treatment (TDI) and control group (usual care) at 10 weeks (end of program)? <ul style="list-style-type: none"> ➤ Measure: Mean number of days relapsed to smoking since quit date during the program 	<ul style="list-style-type: none"> • Chi square • Chi Square • t-test • t-test

Table 2. (Continues) Statistical Analyses for Research Questions

Research Questions and Main Outcomes	Type of Analyses
<p>Questions for Objective 1 (continues)</p> <ul style="list-style-type: none"> • Question 5: Are there differences demographic characteristics and smoking characteristics between treatment groups that impact the outcome at 10 weeks? ➤ Measured: <ul style="list-style-type: none"> ▪ Gender ▪ Age ▪ Ethnic Group ▪ Marital Status ▪ Military Status ▪ Service Branch ▪ Military Rank ○ Smoking Characteristics <ul style="list-style-type: none"> ▪ Motivational Scores ▪ Initial Exhaled CO ▪ Initial Number of Cigarettes Per Day ▪ Pharmacologic Aid ▪ Total Fagerstrom Score ▪ Total Withdrawal Score ▪ Total Profile of Mood States ▪ Age of Initiation to Smoking ▪ Smoking Status of Spouse ▪ Weekly use of alcohol ▪ Mother Current or Former Smoker ▪ Father Current or Former Smoker ▪ Previous experience with withdrawal symptoms 	<ul style="list-style-type: none"> • Frequencies and Percentages/Chi Squares and t – test depending on the characteristic of the data

Table 2. (Continues) Statistical Analyses for Research Questions

Research Questions and Main Outcomes	Type of Analyses
<p>Questions for Objective 2:</p> <ul style="list-style-type: none"> • Question 1: What are the mood states that precede smoking relapse episodes and smoke-free periods of participants who relapse and have received TDI? <ul style="list-style-type: none"> ➤ Measured <ul style="list-style-type: none"> ▪ SUD scores preceding relapse ▪ SUD scores during smoke-free periods (abstinent from smoking) • Questions 2: Are there patterns of mood state that are associated with relapse and periods of abstinence? <ul style="list-style-type: none"> ➤ Measured- <ul style="list-style-type: none"> ▪ SUD scores and number of relapsed days ▪ SUD scores and number of days abstinent from smoking • Questions 3: What are the perceived reasons for smoking relapse reported by participants? <ul style="list-style-type: none"> ➤ Measured: <ul style="list-style-type: none"> ▪ Scores on Reasons for relapse ▪ Reasons for relapse described during the TDI 	<ul style="list-style-type: none"> • Frequencies and Minimum and Maximum scores • Frequencies and Correlations • Frequencies and Percentages/Text Analyses

Table 3. Demographic Characteristics

Variable	N	Frequencies	Valid Percent* %
Gender			
Female	N=60	28	46.7
Male		32	53.3
Age			
18-25	N=60	25	41.7
26-35		22	36.7
36-45		11	18.3
46-55		1	3.3
Ethnic Group			
Caucasian	N=60	46	76.7
African American		8	13.3
Hispanic		3	5.0
Asian American		2	3.3
Native American		1	1.7
Marital Status*			
Married	N=60	31	51.7
Single		25	41.7
Divorced		4	6.7
Military Status			
Active Duty	N=60	45	75.0
Family Member or Retiree		15	25.0
Service Branch			
Army	N=45	31	68.9
Navy		8	17.8
Air Force		4	8.9
Marine Corp		1	2.2
Air Guard		1	2.2
Military Rank			
E1	N=45	1	2.2
E2		17	37.8
E3		2	4.4
E4		10	22.2
E5		12	26.7
E6		3	6.7

* may not equal 100% due to rounded numbers

Table 4. Smoking Characteristics of Participants at Start of Treatment N=60

Characteristic	Range	M	SD	Frequencies	Valid Percent %
Motivation Score	4	8.12	1.12	-----	----- ----
Initial Exhaled CO (ppm)	18	16.78	4.90	-----	----- ----
Initial Number of Cigarettes per day	30	19.57	6.36	-----	----- ----
Age of Initiation to Smoking (yrs)	10	15.8	2.78	-----	----- ----
Total Fagerstrom Score	9	6.20	2.04	-----	----- ----
Total Withdrawal Score	16	22.68	5.12	-----	----- ----
Total POMS*	55	13.9	10.27	-----	----- ----
Pharmacologic Aid Bupropion NRT	-----	-----	-----	39 21	65.0 35.0
Smoking Status of Spouse Spouse Smokes Spouse Non Smoker	-----	-----	-----	17 14	54.8 45.2
Weekly use of alcohol Yes No Did not answer	-----	-----	-----	33 16 11	55.0 26.7 18.3
Mother Current or Former Smoker Current or former smoker Non-smoker Did not answer	-----	-----	-----	22 31 7	36.7 51.7 11.7
Father Current or Former Smoker Current or former smoker Non Smoker Did not answer	-----	-----	-----	35 14 11	58.3 23.3 18.3

Table 5. Comparison of the Study Outcomes.

Outcome Variable	Treatment Group	Control Group	Statistic	p value
Point prevalence abstinence (7 days) a Frequency (%)	n=30 15 (50)	n=30 11 (37)	$\chi^2=1.086$.297
Continuous abstinence (from tqd*) a Frequency (%)	n=30 6 (20)	n=30 2 (7)	$\chi^2=2.308$.129
Reduction of cigarettes smoked at 10 weeks Mean (SD)	(n=11) 14 (7)	(n=14) 14(10)	t=.134	.89
Number of days relapsed at 10 wks Mean (SD)	(n=20) 3.7 (2.9)	(n=23) 4.3 (2.7)	t=.83	.41
* target quit date a. persons lost to follow-up counted as smokers				

Table 6. Comparison of Demographics Characteristics.

Variable	Treatment (n=30) Frequencies (%)	Control (n=30) Frequencies (%)	Statistic	p value
Gender				
Female	17 (57%)	11(37%)	$\chi^2= 2.41$.12
Male	13 (43%)	19(63%)		
Age			$\chi^2 =12.49$.006*
18-25	19 (63%)	6 (24%)		
26-35	7 (23%)	15(50%)		
36-45	4 (13%)	7 (23%)		
46-55	0 (0%)	2 (7%)		
Ethnic Group			$\chi^2 =1.42$.841
Caucasian	22(50.0%)	24(50.0%)		
African Americans	4(50.0%)	4(50.0%)		
Hispanics	2(63.7%)	1(33.3%)		
Asian Americans	1(50.0%)	1(50.0%)		
Native Americans	1(100%)	0(0.0%)		
Marital Status			$\chi^2 =0.072$.965
Married	15(48.4%)	16(51.6%)		
Single	13(52.0%)	12(48.0%)		
Divorced	2(50.0%)	2(50.0%)		
Military Status			$\chi^2 =0.089$.766
Active Duty	22(48.9%)	23(51.1%)		
Family Member or Retiree	8(53.3%)	7(46.7%)		
Service Branch			$\chi^2 =2.511$.643
Army	16(51.6%)	15(48.4%)		
Navy	3(37.5%)	5(62.5%)		
Air Force	2(50%)	2(50%)		
Marine Corp	1(100%)	0(0%)		
Air Guard	0(0%)	1(100%)		
Military Rank			$\chi^2=16.077$.024*
E1	0	1(3)		
E2	14 (47)	3(10)		
E3	0	2(7)		
E4	3(10)	7(23)		
E5	4(13)	8(27)		
E6	1(3)	2(7)		
Dependent/ Retired	8(27)	7(23)		

* significant at p < .05

Table 7. Comparison of Groups by Selected Smoking Characteristics

Variables	Treatment (n=30)	Control (n=30)	Statistic	p value
Motivation Score Mean (SD)	8.1 (1.1)	8.2 (1.2)	t=.343	.733
Initial Exhaled CO (ppm) Mean (SD)	16.2 (4.7)	17.4 (5.1)	t=.972	.335
Initial Number of Cigarettes per day Mean (SD)	18.5 (5.9)	20.7 (6.7)	t=1.35	.182
Age of Initiation to Smoking (yrs) Mean (SD)	15.5 (2.6)	16.0 (2.9)	t=.646	.521
Total Fagerstrom Score Mean (SD)	6.01 (1.8)	6.3 (2.3)	t=.503	.617
Total Withdrawal Score Mean (SD)	23.5 (4.9)	21.8 (5.3)	t= 1.29	.201
Total POMS Mean (SD)	14.1 (7.8)	13.7 (12.4)	t=.150	.882
Pharmacologic Aid Bupropion NRT Frequency (%)	10 (33) 20 (67)	11(37) 19 (63)	$\chi^2=.073$.787
Smoking Status of Spouse Spouse Smokes Spouse Non Smoker Frequency (%) <i>n=married</i>	6 (40) 9 (60)	8 (50) 8 (50)	$\chi^2=.313$.576
Weekly use of alcohol Yes No Did not answer Frequency (%)	9 (30) 17 (57) 4 (13)	7 (23) 16 (53) 7 (23)	$\chi^2=1.10$.577
Mother Current or Former Smoker Current or former smoker Non-smoker Did not answer Frequency (%)	16 (80) 3 (15) 1 (5)	15 (50) 9 (30) 6 (20)	$\chi^2=3.44$.179

Table 7. (Continues) Comparison of Groups Selected Smoking Characteristics

Variables	Treatment (n=30)	Control (n=30)	Statistic	p value
Father Current or Former Smoker				
Current or former smoker	9 (30)	5 (17)	$\chi^2=3.44$.179
Non Smoker	18 (60)	17(57)		
Did not answer	3 (10)	8 (27)		
Frequency (%)				

Table 8. Comparison of Groups by Previously Experienced Withdrawal Symptoms

Variable	Treatment Group M	Control Group (SD)	Statistic t-test	p value
Craving	3.4 (.81)	3.0 (.74)	t=1.0	.05*
Increased appetite	2.77 (1.00)	2.63 (1.10)	t=.52	.61
Depressed mood	2.30 (.75)	2.13 (.860)	t=.80	.43
Anxiety	2.63 (.77)	2.50 (.94)	t=.60	.549
Difficulty concentrating	3.17 (1.0)	2.53 (.97)	t=2.46	.017*
Irritable, angry and frustrated	2.47 (.97)	2.57 (.82)	t=.431	.668
Restlessness	3.17 (.79)	2.97 (.89)	t=.92	.361
Difficulty sleeping	2.93 (.91)	2.60 (1.0)	t=1.33	.190
* significant at p < .05				

Table 9. Summary of Frequencies of the Subjective Units of Discomfort
 Preceding Relapses and During Abstinence
 N=30

Subjective Units of Discomfort	Relapse (*Freq)	Minimum Maximum	Subjective Units of Discomfort	Abstinence (*Freq)	Minimum Maximum
Tense	24	2-7	Lively	30	1-6
Nervous	24	1-7	Active	30	1-9
Discouraged	22	2-9	Grouchy	22	2-6
Anxious	22	1-7	Wornout	1	2-2
Angry	20	4-7	Tense	nr	-----
Badtempered	20	2-6	Angry	nr	-----
Grouchy	18	1-6	Shaky	nr	-----
Shaky	15	2-8	Sad	nr	-----
Wornout	14	1-8	Worthy	nr	-----
Exhausted	14	1-5	Uneasy	nr	-----
Fatigued	11	2-8	Fatigued	nr	-----
Sad	8	1-2	Annoyed	nr	-----
Annoyed	6	2-6	Discouraged	nr	-----
Lonely	3	1-2	Nervous	nr	-----
Gloomy	3	2-4	Lonely	nr	-----
Weary	3	4-6	Exhausted	nr	-----
Uneasy	2	2-6	Anxious	nr	-----
Worthy	1	3-3	Gloomy	nr	-----
Lively	nr ^a	2-2	Weary	nr	-----
Active	nr	-----	Badtempered	nr	-----

*Frequency refers to number of times SUDS was reported
^a nr= not reported

Table 10. Correlates of the Scores of the Subjective Units of Discomfort Preceding Relapses and the Number of Days of Relapse to Smoking

Subjective Units of Discomfort (SUDS)	r
Lonely	.872**
Uneasy	.855**
Gloomy	.778*
Annoyed	.496*
Discouraged	.492*
Tense	-.314
Anxious	-.175
Nervous	-.064
Exhausted	.056
Fatigued	.074
Grouchy	.195
Tense	.197
Angry	.213
Sad	.308
Wornout	.311
Shaky	.372
**Correlation is significant at the 0.01 level (two-tailed)	
*Correlation is significant at the 0.05 level (two-tailed)	

Table 11. Reasons for Relapses to Smoking N=24

Reason for Relapse	Treatment Group Frequency	Control Group Frequency (%)*
Illness in family		
Not important	8 (73%)	7 (50%)
Some importance	3 (27%)	6 (50%)
Important	0	0
Very important	0	0
Extremely important	0	0
Could not function without cigarettes		
Not important	4 (36%)	3 (23%)
Some importance	4 (36%)	6 (46%)
Important	2 (18%)	4 (31%)
Very important	1 (10%)	0
Extremely important	0	0
Strong cravings		
Not important	0	2 (15%)
Some importance	2 (18%)	1 (8%)
Important	0	1 (8%)
Very important	5 (45%)	7 (54%)
Extremely important	4 (37%)	2 (15%)
Life not worth living		
Not important	3 (27%)	1 (8%)
Some importance	5 (45%)	8 (62%)
Important	0	2 (15)
Very important	2 (18%)	2 (15)
Extremely important	1 (10%)	0
Temptation too strong		
Not important	1 (9%)	1 (8%)
Some importance	3 (27%)	3 (23%)
Important	0	2 (15%)
Very important	3 (27%)	6 (46%)
Extremely important	4 (37%)	1 (8%)

Table 11. (Continues) Reasons for Relapse to Smoking N=24

Reason for Relapse	Treatment Group Frequency (%)*	Control Group Frequency (%)*
Wrong timing		
Not important	0	2 (15%)
Some importance	5 (45%)	4 (31%)
Important	0	0
Very important	2 (18%)	3 (23%)
Extremely important	4 (36%)	4 (31%)
Gained too much weight		
Not important	2 (18%)	1 (8%)
Some importance	3 (27%)	3 (23%)
Important	0	3 (23%)
Very important	4 (36%)	4 (31%)
Extremely important	2 (18%)	2 (15%)
Not enough social support		
Not important	1 (9%)	0
Some importance	3 (27%)	2 (15%)
Important	4 (36%)	9 (69%)
Very important	3 (27%)	1 (8%)
Extremely important	0	1 (8%)
Too many problems at work		
Not important	1 (9%)	5 (38%)
Some importance	4 (36%)	5 (38%)
Important	6 (55%)	0
Very important	0	2 (15%)
Extremely important	0	1 (8%)

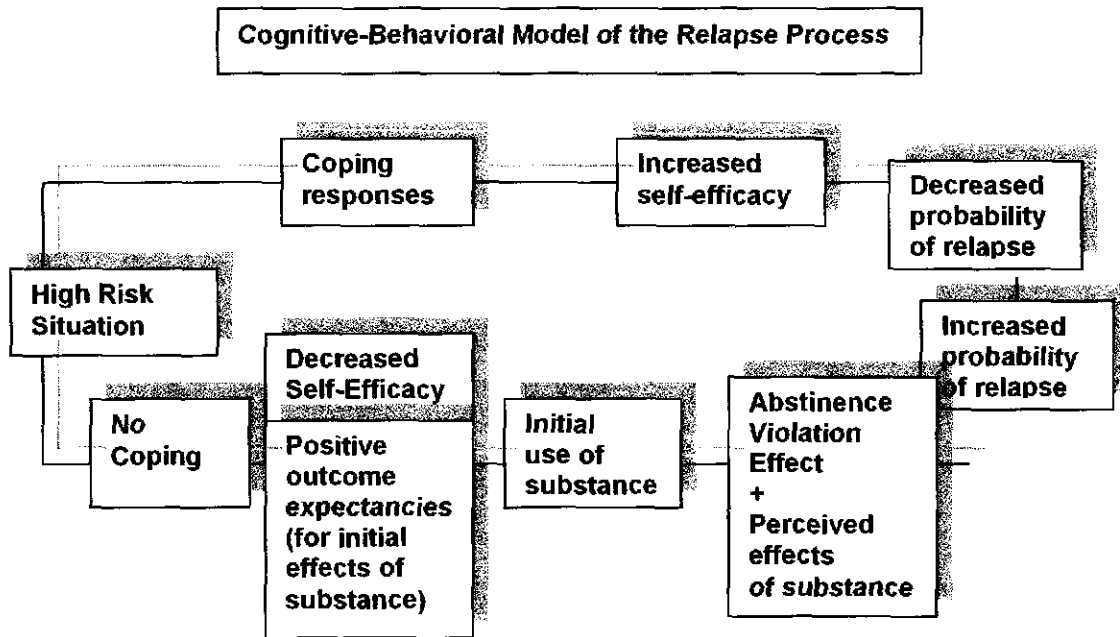


Figure 1. Marlatt and Gordon's Cognitive Behavioral Model of the Relapse Process

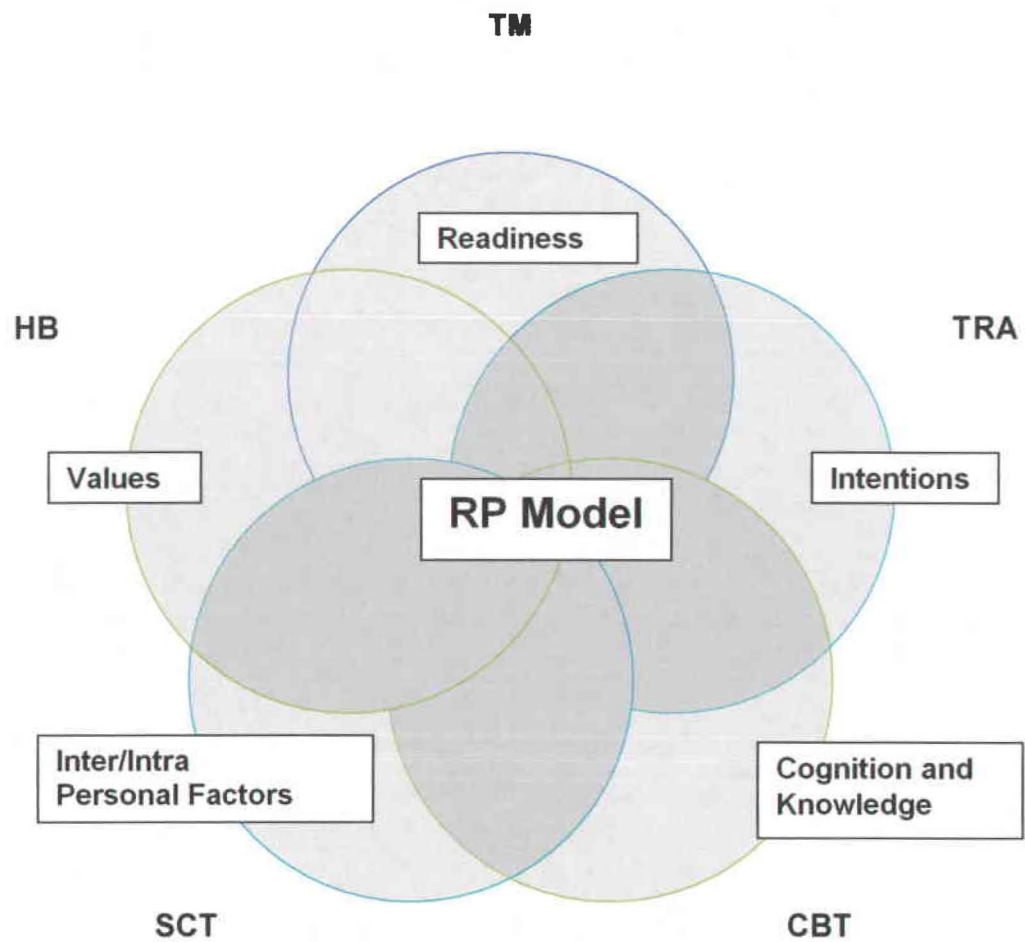


Figure 2. Interaction of Transtheoretical Model (TM), Health Belief (HB), Theory of Reasoned Action/ Theory of Planned Behavior (TRA), Social Cognitive Theory (SCT) and Cognitive Behavioral Theory (CGT) with Marlatt and Gordon's Model of Relapse Prevention (RP).

Data Collection Timeline for Each Cohort

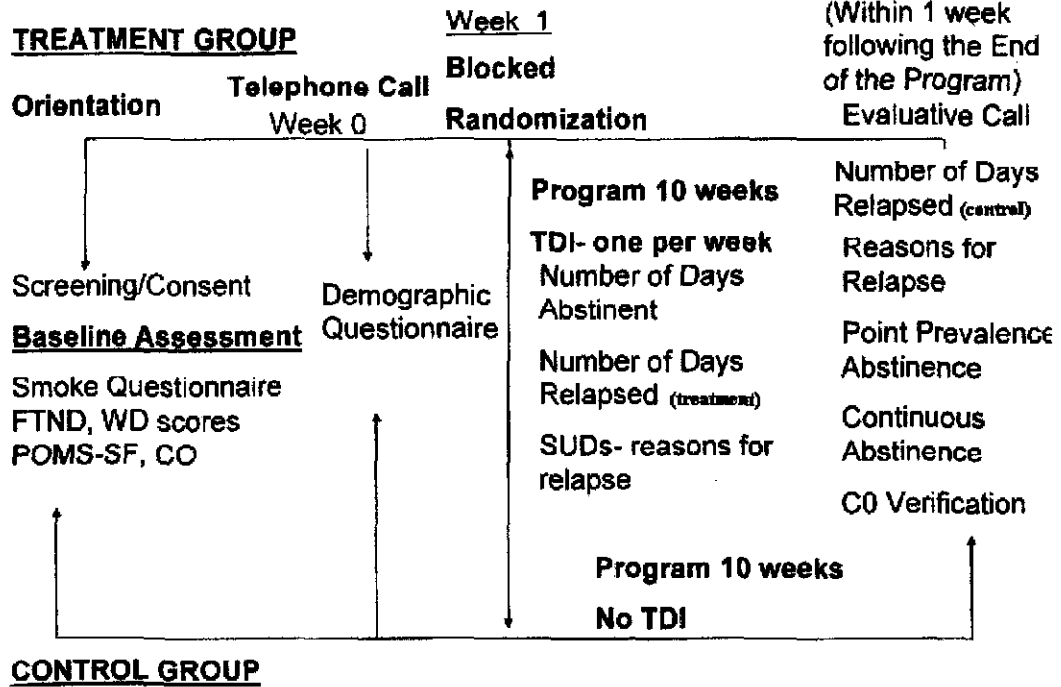


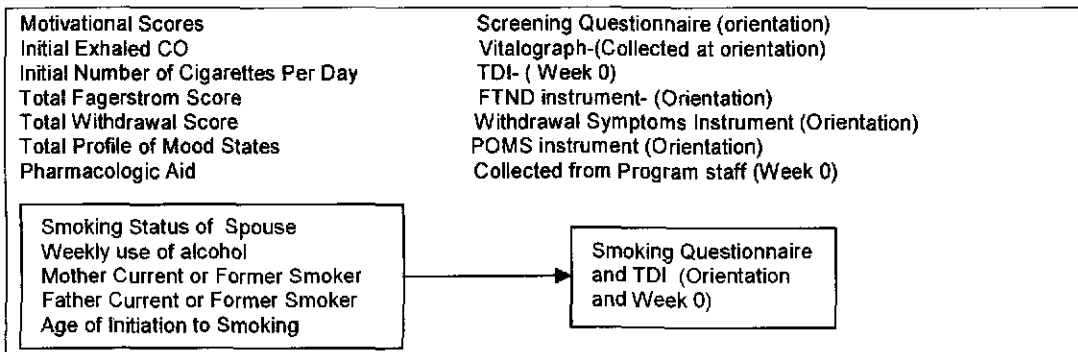
Figure 3. Study Timeline

Objective 1- Research Questions

Instrument / When Measured

1. Is there a difference in the point prevalence abstinence between treatment and control group at 10 weeks?	Follow-up Phone Call Questionnaire (Within 1 week following the End of the Program)
2. Is there a difference in continuous abstinence between treatment and control group at 10 weeks?	Follow-up Phone Call Questionnaire (Within 1 week following the End of the Program)
3. Is there a reduction in the mean number of cigarettes smoked between treatment and control group at 10 weeks?	Initial cigarettes per day smoked- (Orientation) Follow-up Phone Call Questionnaire (Within 1 week following the End of the Program)
4. Is there a difference in the mean number of days of relapse to smoking between treatment and control group at 10 weeks?	Determined after the follow-up call (Weekly TDI(10 weeks) and Follow-up Call)
5. Are there differences in demographic and selected smoking characteristics between treatment groups that impact the outcome at 10 weeks?	(Week 0)

age, gender, ethnic group, marital status service branch, military rank, military status,	Demographic Questionnaire (Week 0)
--	---------------------------------------



Objective 2- Research Questions

1. What are the mood states that precede smoking relapse episodes and smoke-free periods of participants who relapse and have received TDI?	SUDs
2. Are there patterns of mood state that are associated with relapse and periods of abstinence?	SUDs
3. What are the perceived reasons for smoking relapse reported by participants?	Follow-up Questionnaire

Figure 4. Research Questions and their Link to Instruments/Measures Used

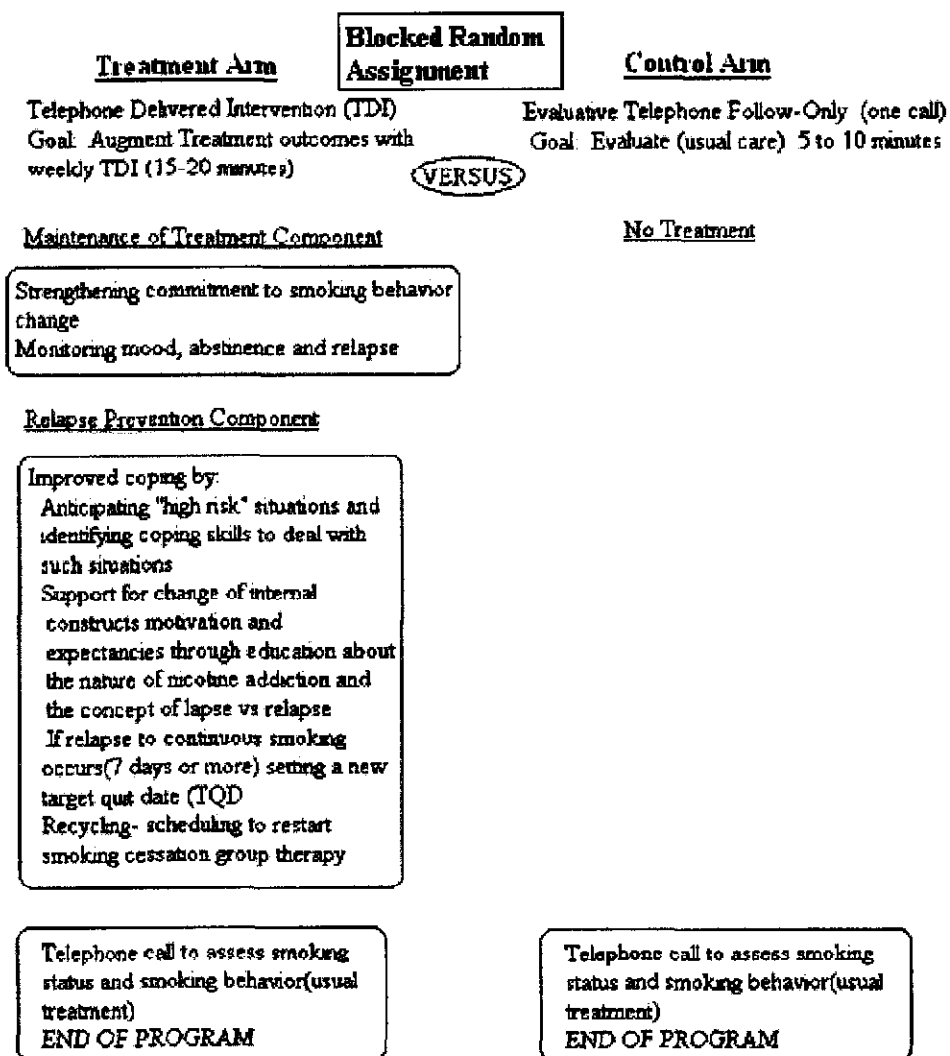


Figure 5. Flow and Comparison of Treatment and Control Arms of the Study

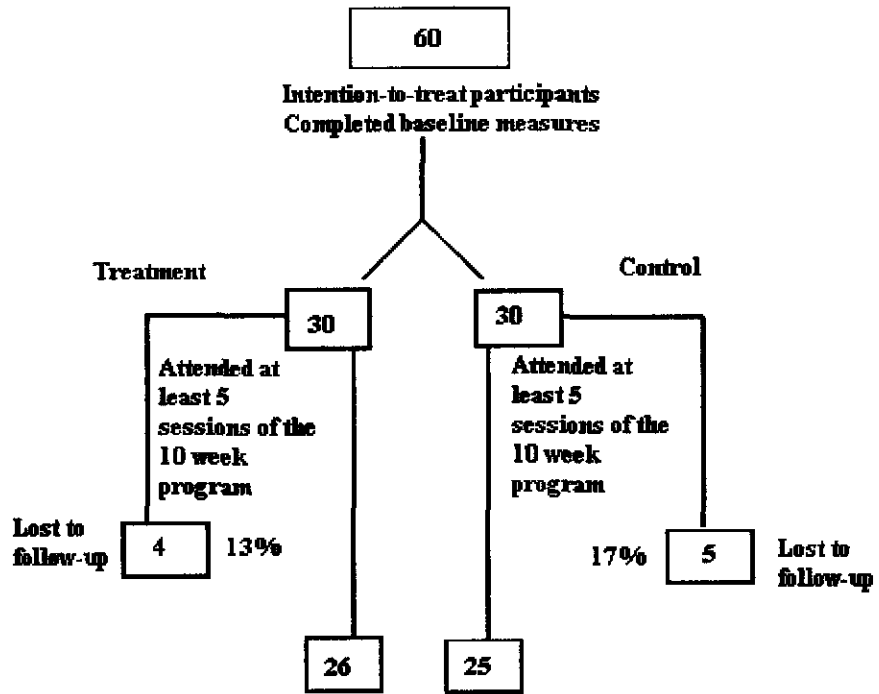


Figure 6. Study Attrition of Participants

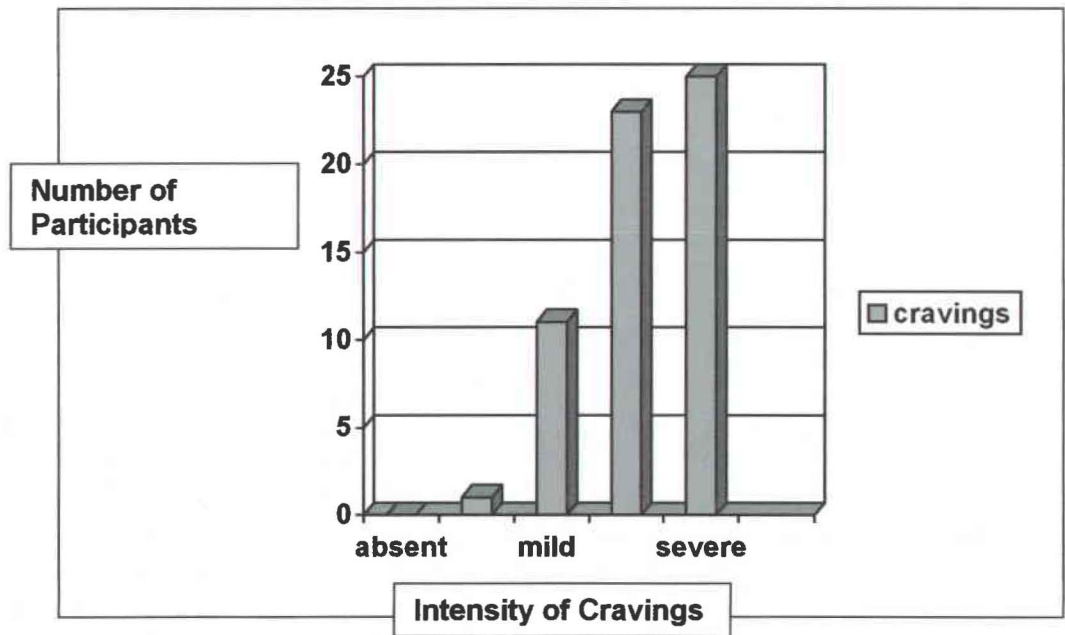


Figure 7. Withdrawal Frequencies- Cravings N=60

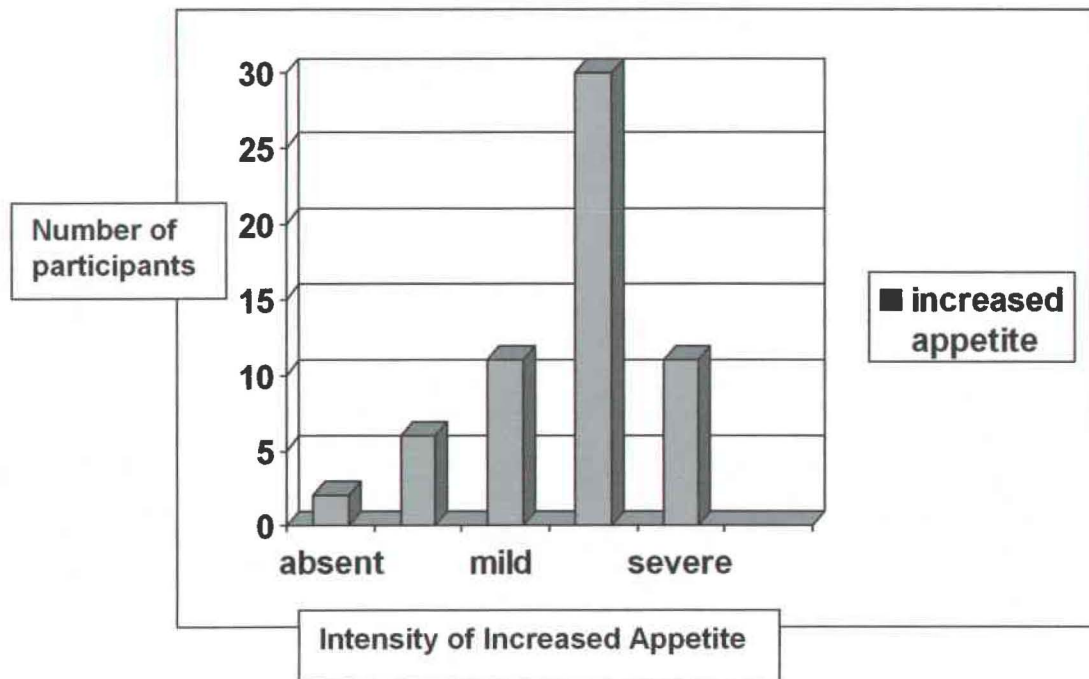


Figure 8. Withdrawal Frequencies- Increased Appetite N=60

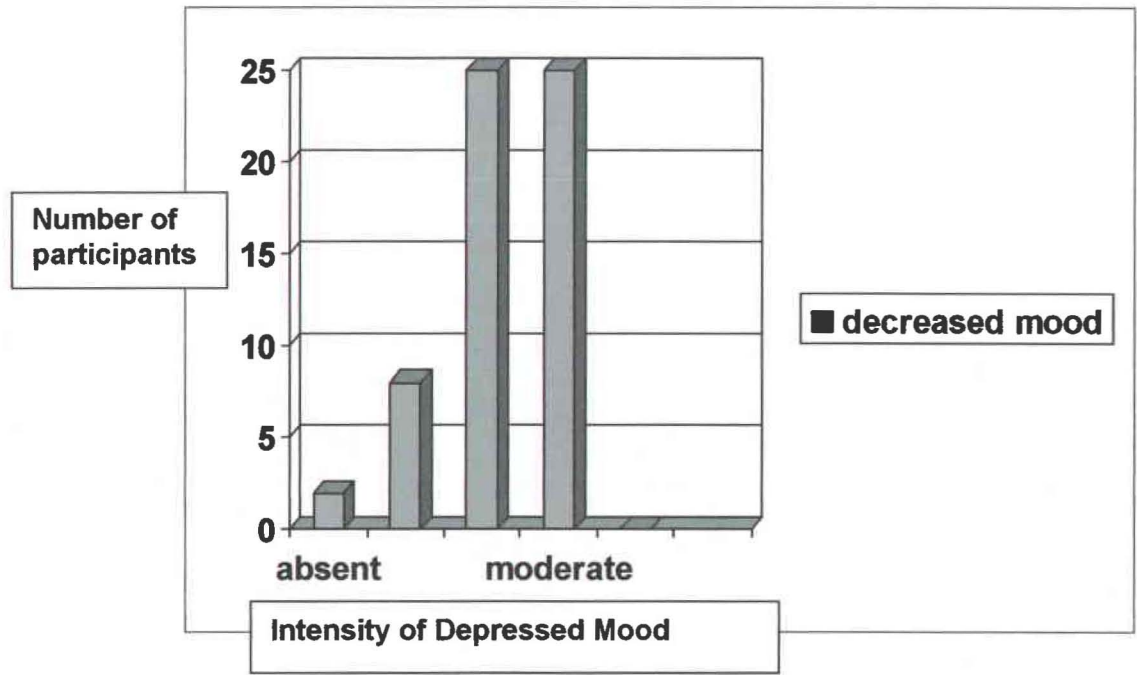


Figure 9. Withdrawal Frequencies- Depressed Mood N=60

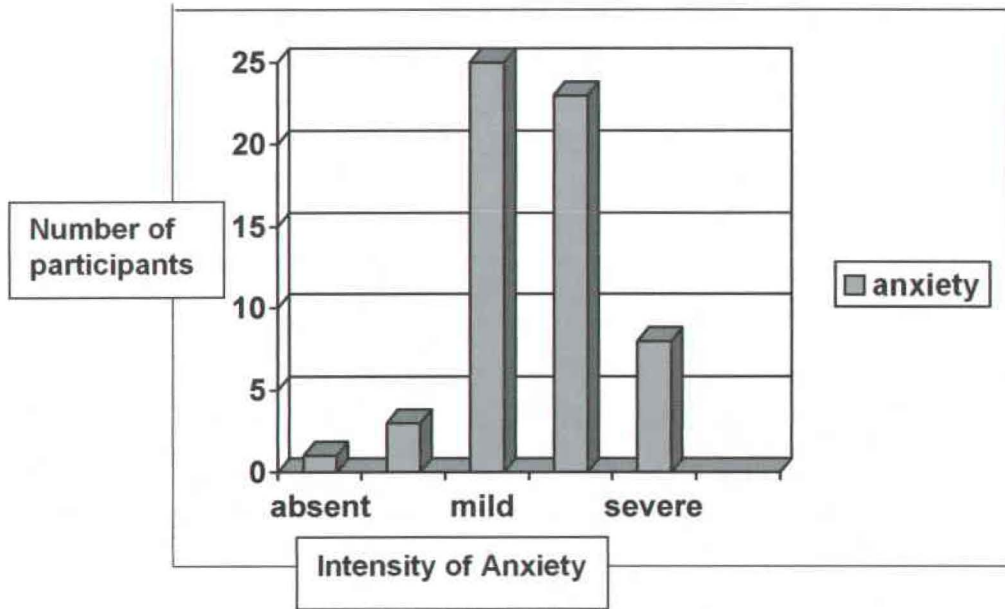


Figure 10. Withdrawal Frequencies- Anxiety N=60

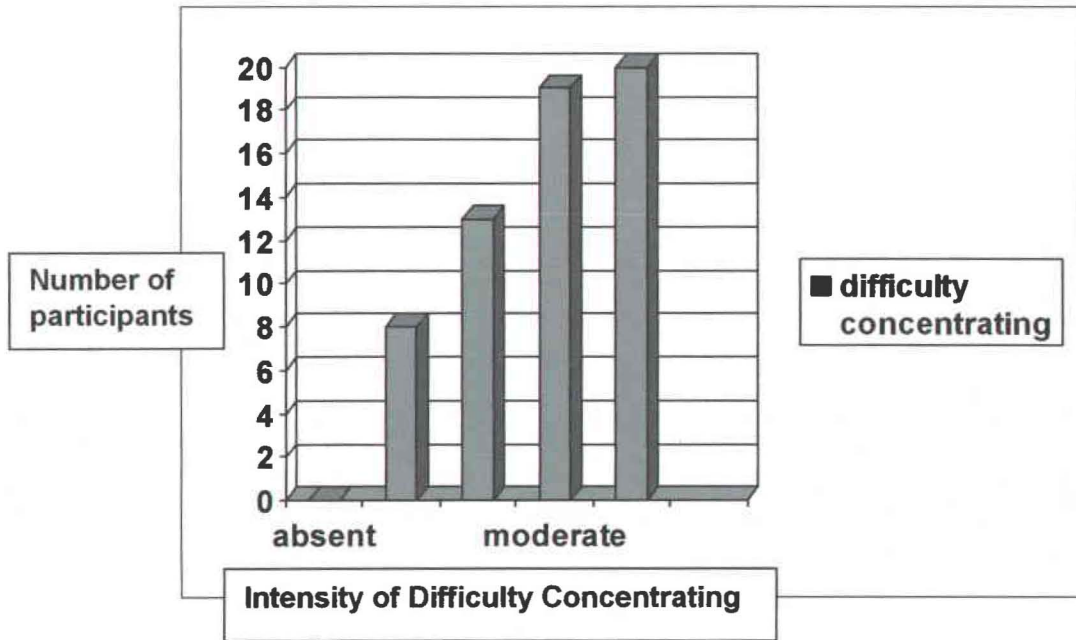


Figure 11. Withdrawal Frequencies- Difficulty Concentrating N=60

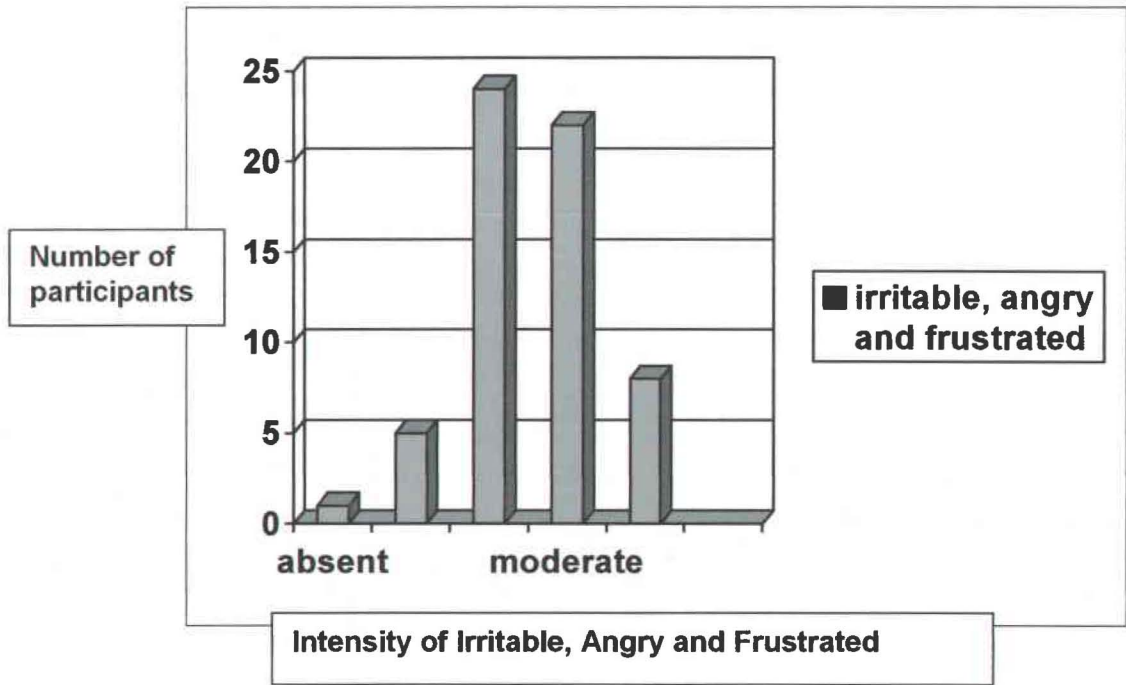


Figure 12. Withdrawal Frequencies- Irritable, Angry and Frustrated N=60

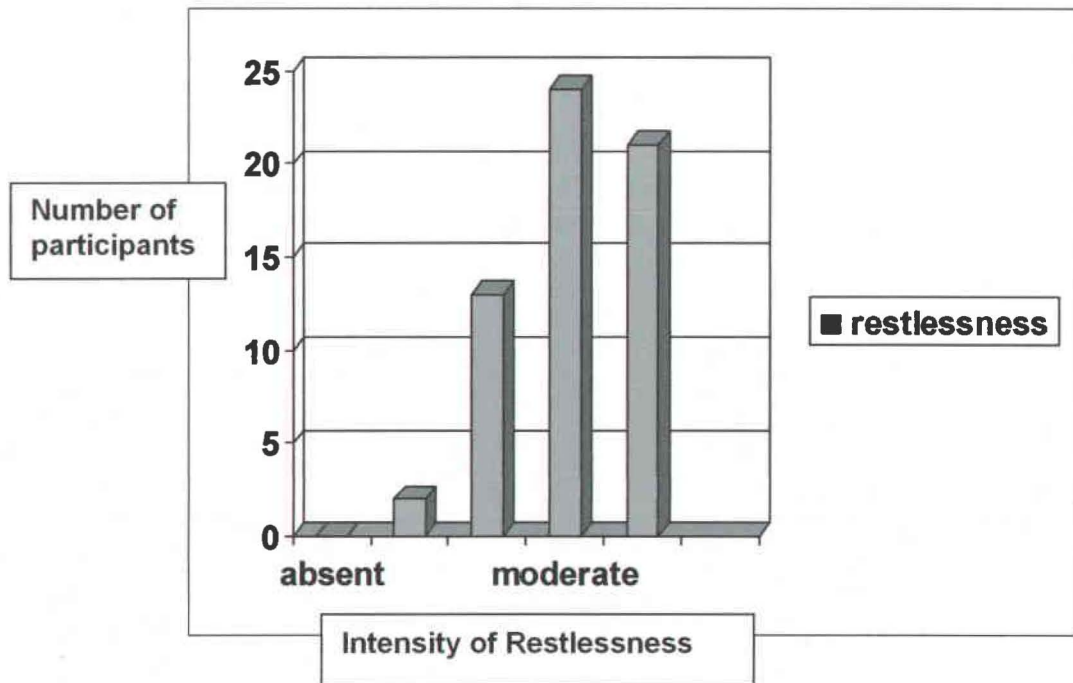


Figure 13. Withdrawal Frequencies- Restlessness N=60

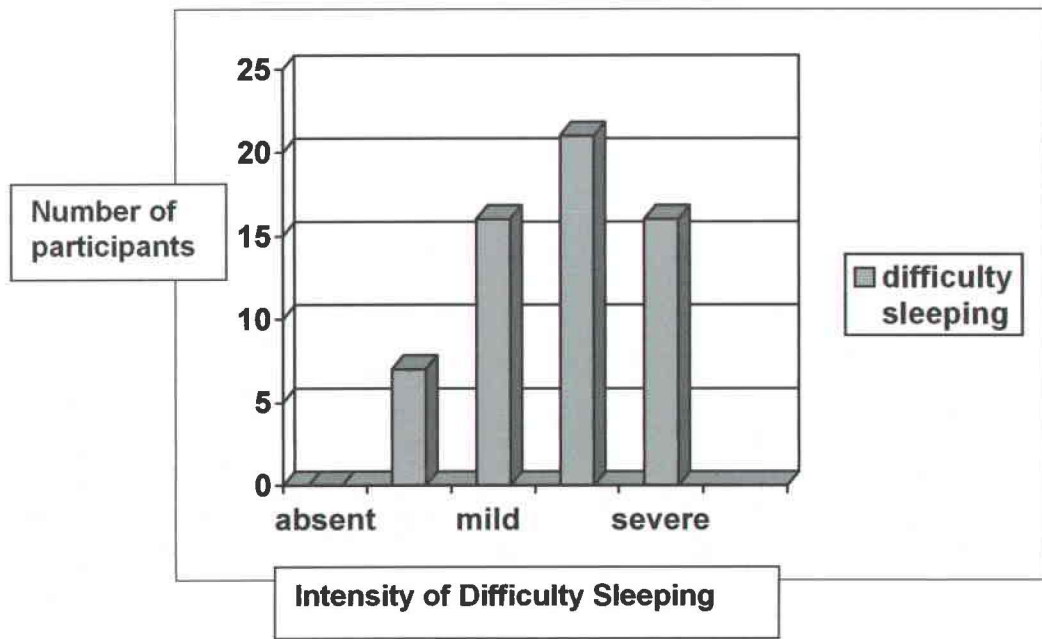


Figure 14. Withdrawal Frequencies- Difficulty Sleeping N=60

APPENDIX A

Literature Reviews of Interventions Delivered by Multiple Devices

Authors and Topic	Methods	Type of Device Reviewed	Effectiveness	Future Research
Revere et al, 2001 (From 1966 to 1999) Computer generated health behavior interventions in ambulatory setting	Systematic qualitative literature review Randomized controlled studies with some evidence of instrument reliability and validity	37 eligible trials that described delivery device (print, automated telephone, computer, mobile communication) and intervention type(personalized, targeted, and tailored)	34 of the 37 eligible trials (91.9%) reported either statistical significant or improved outcomes.	To identify which theoretical models are best suited for each type of health behavior and delivery device.
McBride and Rimer 1999 Telephone delivered	Descriptive qualitative literature review	74 studies of randomized experimental design	Design of the study did not allow for TDI component to be evaluated separately. Multiple behavior outcomes was assessed with multiple variable follow-up	Seven questions are generated for future research . Among these are the usefulness of TDI's reaching underserved populations, understanding the effectiveness of the timing the length and number of calls
Balas et al 1997 Electronic Communications with extracted categories including telephone delivery systems	Thematic Literature Review	80 controlled clinical trials	63% reported positive outcomes (4 smoking cessation articles reported negative outcomes)	Distance technology improves access, continuity of care and support to clinicians Applications should not be limited to physician to physician communication

APPENDIX B

**Review of Evidence of Smoking Cessation
Using Telephone-delivered Interventions (1995 - 2002)**

Author/Year Level Evidence	Participants	Intervention	End Point	Effect on Abstinence	Verified
Miguez (2002) A	N=200 Adult smokers	TDI plus self-help smoking cessation program through the mail VS no TDI	3,6 and 12 months,	continuous abstinence rates 48%vs 21% control at 3 months 40% vs 18% at 6 months and 27% vs 14% at 12- months	CO <8(ppm)
Wadland (2001) A	N=233 Low income adult smokers	TDI plus physician advice VS physician- advice and one follow-up visit	3 months after physician advice	8.1% usual-care and 21% treatment	CO <8(ppm)
Zhu (2000) B	N=664 Smokers calling the California Smoking Hotline	TDI as support for physician advice plus NRT 79% Multiple TDIs(average 4.2) sessions VS 21% single TDI	13 months after end of program	Rates Multiple 84.4% vs 77.1% single	Not verified
Wewers (2000) B	N=16 HIV-positive smokers	TDI plus NRT and skills training VS booklet	8 weeks end of (program) and 8 months	8weeks, Rates 62.5% VS 0% 8 months 50% VS 0%	Urine cotinine
Johnson (2000) A	N=254 Post-partum women that quit smoking during pregnancy	TDI alone VS No TDI	6 months after delivery	continuous rate 38% vs 27% control reduced daily smoking 34% vs 38%	CO <10(ppm)
McBride (1999) A	N=580 Women smokers as follow-up to cervical cancer screening	TDI self-help booklet, a smoking and reproductive health information card, and three telephone counseling calls VS Usual Care		Did not differ at the 6-month UC 10.5% vs. SH 10.9% 15-month follow-up UC 15.5% vs. SH 10.6%	Self report

APPENDIX C

Tripler Army Medical Center Consent Form

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38, the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087
Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program SSN and home address will be used for identification and locating purposes
Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study, implementation of medical programs, adjudication of claims, and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.
Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____ having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal representative for _____ to participate in _____

Augmenting Tobacco Cessation Treatment Outcomes with Telephone Delivered Interventions (Research Study)

under the direction of Dr. Raymond Folen conducted at Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by _____

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact _____

The Center Judge Advocate 1 Jarrett White Road Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (808) 433-5311

(Name, Address and Phone Number of Hospital (Include Army Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw the person I represent withdrawn from the study without further penalty or loss of benefits; however, the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)

I, _____ SSN _____ having full capacity to assent and having attained my _____ birthday, do hereby volunteer for _____ to participate in _____

(Research Study)

under the direction of _____ conducted at _____ (Name of Institution)

(Continue on Reverse)

APPROVED BY TAMC IRB

OCT 01 2001

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd.)

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

at

(Name, Address, and Phone Number of Hospital (include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT (Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25)

PARTICIPATION INFORMATION: You have been invited to participate in a clinical investigational/research study conducted at Tripler Army Medical Center. It is very important that you read and understand the following general principles that apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: The purpose of this study is to see if telephone calls containing different questions and made at different times will increase the number of people that stop smoking and also do not return to smoking six months after finishing the ten week smoking cessation therapy group. To our knowledge no similar studies similar to this one have been done.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: The length of participation will depend on which group you are selected to participate. All participants will attend the 10 week core smoking cessation treatment program. Group 1 (high intensity) will be provided weekly telephone intervention for 34 weeks (10 weeks during the standard core treatment program and continuing for 24 weeks after the end of the core program.) Group 2 (low intensity) will receive the standard core treatment program and receive evaluations by phone at 3 months and six months after completion of the standard core treatment program.

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OCT 01 2011

Witness'
Initials

Patient's
Initials

Volunteer Agreement Affidavit

WHAT WILL BE DONE: If you agree to participate in this study, by a random process similar to flipping a coin, you will receive either the Tripler Tobacco Cessation Program with standard follow-up telephone (less calls) or the Tripler Tobacco Cessation Program with a more intensive follow-up (weekly telephone calls). The Tripler Tobacco Cessation Program consists of one hour weekly smoking cessation group treatment for ten weeks led by a licensed psychologist, and use of either Welbutrin or Nicotine Replacement Therapy when not contraindicated. During these sessions you will be able to select either nicotine replacement therapy or Welbutrin to assist you to stop smoking. Instructions of how to use the Nicotine Replacement Therapy or Welbutrin medication and the potential side effects will be provided during these group sessions by the psychologist leading the group. In addition you will receive telephone calls at the place of your choice by a registered nurse that is specially trained in assisting persons to quit smoking. The number of telephone calls will vary throughout the weeks of the study and each telephone call will contain various questions about your smoking behavior for a period of 34 weeks. Prior to attending the group sessions you will be asked to complete several questionnaires, which will measure your dependency on nicotine, your mood and your smoking history. Also your breath will be analyzed weekly during each group session for carbon monoxide which will provide a physiological measure of your smoking status.

Additionally you will be asked to return two times to Tripler Medical Center Behavioral Medicine Department to provide a breath analyses for carbon monoxide. The first time that you will be asked to return to TAMC will be at three months and six months after completion of the group sessions.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS: The discussions about your mood and smoking behavior may or may not cause you anxiety. Also the side effects from Welbutrin and Nicotine Replacement Therapy which are explained as part of the Tripler Tobacco Cessation Program may develop. These explained potential side effects of Welbutrin are: dry mouth, difficulty sleeping, central nervous system effects such as dizziness and anxiety, rashes, constipation, fever, headaches, lack of appetite, gastrointestinal effects and or changes in urinary frequency. The explained potential side effects of nicotine replacement therapy are: skin irritation due to the patch, a faster heart rate and spontaneous abortion if pregnant. In the unlikely event any of this would happen, you will be referred to the licensed psychologist leading the group sessions which will counsel and make the appropriate referral depending on the symptom to assist you in decreasing the discomfort and/or stopping the smoking cessation aids.

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: There may not be benefit to you from participating in this study. Potentially you may benefit by increasing your success in quitting smoking from the additional telephone follow-up. Other potential benefits of participating in this study will be helping other health care professionals to better assist other smokers obtain smoke-free status.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: If you do not wish to be in the study, you will be referred to the Tripler Tobacco Cessation Program or you can choose not to have any intervention at this time. If you were to become pregnant during the course of the study you will be referred to the Tripler Tobacco Cessation Program for continued assistance in smoking cessation, however, Welbutrin or Nicotine Replacement Therapy will be discontinued.

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OCT 01 2001

Witness' Patient's
Initials Initials

Volunteer Agreement Affidavit

CONFIDENTIALITY: Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. Complete confidentiality cannot be promised to active-duty military personnel because information bearing on your health may be required to be reported to appropriate medical or command authorities.

PRECAUTIONS TO BE OBSERVED BY SUBJECT BEFORE AND FOLLOWING THE STUDY: No precautions other than those that are part of the Tripler Tobacco Cessation Program are required for your participation in the study.

CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to you or your health; (b) if military contingency requires it; (c) if you become ineligible for military care as authorized by Army regulation; (d) if the safety monitor determines that continued treatment under this study may be harmful to you.

ADDITIONAL COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY: In accordance with AR 40-38, paragraph 3-3(j)(2), daily charges for inpatient care will be waived while the volunteer is in the hospital if the volunteer would not normally enter the hospital for treatment but is requested to do so as part of a research study or as a result of adverse reaction to the drug(s) or procedure(s) used in this study. This also applies to the volunteer's extension of time in a hospital for a research study when the volunteer is already in the hospital.

SIGNIFICANT NEW FINDINGS: Any significant new findings developed during the course of this study which could affect your willingness to continue participation will be made available to you. The results of the research will be made available to you if you so desire. Complete results may not be known for several years.

APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: 120 subjects will be recruited from Tripler Army Medical Center.

DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: Please contact the Principal Investigator:

Raymond A. Folen, Ph.D. ABPP
Tripler Army Medical Center, MCHK-PH
1 Jarrett White Road
Tripler AMC, HI 96859-5000
(808) 433-5865

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Witness'
Initials

Patient's
Initials

Volunteer Agreement Affidavit

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

I have read the above explanation and agree to participate in the investigational study described.

Typed Name & Signature of Volunteer Date

Typed Name & Signature of Witness Date

APPROVED BY TAMC IRB
OCT 01 2001

Witness'
Initials

Patient's
Initials

APPENDIX D

University of Hawaii at Manoa Consent Form

AGREEMENT TO PARTICIPATE IN

Augmenting Tobacco Cessation Treatment Outcomes with Telephone Delivered Interventions

(Title of Project)

Patti Urso, 1021 Hoa Street, Honolulu, HI 96825 808 396 1801

(Principal Investigator's name, address, and phone number)

The purpose of this study is to see if telephone calls added to the Tripler Tobacco Cessation Program will increase the number of persons that quit smoking without relapse to smoking, for six months, after finishing the ten-week smoking cessation program offered at Tripler Army Medical Center.

There will be 120 participants in this study. If you choose to participate you will have an equal chance to be assigned to one of two smoking cessation groups. One group will receive a variation in the telephone calls provided. All other smoking cessation treatment is the same as usually offered in the Tripler Tobacco Cessation Program, which meets at the Tripler Medical Center Conference Room. This treatment will consist of attending a one hourly weekly smoking cessation group treatment for ten-weeks and will be led by a licensed psychologist. During these sessions you will be able to select either nicotine replacement therapy or Welbutrin to assist you to stop smoking. Instruction of how to use the nicotine replacement therapy and Welbutrin, as well as what to do in case of unlikely side effects will be provided during these group sessions by the psychologist. Additionally, you will receive telephone calls at the place of your choice by a registered nurse that is specially trained in assisting persons to quit smoking and is also the principal investigator for this study. The telephone calls will vary in frequency throughout the weeks of the study and will contain various questions about your smoking behavior for a period of 34 weeks. Prior to attending the group sessions you will be asked to complete several questionnaires about your mood and your smoking history. Also your breath will be analyzed weekly during the group sessions for carbon monoxide, which will provide another measure of your smoking status. Additionally you will be asked to return two times during a six-month period to Tripler Medical Center Behavioral Medicine Department to provide a breath analyses. The first time that you will be asked to return to TAMC will be at three months and six months after completion of the group sessions. There is a risk that discussions about your mood and smoking behavior during the telephone calls may cause you anxiety and that you may have questions about the side effects of the smoking cessation aids. In the unlikely event this would happen you will be referred to the licensed psychologist leading the group sessions which will counsel you in decreasing the discomfort and what actions to take. There is no compensation provided

and there may not be a benefit to you from participating in this study. The potential benefits of participating in this study will be to help other health care professionals to better assist smokers obtain smoke-free status. If you do not wish to participate in the study you will be referred to the Tripler Tobacco Cessation Program. Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of the health sciences. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. All records will be maintained by the principal investigator at 1021 Hoa Street and all efforts will be made to maintain confidentiality. Complete confidentiality cannot be promised to active-duty military personnel because information bearing on your health may be required to be reported to appropriate medical or command authorities. Any significant new findings developed during the course of this study which could affect your willingness to continue participation will be made available to you and additionally you can withdraw from the study without penalty at any time. The results of the research will be made available to you if you so desire.

I certify that I have read and that I understand the foregoing, that I have been given satisfactory answers to my inquiries concerning project procedures and other matters and that I have been advised that I am free to withdraw my consent and to discontinue participation in the project or activity at any time without prejudice. *I herewith give my consent to participate* in this project with the understanding that such consent does not waive any of my legal rights, nor does it release the principal investigator or the institution or any employee or agent thereof from liability for negligence.

Date _____

Signature of individual participant

**(If you cannot obtain satisfactory answers to your questions or have comments or complaints about your treatment in this study, contact:
Committee on Human Studies, University of Hawaii, 2540 Maile Way, Honolulu,
Hawaii 96822. Phone: (808) 956-5007.)**

CHSAGR-A.WP5 (5/96)

APPENDIX E

Approval from Committee on Human Subjects, University of Hawaii at Manoa


UNIVERSITY OF HAWAII

Committee on Human Studies

MEMORANDUM

August 22, 2001

TO: Patti Urso, MSN, ARNP
Principal Investigator
Department of Nursing

FROM: William H. Dendle, Executive Secretary 
Committee on Human Studies

SUBJECT: CHS #11327 – “Augmenting Tobacco Cessation Treatment Outcomes
with Telephone Delivered Interventions”

Your project identified above was reviewed by the Chair of the Committee on Human Studies through Expedited Review procedures. The project qualifies for expedited review by CFR 46.110 and 21 CFR 56.110, Category (7) of the DHHS list of expedited review categories.

This project was approved on August 20, 2001, for one year. If in the active development of your project you intend to change the involvement of humans from plans indicated in the materials presented for review, prior approval must be received from the CHS before proceeding. If unanticipated problems arise involving the risks to subjects or others, report must be made promptly to the CHS, either to its Chairperson or to this office. This is required in order that (1) updating of protective measures for humans involved may be accomplished, and (2) prompt report to DHHS and FDA may be made by the University if required.

In accordance with the University policy, you are expected to maintain, as an essential part of your project records, all records pertaining to the involvement of humans in this project, including any summaries of information conveyed, data, complaints, correspondence, and any executed forms. These records must be retained for at least three years from the expiration/termination date of this study.

The CHS approval period for this project will expire on August 20, 2002. If your project continues beyond this date, you must submit a continuation application to the CHS at least four weeks prior to the expiration of this study.

We wish you success in this endeavor and are ready to assist you and your project personnel at any time.

Enclosed is your certification for this project.

Enclosures

UNIVERSITY OF HAWAII

Committee on Human Studies

August 22, 2001


Tripler Army Medical Center
Jarrett White Road
Tripler AMC, HI 96859

Dear Madam/Sir:

This refers to an application entitled "Augmenting Tobacco Cessation Treatment Outcomes with Telephone Delivered Interventions," by Patti Urso, principal investigator.

This application has been reviewed and approved for one year by the University of Hawaii institutional review board, the Committee on Human Studies. Enclosed is our certificate for this project.

Sincerely yours,


William H. Dendle
Compliance Officer

Enclosure

c: Patti Urso
CHS #11327

APPENDIX F

Approval from Committee on Human Subjects, Tripler Army Medical Center

MCHK-CI

OCT 01 2001

MEMORANDUM FOR Raymond A. Folen, PhD, Department of Psychology (ATTN: MCHK-PH), Tripler AMC, HI

SUBJECT: Approval of Study Initiation

1. Your clinical investigation protocol entitled "Augmenting Tobacco Cessation Treatment Outcomes with Telephone Delivered Interventions" was reviewed and approved as Minimal Risk by the Institutional Review Board (IRB) at Tripler Army Medical Center on 23 July 2001. The protocol has been assigned TAMC Protocol No. 45H01 and may now be initiated.
2. The protocol is approved for a period of **one year** and must be reapproved for continuation *no later than 22 July 2002*. You must report your study findings, including number of patients and adverse effects, to the Human Use Committee prior to one year from this date.
3. In accordance with AR 40-38, the principal investigator must report any serious or unexpected adverse reactions to drugs or procedures to the IRB through the Chief of Clinical Investigations. AR 40-7 and 21 CFR 312.32 define a serious adverse reaction as one that results in: (a) death, (b) persistent or significant disability or incapacity, (c) life-threatening situation, (d) inpatient or prolonged hospitalization, or (e) congenital anomaly/birth defect in an offspring, or (f) an important medical event that, based upon appropriate medical judgment may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.
4. Changes to either the protocol or the consent form must be approved by the Human Use Committee prior to implementation. It is your responsibility to maintain an accurate and accessible file on all consent forms of human subjects participating in the research. Your study and its documentation, including a list of volunteers and the executed informed consent statements, are subject to inspection at any time by your chain of command and by such inspectors of official audit agencies. You must maintain your records to facilitate such inspections. Upon completion of the study, you should report this to the Department of Clinical Investigation.
5. Please note that this is **NOT** an approval to receive extramural resources nor an indication of guaranteed funding from the Department of Clinical Investigation. You must coordinate extramural resource approvals with the Department of Clinical Investigation, Bldg. 40, 433-6709. If any extramural resources are received without DA or MEDCOM approval, the individual who receives them may be found in ethics violation and prosecuted for criminal misconduct.

OCT 01 2001

MCHK-CI

SUBJECT: Approval of Study Initiation

6. All manuscripts, abstracts, or publicly-released information related to research conducted at or sponsored by TAMC must be submitted to the TAMC technical management board as stated in TAMC Pamphlet 40-31 prior to submission for public release or publication. This includes academic lectures given outside TAMC, letters to the editor and press releases.

7. Your research study has been determined to be of potential importance to the academic and professional program of Tripler AMC. You are to give all possible priority to its completion. Should any problem arise that jeopardizes the success of your research, notify the Chief, Clinical Investigation, at 433-7171.

Catherine M. Schempp

CATHERINE M. SCHEMPP

COL, AN

Chief, Dept of Clinical Investigation

Deputy Chair, Human Use Committee

APPENDIX G

Study Screening Questions

You are invited to participate in this study if:

1. Are you at least 18 years of age? Yes No
2. Do you smoke at least 10 cigarettes per day? Yes No
3. How motivated are you to stop smoking? Rate yourself (1=lowest....10=highest)
1 2 3 4 5 6 7
8 9 10
4. Will you be available and willing to adhere to the protocol requirements. (see informed consent)? Yes No

Please circle YES or NO :

5. Do you use any tobacco products other than cigarettes?
Yes No
6. Do you have a serious or unstable cardiac, renal, hypertensive, pulmonary, endocrine, or neurological disorders?
Yes No
7. Do you have a predisposition to seizures?
Yes No
8. Do you have a history of eating disorder, panic disorder, psychosis, or bipolar disorder?
Yes No
9. Do you have a current major depressive episode?
Yes No
10. Are you pregnant or breastfeeding?
Yes No
11. Do you currently use any nicotine replacement therapy and/or psychotropic medication?
Yes No
12. Do you have a history of drug or alcohol abuse within the preceding year?
Yes No

APPENDIX H
Demographic Interview

Age _____

Gender _____

Ethnic group _____

Marital status _____

Military status _____

Service branch _____

Military rank _____

OTHER VARIABLES COLLECTED AT START OF PROGRAM

Initial CO _____

Initial number of cigarettes _____

Pharmacologic Aid _____

APPENDIX I

Smoking History Questionnaire

Participant number _____ Date _____

1. When did you smoke your first
cigarette? _____

2. How long have you been
smoking? _____

3. When was the last time you had a
cigarette? _____

4. What is the longest period of time you've abstained from smoking since you've had a smoking
problem? _____

5. What are your favorite brands? List your most favorite brand first.
 - a. _____
 - b. _____
 - c. _____
 - d. _____
 - e. _____
 - f. _____

6. Does your spouse or significant other smoke? (Circle one) Yes No

If yes, how much and how often? _____

8. Does, or did, your father smoke? (Circle one) Yes No If so, how
much? _____

9. Does, or did, your mother smoke? (Circle one) Yes No If so, how
much? _____

10. Do you drink alcoholic beverages? Yes No If so, what kind and
how much ?

11. Do you drink coffee? Yes No
Cups per day _____

12. Do you drink milk? Yes No
Glasses per day _____

13. Do you drink soda pop? Yes No
Glasses per day _____

14. Do you drink juices? Yes No
Glasses per day _____

15. Do you chew gum? Yes No
Sticks/day or week _____

16. Why do you smoke?

Please give possible reason. _____

17. Do you want to stop? If so,

Why? _____

APPENDIX K

Nicotine Withdrawal Questionnaire

Participant code _____
Date _____

1. Craving for cigarettes
(0)absent (1)slight (2) mild (3)moderate
(4)severe
2. Increased appetite
(0)absent (1)slight (2) mild (3)moderate
(4)severe
3. Depressed mood
(0)absent (1)slight (2) mild (3)moderate
(4)severe
4. Anxiety
(0)absent (1)slight (2) mild (3)moderate
(4)severe
5. Difficulty concentrating
(0)absent (1)slight (2) mild (3)moderate
(4)severe
6. Irritability, frustration, or anger
(0)absent (1)slight (2) mild (3)moderate
(4)severe
7. Restlessness
(0)absent (1)slight (2) mild (3)moderate
(4)severe
8. Difficulty sleeping
(0)absent (1)slight (2) mild (3)moderate
(4)severe

APPENDIX L

Profile of Mood States—Short Form

SAMPLE

NAME _____

SEX: Male Female

Below is a list of words that describe feelings people have. Please read each one carefully. Then, in the circle under the number to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.

- 1. Not at all
- 2. A little
- 3. Moderately
- 4. Quite a bit
- 5. Extremely

	Not at all A Little Moderately Quite a bit Extremely		Not at all A Little Moderately Quite a bit Extremely		Not at all A Little Moderately Quite a bit Extremely
1. Tense	(0) (1) (2) (3) (4) (5)	12.	(0) (1) (2) (3) (4) (5)	23.	(0) (1) (2) (3) (4) (5)
2. Anxious	(0) (1) (2) (3) (4) (5)	13.	(0) (1) (2) (3) (4) (5)	24.	(0) (1) (2) (3) (4) (5)
3. Worried	(0) (1) (2) (3) (4) (5)	14.	(0) (1) (2) (3) (4) (5)	25.	(0) (1) (2) (3) (4) (5)
4. Lethargic	(0) (1) (2) (3) (4) (5)	15.	(0) (1) (2) (3) (4) (5)	26.	(0) (1) (2) (3) (4) (5)
5. Confused	(0) (1) (2) (3) (4) (5)	16.	(0) (1) (2) (3) (4) (5)	27.	(0) (1) (2) (3) (4) (5)
6. Irritable	(0) (1) (2) (3) (4) (5)	17.	(0) (1) (2) (3) (4) (5)	28.	(0) (1) (2) (3) (4) (5)
7. Depressed	(0) (1) (2) (3) (4) (5)	18.	(0) (1) (2) (3) (4) (5)	29.	(0) (1) (2) (3) (4) (5)
8. Hostile	(0) (1) (2) (3) (4) (5)	19.	(0) (1) (2) (3) (4) (5)	30.	(0) (1) (2) (3) (4) (5)
9. Bored	(0) (1) (2) (3) (4) (5)	20.	(0) (1) (2) (3) (4) (5)		
10. Exhausted	(0) (1) (2) (3) (4) (5)	21.	(0) (1) (2) (3) (4) (5)		
11. Satisfied	(0) (1) (2) (3) (4) (5)	22.	(0) (1) (2) (3) (4) (5)		

MAKE SURE
YOU HAVE ANSWERED
EVERY ITEM

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University of Hawaii at Manoa

Tripler Army Medical Center

Patti Urso, MSN, ARNP
1021 Hoa Street
Honolulu, HI 96826

September 17, 2001

Dear Ms. Urso:

This letter grants you permission to use the Profile of Mood States (POMS) Short-Form, © 1989 EdITS Publishing, for use in your research study entitled Augmenting Tobacco Cessation Treatment Outcomes with Telephone Delivered Interventions with investigators Dr. Raymond Folen and Dr. Rosanne Harrigan. The POMS Short Form may not be reproduced in any manner. The term of this permission is for one calendar year from this date.

If you have any further questions please contact me at 1-800-416-1666 or via email at edits@k-online.com.

Sincerely,

A handwritten signature in cursive script that reads 'Ellen Philips'.

Ellen Philips
Permissions Dept.

Mailing address: P.O. Box 7234 • San Diego, California 92157

APPENDIX M

Codes for SUDs

Codes for mood analysis – Scoring by subjective units of discomfort scores (SUDS) 1=lowest.....10=highest (Adapted from POMS)

Tense	Unworthy	Gloomy
Angry	Uneasy	Sluggish
Worn out	Fatigued	Weary
Lively	Annoyed	Bewildered
Confused	Discouraged	Furious
Shaky	Nervous	Efficient
Sad	Lonely	Full of pep
Active	Muddled	Bad-tempered
Grouchy	Exhausted	Forgetful
Energetic	Anxious	Vigorous

APPENDIX N

Follow-up Phone Call Questionnaire Form

"I'm calling from the Tripler Army Medical Center to talk with people who participated in our Smoking Cessation group to see how helpful it was and to improve the quality of our program.

May I ask you a few questions? No Yes

On a scale of 1 to 5, with 1 meaning not helpful at all and 5 meaning extremely helpful, how helpful would you rate: (after item #3 say: remember, 1 means not helpful. 5 means extremely helpful) -

1. _____ The overall program
2. _____ Your own effort and ability
3. _____ New ways you learned to cope with stress in general
4. _____ New ways you learned to cope with the difficulties of quitting smoking
5. _____ The nicotine patch or Wellbutrin SR
6. _____ Support from others in the group

When you attended the first meeting, you set a quit: date to stop smoking . Have you smoked, even a puff, or used other forms of tobacco since- that date? No Yes

If No, then:

Thank you for your help, that was the last question. Congratulations for successful quitting

If Yes, then:

When did you smoke your last cigarette, even a puff? (date) _____
(If date is within previous 7 days, go to b. If greater than 7 days, skip b and c then go to d)

b. How many cigarettes do you smoke on the average per day?

c. What was the number of cigarettes when you smoked when you started attending the smoking cessation group?-,

d. How many days after your quit date did you first resume smoking ? ____ within 10 day
_____ longer than 10 days after your quit date

e. Many people relapse at least once before they finally quit. A relapse means that, at some time since the quit date you stopped smoking for at least one day but then started smoking for more than 6 days and then you quit again. How many relapses would you say you've had since your quit date? _____

Can you tell me the approximate date(s) and why you think you relapsed?

1. Date: _____ Reason: _____
2. Date: _____ Reason: _____
3. Date: _____ Reason: _____
4. Date: _____ Reason: _____
5. Date: _____ Reason: _____

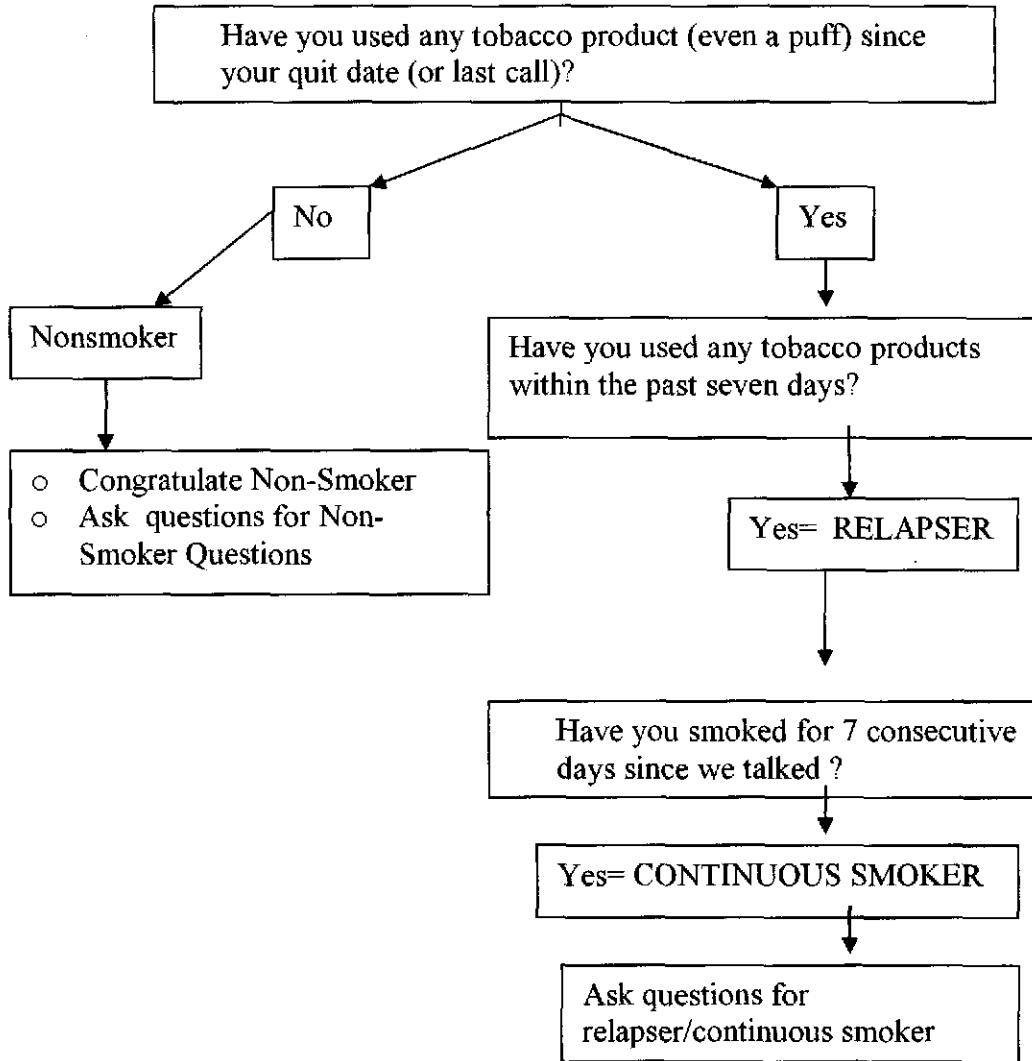
f. On a scale of 1 to 5, with 1 meaning not important and 5 meaning extremely important, how would you rate the following reasons for not quitting smoking. (after # 6, say, remember, 1 means not important. 5 means extremely important)

- _____ There was an illness or death in my family
- _____ I could not function without cigarettes
- _____ Cravings for cigarettes was too strong
- _____ Life is not worth living without cigarettes
- _____ Temptations to smoke were too strong
- _____ I relapsed by chance and could not stop again
- _____ The timing was wrong for me
- _____ I gained too much weight
- _____ I didn't have enough social support
- _____ Too many problems at work
- _____ I tried to stop for the wrong reason
- _____ When I drink alcohol. I can't resist not smoking
- _____ (other) _____

Thank you for your help, that's the last question. Many people who resume smoking find that when they attend another smoking cessation group, they are successful at permanently quitting smoking. If you are interested, I can sign you up now or you can call TAMC Health Psychology at 433-6060 and sign up later. Thank you.

APPENDIX O

Telephone-delivered Intervention Algorithm



APPENDIX P

Protocol and Frequency of TDIs

Overall Goals of Interventions TDIs

1. To assist participant in preparing for quit date.
2. Staying off tobacco use after quitting

Week 0 - First call Within the week after orientation.

Goal-

1. Maintain participant's goal of program attendance.
2. Establish a collaborative rapport to boost participant's level of motivation

Week 1- Second call

Goals-

1. Sustain commitment to behavior change.
2. Assist participant in preparing to quit date.
3. Answer participant's questions about pharmacological agents (bupropion and nicotine patch) monitor for effects and side effect and use.
 - Enhance motivation
 - Boosting self-efficacy
 - Planning: Identifying difficult situation and develop coping strategies
 - Set a quit date-

Week 3-10 Weekly calls – Ask the scripted questions

Goals-

- Enhance motivation
- Boosting self efficacy
- Planning: Identifying difficult situation and develop coping strategies

Sample script for weekly calls (Adapted from WINS)

1. Have you used any tobacco product (even a puff) since your quit date (or last call)? (No=Nonsmoker)
2. Have you smoked cigarettes within the past seven days? (Yes= Relapser)
3. Have you smoked for 7 consecutive days since we talked? (Yes=Continuous Smoker)

Ask these questions for nonsmokers:

Non Smokers

1. Recall your mood since last call? In a scale of 1-10 being the highest, how would you rate your mood since the last call?
2. Have you had any nicotine withdrawal symptoms? If yes, how severe have they been? (not at all, mild, moderate, severe, very severe) (ask nicotine withdrawal questionnaire)
3. Have you been using the nicotine patch? If yes what is the number of milligrams you are using? **OR** Have you taken the pills (bupropion) to help you stop smoking? If yes, number of pills? Times per week?
4. Have you used methods of relaxation? How many times per week?
5. Have you been exercising regularly? If yes, what kind ? Number times/ per week? What kind of intensity (low, moderate, or high)
6. On a scale of 1 to 7, what is your intention of maintaining your nonsmoking status? (1= definitely no, 4= maybe yes, 7=definitely yes)
7. On a scale of 1 to 10, how confident are you that you will not start smoking again? (0=no confidence to 10=total confidence)

Relapsers and Continuous Smokers

1. When did you begin smoking again?
2. Where were you when you started smoking ?
3. What triggered your relapse? (emotions, alcohol, familiar situation associated with smoking, peer pressure, stress withdrawal symptoms, to test myself, other)
4. On a scale of 1 to 10, how strong was your urge to smoke at that time?(ask questions on the nicotine withdrawal questionnaire)
5. Did you smoke more than one cigarette at that time?
6. When you began smoking how many days did you smoke?
7. When you woke up this morning, how many minutes/hours passed before you used tobacco?
8. On the average how many cigarettes did you smoke per day?
9. Have you had more than 1 lapse since we talked? If yes, how many? What was the average number of days you smoked each time?
10. When did you smoke your last cigarette ?

11. On a scale of 1 to 7 what is your intention of quitting using tobacco now? (1=definitely no, 4= maybe yes, 7= definitely yes)
12. On a scale of 1 to 10, how confident are you that you can quit tobacco now? (0=no confidence to 10= total confidence)
13. Have you had any nicotine withdrawal symptoms? If yes, how severe have they been? (not at all, mild, moderate, severe, very severe)
14. Have you been using the nicotine patch? If yes what is the number of milligrams you are using? **OR** Have you taken the pills (Welbutrin) to help you stop smoking? If yes, number of pills? Times per week?
15. Have you used methods of relaxation? How many times per week?
16. Have you been exercising regularly? If yes, what kind ? Number times/ per week? What kind of intensity (low, moderate, or high)
17. On a scale of 1 to 7, what is your intention of attaining non-smoking status? (1= definitely no, 4= maybe yes, 7=definitely yes)
18. Would you like a referral to attend group sessions?

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