Published in final edited form as:

Contemp Clin Trials. 2012 September ; 33(5): 959–968. doi:10.1016/j.cct.2012.04.009.

Efficacy of a smoking quit line in the military: Baseline design and analysis

Phyllis A. Richey^{a,*}, Robert C. Klesges^a, Gerald W. Talcott^a, Margaret DeBon^a, Catherine Womack^a, Fridtjof Thomas^a, and Ann Hryshko-Mullen^b

^aUniversity of Tennessee Health Science Center, United States

^bUnited States Air Force, Wilford Hall Medical Ctr., United States

Abstract

Thirty percent of all military personnel smoke cigarettes. Because of the negative health consequences and their impact on physical fitness, overall health, and military readiness, the Department of Defense has identified the reduction of tobacco use as a priority of US military forces. This study aims to evaluate the one-year efficacy of a proactive versus reactive smoking quit line in the US military with adjunctive nicotine replacement therapy (NRT) in both groups. This paper reports on the baseline variables of the first 1000 participants randomized, the design, and proposed analysis of the randomized two-arm clinical trial “Efficacy of a Tobacco Quit Line in the Military”. Participants are adult smokers who are Armed Forces Active Duty personnel, retirees, Reservist, National Guard and family member healthcare beneficiaries. All participants are randomized to either the Counselor Initiated (proactive) group, receiving 6 counseling sessions in addition to an 8-week supply of NRT, or the Self-Paced (reactive) group, in which they may call the quit line themselves to receive the same counseling sessions, in addition to a 2-week supply of NRT. The primary outcome measure of the study is self-reported smoking abstinence at 1-year follow-up. Results from this study will be the first to provide evidence for the efficacy of an intensive Counselor Initiated quit line with provided NRT in military personnel and could lead to dissemination throughout the US Air Force, the armed forces population as a whole and ultimately to civilian personnel that do not have ready access to preventive health services.

Keywords

Randomized controlled clinical trial; Cigarette smoking; Smoking cessation intervention; Tobacco quit lines; Proactive intervention; Military

1. Introduction

Cigarette smoking is one of the leading preventable causes of morbidity and mortality in the United States causing approximately 443,000 deaths annually [1-3]. Currently, 19.3% of US adults smoke cigarettes [4]. An even more alarming rate of smoking exists among active

*Corresponding author at: Preventive Medicine and Pediatrics, University of Tennessee Health Science Center, Department of Preventive Medicine, 600 Jefferson Ave, Room 336, Memphis, TN 38105, United States. Tel.: +1 901 448 8635; fax: +1 901 448 3770. prichey@uthsc.edu (P.A. Richey).

duty personnel with ranges from approximately 23% for the U.S. Air Force (USAF) to nearly 37% for Marines; thereby making active duty military personnel at particularly high risk for cigarette smoking, but yet representing an often neglected and underserved group [5]. Given the negative health consequences of cigarette smoking and their impact on physical fitness and readiness, the Department of Defense (DoD) has identified the reduction of tobacco use as a priority for improving the health of U.S. military forces [6]. Of further concern is that cigarette use is most prevalent in young military personnel, between the ages 18 and 25. Because of the unique challenges in the military, including frequent deployments of troops to remote locations, the high stress of combat and limited access to healthcare services when deployed, coupled with accessibility to lower priced tobacco products on military bases and availability of designated smoking areas within “tobacco-free” zones, many intervention programs that show strong efficacy in civilian populations often show limited or no efficacy in military populations [6]. As such, validating new and promising programs in the military population is important.

Self-help interventions for smoking cessation (e.g. mailings, pamphlets, audio and video tapes, internet and computer programs, and community programs) have been shown to increase smoking abstinence more than no intervention although these effects are weak [7]. A promising, and widely disseminated, approach that can effectively reach large numbers of smokers is the use of telephone-based Tobacco Quit Lines (QLs). Given that virtually all military personnel have access to telephones as part of the Defense Communication Network, QLs are particularly well suited for this population. A number of studies have evaluated the efficacy of “proactive” QLs but “reactive” interventions have not been as widely evaluated. In a proactive or Counselor Initiated QL, the counselor contacts the participant to provide a standardized intervention protocol. This type of quit line has been shown to be more than 1.5 times more effective than other self-help interventions [8]. In contrast, reactive QLs or client initiated intervention leaves the calling up to participants [7].

In response to the dearth of QL research in the U.S. Military, the National Heart, Lung, and Blood Institute funded “Efficacy of a Smoking Quit Line in the Military” (HL053478, [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00632411) #NCT00632411). The trial has been randomizing participants since 2008 and is described below. While the study continues to accrue participants, this paper reports on the design, proposed analysis and the baseline variables of the first 1000 randomized participants of the randomized two-arm clinical trial.

2. Methods

2.1. Design

This project is a randomized two-arm clinical trial designed to evaluate the one year efficacy of a proactive smoking quit line as compared with a reactive quit line. The study targets the US military and their family member healthcare beneficiaries. Participants randomized to the Counselor (proactive) Initiated group receive 6 counseling sessions, where a counselor proactively schedules appointments and calls them directly. The counseling sessions are completed within an 8-week period. Counselor Initiated participants also receive an 8 week supply of NRT. Participants randomized to the Self-Paced (reactive) group may call the QL as many times as they want during an 8 week period to receive the same counseling sessions

as the Counselor Initiated group. Self-Paced participants receive a 2-week starter kit of NRT.

This design was agreed upon by a panel of quit line experts, convened in Chicago, Illinois in 2007. There is now ample evidence that NRT improves cessation rates of QLs but in the “real world” participant initiated QLs tend to administer starter kits while Counselor Initiated QLs tend to administer longer amounts of NRT. Hence, this design evolved from the originally planned design that was Counselor Initiated plus NRT versus Participant Initiated without NRT [7].

The study site is Wilford Hall Medical Center at Lackland Air Force Base in San Antonio, Texas. The official name of the study is administered as the Wilford Hall Tobacco Quit Line. The protocol and consent form have been approved by the Institutional Review Boards at both The University of Tennessee Health Science Center in Memphis, Tennessee and Wilford Hall Medical Center in San Antonio, Texas.

2.2. Recruitment methods

2.2.1. Study participants—The study is recruiting 1200 adult smokers who are DoD military healthcare (Tricare) beneficiaries. To be included in the study individuals must be Armed Forces Active Duty personnel, or eligible Reservists, National Guard, retirees or family members, who are at least 18 years old and have smoked five or more cigarettes a day for at least one year. Participants must have the ability to understand consent procedures (in English), have access to a telephone for participation, and may not be a Basic Military Trainee. Of particular note, persons who have a contraindication to NRT, and woman who are pregnant, breastfeeding or planning to become pregnant during the next 12 months, are eligible to participate in the study however they must agree to receive the behavioral counseling alone and will not receive NRT. Since state funded quit lines accept “all comers”, i.e. even pregnant women, into treatment, the decision was to mirror usual QLs protocols.

2.2.2. Screening for eligibility—Smokers, are being recruited from 15 of the 71 Air Force bases throughout the country, particularly those within San Antonio, Texas, for participation in this study. Although we accepted all TRICARE beneficiaries who contacted the Quit Line, we attempted to target active duty Air Force members. Considering that 23% of Airmen smoke, there are approximately 15,000 potential Airmen participants alone for this study, not considering other active duty service members or family members [5]. It should be noted that the Air Force term for their personnel is “Airmen”, regardless of gender or rank. By utilizing adequate marketing strategies at individual military installations, securing installation leadership endorsement and receiving support from the Office of the Surgeon General for Air Force Health Promotion we anticipated that the QL could potentially recruit up to 20% of active duty smokers to participate in this study.

2.2.3. Challenges to recruitment—It is of special note however, that the recruitment process, specifically support for recruiting military personnel on Air Force bases, has been one of the greatest challenges encountered in this study to date. Securing appropriate support in order to recruit at military installations is a timely process that must not go under

appreciated. Before any recruitment actions, it is advisable to ensure that the appropriate installation chain-of-command is aware of the research effort. Although the minimum requirement to conduct this clinical trial is approval from the Wilford Hall Institutional Review Board (which serves as an Air Force IRB), it is important to ensure that key personnel at Air Force installations are aware and supportive of the intervention effort. More importantly, Airmen should not be receiving clinical services unknown to the medical authority at the installation. Air Force installations are located throughout the world and in order to build support it is critical to coordinate with the installation units responsible for providing tobacco cessation. The Health and Wellness Center (HAWC – pronounced “hawk”) is the responsible unit for providing tobacco cessation efforts on the installation.

Additionally, establishing a point-of-contact, which can be another lengthy process, is required at each individual base before the chain-of-command can even be initiated. We have been very fortunate to receive critical assistance with this process through endorsement of the study from the Office of the Surgeon General for Health Promotion. The Air Force Surgeon General’s Office of Health Promotion developed a letter of support for this research protocol that significantly improved the ability to gain installation support throughout the Air Force.

2.2.4. Specific recruitment strategies—Recruitment at the individual base level is initiated by first contacting the HAWC to brief them on the program and secure their endorsement and support. There is a HAWC at every Air Force base in the country and they are responsible for health promotion activities. While their primary mission is to conduct fitness tests, they also have a variety of health and wellness functions, including smoking cessation. We describe our project, and develop a collaborative verbal working agreement for advertising strategies. The HAWC is always briefed first as it is the office that is responsible for tobacco control activities on the installations.

We also brief the Office of Public Affairs. After describing the study, a smoking cessation example is provided that they may include in the base newspaper. A press release is then prepared that will appear in the local base paper, informing but not endorsing our study.

As a result of this time-consuming process, recruitment to the study was delayed for a one and a half year period of time. National Heart, Lung, and Blood Institute program officers, who were knowledgeable of the military and subsequent time delays, issued our project a two year no cost extension to allow us fulfill all the aims of the study.

Our recruitment strategy also includes an e-mail campaign in addition to several traditional approaches. First, we are utilizing military e-mail list serves to target study announcements and recruitment materials directly to active duty, Reservist and National Guard personnel. This method has produced the highest screening and enrollment rates of all our recruitment strategies, to date. Secondly, several more traditional approaches we are employing include publicizing the study via posted advertisements (e.g., flyers, posters, business cards), the study website, newspaper articles and ads, and ads on the base community access channels. We also received referrals from the HAWCs as well as medical and dental clinics located on Air Force Bases throughout the country. It is important to note that patients at all military

hospitals and outpatient clinics, across all service branches (i.e., Army, Navy, Air Force, Marines, Coast Guard) qualify for care. As such, we accepted a diversity of service branches into the study.

Individuals interested in the study call the tobacco QL using its toll free number (1-877-726-6211) to speak to research intervention staff. During the call, the staff provides callers with additional background information regarding the intervention and administers the screening interview to those interested in participating. During the screening interview verbal consent is obtained and baseline measures including eligibility (i.e., inclusion and exclusion criteria described above) and demographics are collected in addition to contact information.

For those who do not wish to participate, or refuse to give verbal consent, a list of smoking cessation resources is provided. It is important to note that due to the time constraints and the high mobility of active duty personnel and the heterogeneous geographic location of this study's potential participants, an alteration in requirements for informed consent was requested per 45 CFR 46.117(c) to allow for waiver of consent documentation. This request was awarded given that the interventions include confidential, standardized smoking cessation behavioral methodology administered by trained study staff per the Clinical Practice Guidelines [7] and involve minimal risk to participants as the NRT, which is available over-the-counter, pose minimal contraindications, has generally mild side effects, and no written consent is required for its usage outside the research context. The IRB also was mindful of the fact that refusing to consent and discontinue the study could be easily accomplished simply by either hanging up the phone or not calling back.

2.2.5. Randomization—The group assignment is accomplished via computerized block design which allows study staff enrolling participants to remain blinded to group assignment until the randomization process is complete. Participants are randomized to either the Counselor Initiated or Self-Paced group via this blinded process performed using FileMaker Pro v11.03 (FileMaker Inc., Santa Clara, CA, 95054). Blocking is applied to assure balanced assignment to both groups throughout the duration of the study. Specifically, one of the six possible ways to consecutively assign four participants to two conditions is randomly selected and determines the assignment of a set of four participants. After enrollment of these four participants a new block of length four is randomly determined. Study staff remains blinded toward which random block has been selected as well as when new blocks are selected and consequently cannot predict upcoming group assignments. Once the group assignment is revealed by FileMaker study staff notifies the participant about their assignment to either the proactive or reactive group.

2.3. Intervention conditions

2.3.1. Behavioral intervention—All participants enrolled in the study, regardless of their group assignment, are offered the same smoking cessation behavioral intervention that is based on Social Cognitive Theory [9,10] Social Cognitive Theory places considerable emphasis on an individual's ability to self-regulate behavior, making the person the principal agent of his or her own change [9,10]. According to SCT, behavior is motivated and

regulated, in part, by a person's internal standards and self-evaluative reactions to their own behavior [10]. Successful obtainment of goals helps to foster self-efficacy and serves as a basis for self-managed reinforcement [9]. Several of the specific components that comprise the smoking cessation intervention were derived from these key elements of SCT. The intervention utilizes strategies for enhancing self-efficacy for behavior change by providing opportunities for mastery experiences through short-term goal setting and by helping participants to alter cognitions associated with their perceived ability to successfully execute the behaviors associated with cessation [9,11], see Table 1 and Fig. 1. In addition, the intervention focuses on developing effective self-regulatory skills [12].

There are three phases of the behavioral intervention (preparing to quit, quitting, and preventing relapse). The preparing to quit phase includes scheduled, time based rate reduction, breaking of the cues related to smoking and carrying out a "ritual" to stop smoking (e.g., remove all cigarettes from the house, get rid of ashtrays, clean the interior of the car) prior to actually quitting. In addition, the intervention involves modifying outcome expectancies related to the targeted behavior changes in an effort to provide more accurate expectations regarding what they can expect to experience after quitting smoking (e.g., improved stamina, improved social image, nicotine withdrawal symptoms, weight gain). This phase is done once the participant sets a quit date and adheres to instructions regarding NRT medication use. Lastly, self-monitoring, goal setting, skills training, modeling, and self-reinforcement are employed to build self-regulatory skills. During this phase the participant and counselor work together to identify high-risk situations when they would be most likely tempted to slip and relapse and discuss maintaining short and long-term smoking abstinence. Participants in both conditions are encouraged to use the line as often as they like. Each of the six weekly sessions are approximately 15-30 minute telephone counseling sessions.

2.3.2. Pharmacologic intervention—Nicotine replacement therapy (NRT) is the pharmacological intervention provided to the participants of both the Counselor Initiated and Self-Paced group. The NRT types utilized in this intervention are the nicotine patch and nicotine gum. We are using the nicotine patch as the primary method for NRT due to its ease of use for most participants, its ability to deliver a more predictable nicotine dose, and its social acceptability for most patients as it is easily concealed under clothing. The initial NRT distributed to the Counselor Initiated participants includes four weeks-worth of nicotine patches in the dosage appropriate to their current smoking level while those in the Self-Paced group receive two weeks-worth of NRT (see Table 2) [7]. The Counselor Initiated participants also receive an additional 4 weeks-worth of nicotine patch at a later date if they have successfully quit or have reset their quit date after only one failure. Additionally, in a few cases, some participants request nicotine gum in lieu of nicotine patches because of previous experience with the patch (e.g., failure to curb urge to smoke, unmanageable side effects, etc.). We offer these alternatives as there is ample evidence that NRT, regardless of the type (e.g., patch vs. gum) is equally efficacious [7]. NRT use for all participants begins on the day of their quit date.

The rate reduction gum dosage distributed (see below) follows the same schedule shown in Table 2 however the total allotment provided is dependent upon the session call in which the

participant was triaged to the rate reduction intervention. Those initiating rate reduction during call 3 receive a three-week supply of nicotine gum, during call 4 receive a two-week supply, during call 5 receive a one-week supply, and those triaged to rate reduction during call 6 do not receive any nicotine gum.

2.3.3. Counselor Initiated (proactive) condition—For participants randomized to the Counselor Initiated (proactive) group the screening call continues into the first counseling session if they have time (approximately 20 additional minutes). For participants who cannot continue the conversation, an appointment is scheduled for the first session within the next 7-10 days in which the research staff calls the participant at the agreed upon time and date. Each additional Counselor Initiated session call is then scheduled around the participant's quit date. In cases where counselors have a difficulty reaching the individual, they will re-contact them to reschedule the session. Following completion of this initial enrollment call, a packet is mailed to the participant that contains a summary copy of the verbal consent and their NRT starter pack and NRT usage instructions. The verbal consent summary explains the risks associated with participating in the research study, states the intervention group the participant was randomized to, and states that the information collected will not be shared with any parties outside of the research study. It also states that the care of the participant will not be affected by choosing to participate or not participate in the research study. Although few participants fall into this category, individuals with contraindications for NRT are eligible to participate in this study but not receive NRT.

The six-session phone protocol follows a similar basic format as the brief four session face-to-face protocol we have used previously in multiple settings and locations with emphasis on calling around the quit date [13,14]. Each of the sessions lasts approximately 40 min or less in duration. Although participants in both groups receive only 6 formal intervention counseling sessions, a participant may call more than the six times, regardless of group assignment, to ask questions. The counseling sessions, outlined in Table 3, include the following:

- Session 1 — rate reduction: prepares the participant to quit smoking by rate reducing the number of cigarettes per day and primes them for setting quit date.
- Session 2 — pre-quit: sets a specific quit date and discussed the steps involved in preparing to quit including the 5 As for staying tobacco-free, challenges experienced during previous quit attempts, methods for managing nicotine withdrawal symptoms, and talk proper use of the nicotine patch.
- Session 3 — quit date: continues to build rapport and provides support for the participant by assessing progress, reviewing review the 5 As and discussing problem solve strategies for dealing with difficult situations.
- Session 4 — post-quit: provides support for the participant, praises them for their successes, trouble shoots problem areas and assesses NRT patch use.
- Session 5 — short-term relapse prevention: reviews progress to date and patch use as well as beginning development of an individualized relapse prevention plan.

- Session 6 — long-term relapse prevention: reviews progress to date and patch use as well as completes development of an individualized relapse prevention plan.

2.3.4. Self-Paced (reactive) condition—To receive the intervention from the counselors, those assigned to the Self-Paced (reactive) group are instructed to call the QL themselves. Phone access to the QL is available any time from 8:00 a.m. to 5:00 p.m. CST. Self-Paced participants are encouraged to call any day during the hours of operation throughout the one year period in which they are enrolled. They are further encouraged to set a quit date, begin patch use on their quit date, call the quit line especially around their quit date and at any time during their year-long involvement in the study. If they call consistently (and they are encouraged to do so), they receive the same interventions as the Counselor Initiated (proactive) group. As indicated above, participants are given two weeks of NRT in the form of a “starter kit” and are encouraged to buy more NRT if they feel it is helping them quit.

2.3.5. Triaged intervention post quit date—This trial triages interventions based on participants experience on their quit date. Participants who fail to stop smoking on their quit date or they relapse prior to the end of the intervention are encouraged to set another quit date. If this is the case, we repeat Sessions 1-3 in a truncated fashion, inserting as much as we can about at least short term relapse prevention. For those that fail to quit smoking, and who are unwilling to set another quit date (see Fig. 2) they are triaged to a rate reduction intervention. This intervention flow is implemented as need for participants in both the Counselor Initiated and Self-Paced groups. There is empirical evidence to support this intervention as a springboard to later cessation and in individuals who are not ready to quit smoking [15]. There are several advantages of this particular approach. First, there is a reduction of number of cigarettes per day making it easier when one does quit. Second, and most importantly, the participant will learn that they are in control of their smoking, not the other way around. Supplemental rate reduction materials are provided to these participants in an attempt to increase the probability that they will quit smoking in the future. Strategies covered with participants receiving the rate reduction protocol are presented in Table 3. See Fig. 2 for how participants are triaged depending on the smoking status and intentions following the quit date.

For those that fail to quit on their quit date and are not ready to set another quit date, they are given the combined behavioral/pharmacologic rate reduction described above. The term “rate reduction” refers to a heterogeneous set of interventions in the literature. One form of rate reduction is designed to reduce harm — for those smokers not willing to quit smoking, the goal is to reduce the number of cigarettes per day, in theory, to reduce risk. However, the research in this area suggests that while one can successfully get smokers to reduce their intake, “harm” itself (as measured by measures such as cancer causing metabolites) is not reduced [16]. A second form of rate reduction is the type we do for all our smokers in the early phases of intervention. This strategy targets reductions in intake prior to a cessation attempt in smokers ready to quit smoking [4]. The other primary form of rate reduction is to use cutting down as a “springboard for cessation” without the specific goal of smoking cessation per se. While rate reduction has shown to enhance smoking cessation in smokers

not ready to quit smoking [17,18], for those ready to quit smoking rate reduction intervention protocols appears to actually impede cessation effects [18]. For these smokers who refuse to set another quit date, by definition they are not ready to quit smoking. As such we offer rate reduction to hopefully assist with the next cessation attempt.

2.3.5.1. Retention and follow-up: To maintain active participation for the entire year of study participation, extensive retention measures are taken. Specifically, contact information, including information on relatives or friends who would know the participant's whereabouts is updated during each contact with a participant. This extensive contact information is maintained in a historical database archive to provide research staff containing every known contact collected from the participant during the course of their enrollment. In the event that a Counselor Initiated participant misses scheduled telephone sessions, research staff attempts to contact them to reschedule. If after three days of numerous unsuccessful rescheduling attempts, to all known points of contact, a "Missed Visit" letter is mailed to the participant at their last known current address. In addition to contact by telephone research staff also utilize text messaging as a retention and follow-up method. In the event that the Counselor Initiated participant does not respond to the retention letter, research staff proceeds on an individual case management approach. Participants in the Self-Paced group receive no such retention measures during the intervention phase due to the nature of that reactive assignment.

All participants receive two follow-up calls at 8-10 weeks (post treatment) and 1 year after enrollment, regardless of group assignment or how many intervention sessions they completed, to assess their smoking status. The protocol for contacting participants for the 8-week and 12-month post treatment calls follows the same procedure as described above, except the retention strategies are used in both the proactive and reactive intervention groups. Additionally, in the situation where all contact points, last known current as well as all historical, have been unsuccessful in contacting the participant to collect the follow-up data, research staff will utilize online paid search tools in an attempt to identify a new point of contact. This process has often proved to be successful with difficult cases.

2.3.5.2. Interventionist training: All interventionists complete standard, National Institutes of Health required, training on the protection of human research participants (i.e., Health Insurance Portability and Accountability Act (HIPAA) and Collaborative IRB Training Initiative (CITI) Program), in addition to an intensive two-week training period on the study intervention. All intervention components are demonstrated for the trainee then performed by the trainee under observation before they are performed alone. This training includes familiarity with all protocols of the project, roleplaying both project procedures (telephone screening) as well as the intervention, quizzes on project procedures and protocols, and direct observation of treatment delivery. The Study Coordinator reviews the quizzes each trainee and re-administers them after a one-week period. For the first two months of the study, and randomly throughout the course of the trial, interventionist's session calls are audio taped or directly observed in order to ensure protocol adherence. Any staff member demonstrating deficits in study protocol undergoes retraining as deemed necessary. Interventionist adherence to the smoking cessation intervention is completed by electronic

chart review. Additionally, each interventionist receives an annual “gold standard” quality assurance check on the delivery of the smoking cessation intervention via the direct audio observation (using conference call technology) of their live participant sessions by a study co-investigator. The quality assurance check is reviewed with the staff member and semi-annual quality assurance reports on all interventionists are provided to the Principal Investigator.

2.3.5.3. Data collection, measures and outcomes: Data are collected at baseline, 8 weeks (post treatment) and 1 year after enrollment. At baseline, several demographic variables are collected, including age, self-reported height/weight, gender, marital status, income, military branch and rank (for active duty participants), years of education, and ethnicity. Several tobacco use/quitting variables are also collected at baseline including the number of years as a cigarette smoker, current amount smoked, prior cessation experience, and the Fagerström Test for Nicotine Dependence.

During intervention calls information on NRT patch use and side effects as well as adverse events are collected. Concomitant medication use is also collected due to its possible effect on successful smoking cessation. We also monitor participation in additional stop-smoking behavioral programs and track participant adherence to treatment sessions.

At 8 weeks (post treatment) and 1 year after enrollment smoking status is assessed in both the Counselor Initiated and Self-Paced groups using both prolonged and 7-day pointprevalence abstinence criteria [19]. Prolonged abstinence refers to sustained abstinence following an initial grace period defined for purposes of this study as the two weeks immediately following a participants’ quit date. Point-prevalence abstinence refers to self-reported smoking status (yes vs. no) at a particular point in time, with no correction for previous or subsequent smoking status.

2.3.6. Participant characteristics—Baseline characteristics of the first 1000 participants randomized are presented in Table 4. There are no significant differences between the two intervention groups on a number of demographic and smoking variables. The average age of the participants was 39 years, they had completed high school (or greater), had smoked for nearly 19 years, and averaged almost 18 cigarettes per day at entry into the study. The study is well represented by women (42%) and ethnic minorities (nearly 35%) with the female participation being overrepresented proportional to the military population and minority participation being proportional to the military population. While all military branches are represented in the study, it is not surprising that 70% were from the Air Force given that we primarily are recruiting on Air Force Bases. The most common participants were active duty military (45%) followed by dependent family members (30.6%).

3. Statistical approach

3.1. Sample size

For sample size requirement, we assumed a 5% cessation rate in the reactive (comparison) condition and a 10% cessation rate in the proactive condition [7]. Controlling the type I error

rate at $\alpha=0.05$ we have 90% power (type II error rate $\beta=0.10$) to detect such a difference when randomizing $n=600$ participants to each study arm, i.e. total $n=1200$ with equal allocation (two-sided Fisher's exact test for equal proportions; the approximate z-test results in a slightly smaller sample size). Since, for the purpose of the primary data analysis, we will classify any participant with unavailable endpoint (lost to follow-up) as relapsed, we do not have to account for attrition for the primary data analysis. Note that for secondary analysis purposes and assuming up to 20% participants lost to follow up, we still have 80% power to detect a 5 percentage point difference in cessation rates when analyzing study completers only. Our experience in studies in the military population suggests that the percentage of lost to follow-up will be considerably less than 20% and we therefore conclude that the $n=1200$ participants give us very good power for the planned primary as well as secondary data analyses.

3.2. Statistical analysis

The purpose of the here presented analysis (Table 4) was twofold. First, we wanted to study whether we indeed succeeded to enroll participants from the entire spectrum of Air Force personnel, especially women and minority groups (see Discussion below for details). Secondly, we assessed the homogeneity or heterogeneity of potentially important baseline covariates between the Self-Paced and the Counselor Initiated group participants. These covariates appear well balanced as detailed in Table 4.

The statistical analysis of the smoking cessation outcome to be reported in the future is planned as follows. Before attempting any assessment of the outcome we will classify every participant as completer or lost to follow-up and we will determine which covariates, if any, are associated with missing data (utilizing logistic regression). If there are variables that affect missingness then these variables will need to be included in any final model. Note that, for the purpose of the primary data analysis, we will classify any participant with unavailable endpoint (lost to follow-up) as relapsed. Our primary outcome is prolonged abstinence defined as self-report of zero cigarettes following the end of the grace period to the one-year follow-up. We will test for equality of (unadjusted) prolonged abstinence proportions as well as model successful quit attempts (binary yes/no) using generalized linear mixed models. The latter approach allows us to account for the possibility of an Air Force base effect and obtain an estimate of that effect in the form of a variance component for base. Therefore, in our basic model we define Air Force base to be a random effect and treatment (Counselor Initiated vs. Self-Paced) as a fixed effect. The model will also include any variable identified as significantly different between the two treatment groups and any variable that influences loss to follow-up. Other potential covariates (all fixed effects) that may be included in a model are the Fagerstrom Test for Nicotine Dependence (FTND) and relevant background information (age, previous quit attempts, etc.). As secondary data analysis we will augment these models to possibly also include program adherence, medication side effects, adverse events during the study on all participants, use of any other product or programs that may have influenced abstinence rates (e.g. nicotine nasal spray), and use of antidepressants (e.g. nortriptyline, bupropion SR). Similarly, we will estimate generalized linear mixed models for point prevalence quit at 8 weeks and one year with

focus on two major factors of interest: time (8 weeks and one year) and treatment (Counselor Initiated vs. Self-Paced) (and possibly the interaction of time and treatment).

4. Discussion

This paper describes the design of the ongoing “Efficacy of a Smoking Quit Line in the Military” that evaluates the one year efficacy of a proactive versus a reactive smoking quit line with adjunctive NRT in both groups.

There are several strengths of this study to date, the first of which is its “real-world” design in which both groups have access to identical quit line intervention sessions and adjunctive NRT, although in the reactive condition NRT length is two weeks. Secondly, this study is the first to examine the efficacy of an intensive Counselor Initiated quit line with provided NRT in military personnel. Finally, given the size and geographic diversity of the recruitment sample, results are very conducive to generalization to other military as well as civilian populations. Despite the strengths of the study, there are some relative weaknesses as well. For example, given its real world nature, a cost effectiveness component could have added to the strength and generalizability of this study. Additionally, there is inherent variability of QL intervention protocols. However, we believe that the randomized controlled design of this study will adequately test the efficacy of an intensive Counselor Initiated QL with provided NRT in military personnel. It is also noted that another QL offered to all Tricare beneficiaries was started by Tricare after our study commenced (military personnel, retirees, dependents, National Guard). Participants of this reactive QL are eligible for participation in our intervention and that prior participation should not impact the causal integrity of the random assignment and we have no indication that it would have impacted our recruitment.

In summary, baseline characteristics on the first 1000 participants randomized showed no significant differences between the proactive and reactive conditions on any demographic variables. A fully 57% of participants are female, significantly higher than the Air Force active duty rate of 19% and the Tricare female beneficiary rate of 9.6%. Although not specifically targeted, the outstanding participation of females in this study is notable and could be attributed to the commonly held assumption, although not proven, that women are more willing to seek help for health issues than are men [20,21]. Ethnic/minorities comprised nearly 35% of the sample. Overall, we have recruited a diverse group of participants that represent the “population” of military personnel well. Following the completion of this study, this intervention could be disseminated not only in the Air Force, but also in other armed forces population as a whole. Given approximately 379,000 active duty Air Force personnel [22] and a smoking prevalence of 23%, a minimally successful (3%) QL would result in an additional 3070 quitters each year assuming dissemination to all installations and proactive outreach to smokers at least once per year. Dissemination to all active duty in the DoD (n=1,427,500; smoking prevalence=33.8%) would result in 14,475 additional quitters each year. Extending QL access to Reservists and National Guard members would further expand the public health impact of this QL (Active Duty+Reserves +Guard=2,280,500; smoking prevalence=33.8%) to an additional 23,225 quitters per year.

Because of the optimal nature of the QL, it is our hope that the impact will greatly exceed our predicted minimum.

Acknowledgment

This study is supported by HL-053478 from the National Heart Lung and Blood Institute.

References

- [1]. Centers for Disease Control and Prevention. Vital signs: current cigarette smoking among adults aged 18 years — United States, 2009. *Morb Mortal Wkly Rep.* 2010; 59:1135–40.
- [2]. Danaei G, Ding EL, Mozaffarian D, Taylor B, Rehm J, Murray CJ, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med.* 2009; 6:e1000058. [PubMed: 19399161]
- [3]. Centers for Disease Control and Prevention. State-specific prevalence of cigarette smoking and smokeless tobacco use among adults— United States, 2009. *Morb Mortal Wkly Rep.* 2010; 59:1400–6.
- [4]. Centers for Disease Control and Prevention. Current cigarette smoking among adults aged 18 years — United States, 2005–2010. *Morb Mortal Wkly Rep.* 2011; 60:1207–12.
- [5]. Bray, RM.; Pemberton, MR.; Hourani, LL.; Witt, M.; Olmsted, KL.; Brown, JM., et al. Department of Defense survey of health related behaviors among active duty military personnel. RTI International; Research Triangle Park, NC: 2008.
- [6]. Institute of Medicine. Combating tobacco use in military and veteran populations. Washington D.C: 2009.
- [7]. Fiore, M.; Jaen, CR.; Baker, TB.; Bailey, WC.; Benowitz, NL.; Curry, SJ., et al. Clinical practice guideline. U.S. Department of Health and Human Service; Rockville, MD: 2008. Treating tobacco use and dependence.
- [8]. Centers for Disease Control, Prevention. Telephone quitlines: a resource for development, implementation, and evaluation. Atlanta, GA: 2004.
- [9]. Bandura, A. Social learning theory. Prentice-Hall, Inc.; Englewood Cliffs, NJ: 1977.
- [10]. Bandura, A. Social foundations of thought and action: a social cognitive theory. Prentice-Hall, Inc.; Englewood Cliffs, NJ: 1986.
- [11]. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977; 84:191–215. [PubMed: 847061]
- [12]. Bandura, A. Self-efficacy: the exercise of control. W. H. Freeman and Company; New York: 1997.
- [13]. Robinson LA, Vander Weg MW, Riedel BW, Klesges RC, McLain-Allen B. “Start to stop”: results of a randomised controlled trial of a smoking cessation programme for teens. *Tob Control.* 2003; 12(Suppl. 4):26–33.
- [14]. Cooper TV, DeBon MW, Stockton M, Klesges RC, Steenbergh TA, Sherrill-Mittleman D, et al. Correlates of adherence with transdermal nicotine. *Addict Behav.* 2004; 29:1565–78. [PubMed: 15451124]
- [15]. Asfar T, Ebbert JO, Klesges RC, Relyea GE. Do smoking reduction interventions promote cessation in smokers not ready to quit? *Addict Behav.* 2011; 36:764–8. [PubMed: 21420791]
- [16]. Hecht SS, Yuan J-M, Hatsukami D. Applying tobacco carcinogen and toxicant biomarkers in product regulation and cancer prevention. *Chem Res Toxicol.* 2010; 23:1001–8. [PubMed: 20408564]
- [17]. Lindson N, Aveyard P, Hughes J. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database Syst Rev.* 2010; (3) Document Number: CD008033.
- [18]. Hughes J, Solomon L, Livingston A, Callas P, Peters E. A randomized, controlled trial of NRT-aided gradual vs. abrupt cessation in smokers actively trying to quit. *Drug Alcohol Depend.* 2010; 111:105–13. [PubMed: 20537810]

- [19]. Hughes JR, Keely JP, Niaura RS, Ossip-Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine Tob Res.* 2003; 5:13–25. [PubMed: 12745503]
- [20]. Addis ME, Mahalik JR. Men, masculinity, and the contexts of help seeking. *Am Psychol.* 2003; 58:5–14. [PubMed: 12674814]
- [21]. Hunt K, Adamson J, Hewitt C, Nazareth I. Do women consult more than men? A review of gender and consultation for back pain and headache. *J Health Serv Res Policy.* 2011; 16:108–17. [PubMed: 20819913]
- [22]. 108th congress. National Defense Authorization Act for Fiscal Year 2005; 2004;

Fig. 1.
Theoretical model of social cognitive and self-efficacy theory for quitting smoking.

Fig. 2.
Intervention flow chart.

Table 1

Rate reduction strategies.

<ul style="list-style-type: none">• Changing to a low tar/low nicotine cigarette• Reduce number of cigarettes by 60%• Delay the first cigarette of the day• Monitor their daily intake in comparison to their daily goal• Carry only the number of goal cigarettes each day.• Situational strategies (limiting smoking to only certain situations)• Temporal strategies (limiting smoking to certain times like 1 per hour)• Access strategies (limiting access to cigarettes for example keeping them in the trunk of car)
--

Table 2

NRT dosing regimen.

A. Patch			
Cigarettes smoking	Starting dose of NRT (Patch)	Dosing schedule for proactive(patch)	Dosing schedule for reactive (patch)
20 per day	21 mg patch	21 mg patch for 28 days, 14 mg patch for 14 days, 7 mg patch for 14 days, Then off.	21 mg patch for 14 days
10-19 per day	14 mg patch	14 mg patch for 28 days, 7 mg patch for 28 days, Then off.	14 mg patch for 14 days
5-9 per day	7 mg patch	7 mg patch for 56 days, Then off.	7 mg patch for 14 days
B. Gum			
Cigarettes smoking	Starting dose of NRT	Dosing schedule and max pieces/24 h (both groups)	
25 per day	4 mg	1-2 h as needed Max 24 pieces/24 h	
<25 per day	2 mg	1-2 h as neededbr Max 24 pieces/24 h	

Table 3**Behavioral intervention outline.**

Session 1: rate reduction (week 0)	<ul style="list-style-type: none"> • Focuses on smoking fewer cigarettes during this first week in preparation for quit date • The participant will be instructed on how to reduce the amount of cigarettes they are currently smoking. • Setting a quit date in the next 7–14 days is discussed. • Mail four weeks supply of NRT to Counselor Initiated participant with instructions to not use it until quit date.
Session 2: pre-quit (weeks 1–2)	<ul style="list-style-type: none"> • Participants go through a preparation phase to quit. • Focus is on preparing to quit and surviving the first days as a nonsmoker. • Quit date is set in the next week. • Quitting rituals, building support and using the “Five As” (Avoid, Alter, Alternatives, Anticipate, and Active) is emphasized. • Detailed instructions for patch use are reviewed.
Session 3: quit date (weeks 1–2)	<ul style="list-style-type: none"> • Involves surviving the first few days surrounding the quit date. • Involves support, problem solving, coping with negative emotions. • Addresses dealing with negative cognitions. • Assess smoking status, patch use, side effects, adherence issues, adverse events.
Session 4: post-quit date (weeks 3–4)	<ul style="list-style-type: none"> • Involves support, problem solving, and coping with negative cognitions • Four week supply of NRT mailed to individual’s in Counselor Initiated group. • Assess smoking status, patch use, side effects, adherence issues, adverse events.
Session 5: short-term relapse prevention (weeks 5–6)	<ul style="list-style-type: none"> • Booster support session • Focus on more short term strategies for relapse prevention • Assess smoking status, patch use, side effects, adherence issues, adverse events.
Session 6: long-term relapse prevention (weeks 7–8)	<ul style="list-style-type: none"> • Focus on more long term strategies for relapse prevention • Review of high-risk situations and difficulties in previous cessation attempts. Discussion of relapse prevention strategies. • Assess smoking status, patch use, side effects, adherence issues, adverse events.
End of treatment assessment phone call (weeks 9–10)	<ul style="list-style-type: none"> • All participants, both Counselor Initiated and Self-Paced groups, receive this call. • Asks about current tobacco use, patch adherence, side effects/adverse events, any concomitant medications.
12 month follow-up phone call	<ul style="list-style-type: none"> • All participants, both Counselor Initiated and Self-Paced groups, receive this call. • Discuss current tobacco use, side effects/adverse events, concomitant medications. • Asks about any promotions within their respective branch. • Inquires as to the current physical location of the subject (deployed, transferred)

Table 4

Participant demographics.

Variable	Total (N = 1000) N (%)	Self-Paced (N = 495) N (49.50%)	Counselor (N = 505) N (50.50%)	p-value
Age	39.2±13.9	39.1±14.2	39.3±13.7	0.80 ^a
Gender				0.41 ^b
Male	423 (42.3)	203 (41.0)	220 (43.6)	
Female	577 (57.7)	292 (59.0)	285 (56.4)	
Ethnicity				0.83 ^b
Hispanic or Latino	95 (9.5)	46 (9.3)	49 (9.7)	
Not Hispanic or Latino	905 (90.5)	449 (90.7)	456 (90.3)	
Race				0.78 ^b
African American/Black	135 (13.5)	64 (13.0)	71 (14.1)	
American Indian/Alaskan native	29 (2.9)	15 (3.0)	14 (2.8)	
Asian/Pacific Islander	33 (3.3)	13 (2.6)	20 (4.0)	
White	749 (75.0)	375 (75.9)	374 (74.1)	
Other	53 (5.3)	27 (5.5)	26 (5.2)	
Education				0.92 ^c
Did not finish elementary school	0 (0.0)	0 (0.00)	0 (0.0)	
Finished elementary school (6th grade)	2 (0.2)	1 (0.2)	1 (0.2)	
Jr. high School (8th grade)	2 (0.2)	1 (0.2)	1 (0.2)	
Some high school	25 (2.5)	12 (2.4)	13 (2.6)	
High school grad or G.E.D.	268 (26.8)	127(25.7)	141 (27.9)	
Vocational/training school after HS	13 (1.3)	8 (1.6)	5 (1.0)	
Some college or associate degree	517 (51.7)	256 (51.7)	261 (51.7)	
College graduate/baccalaureate degree	136 (13.6)	71 (14.3)	65 (12.9)	
Masters degree	35 (3.5)	17 (3.4)	18 (3.6)	
Doctoral degree	2 (0.2)	2 (0.4)	0 (0.0)	
Military branch				0.85 ^c
Army	172 (17.3)	82 (16.7)	90 (17.9)	
army national guard	12 (1.2)	5 (1.0)	7 (1.4)	
Air Force	693 (70.0)	346 (70.3)	347 (69.0)	
Air national guard	31 (3.1)	18 (3.7)	13 (2.6)	
Navy	66 (6.6)	32 (6.5)	34(6.8)	
Marine Corp	14 (1.4)	5 (1.0)	9 (1.8)	
Coast Guard	7 (0.7)	4 (0.8)	3 (0.6)	
Military status				0.65 ^b
Active duty	450 (45.0)	232 (46.9)	218 (33.2)	
Reservist	67 (6.7)	34 (6.9)	33 (6.5)	
Retiree	177 (17.7)	84 (17.0)	93 (18.4)	

Variable	Total (N = 1000) N (%)	Self-Paced (N = 495) N (49.50%)	Counselor (N = 505) N (50.50%)	p-value
Dependent family member	306 (30.6)	145 (29.3)	161 (31.9)	
Years served	5.3±7.6	5.4±7.7	5.8±7.7	0.18 ^d
Marital status				0.75 ^c
Never married	155 (15.5)	76 (15.4)	79 (15.7)	
Divorced/separated	151 (15.1)	77 (15.6)	74 (14.7)	
Widowed	26 (2.6)	16 (3.2)	10 (2.0)	
Presently married	658 (65.9)	321 (64.9)	337 (66.9)	
Living in marriage like relationship	9 (0.9)	5 (1.0)	4 (0.8)	
Income				0.37 ^b
Less than \$40,000	609 (61.0)	308 (62.4)	301 (59.6)	
\$40,000 or more	390 (39.0)	186 (37.7)	204 (40.4)	
Years smoked	18.7±13.2	18.7± 13.1	18.6±13.2	0.85 ^d
Number of cigarettes	17.8±8.7	17.6±8.2	18.0±9.1	0.66 ^d
Number of quit attempts	1.6±2.3	1.4±2.6	1.5±2.1	0.26 ^d
Fagerstrom score	4.2±2.2	4.2±2.2	4.2±2.2	0.97 ^d

^a t-test.

^b Chi-square test.

^c Fisher's exact test.

^d Wilcoxon-Mann-Whitney test.