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Preventing Smoking Initiation or Relapse following 8.5 Weeks of Involuntary Smoking Abstinence in Basic Military Training: Trial Design, Interventions, and Baseline Data

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Abstract

Smoking cessation is a primary method of reducing excess mortality and morbidity. Unfortunately, the vast majority of cessation attempts end in eventual relapse. Relapse-prevention interventions have shown some success at improving the long-term maintenance of tobacco abstinence among individuals motivated to abstain. However, involuntary tobacco abstinence (e.g., military training, hospitalization, incarceration) presents another opportunity for intervention to prevent relapse. During basic military training (BMT), tobacco use is strictly forbidden in all service branches, but tobacco relapse (and initiation) following BMT is extremely high. This paper reports on the design, intervention development, and baseline characteristics of a randomized controlled trial testing minimal interventions designed to prevent tobacco relapse among United States Air Force (USAF) personnel following BMT. Participants are randomized by squadron to receive either a standard smoking-cessation booklet, a new motivation-based booklet designed specifically for USAF personnel, or the latter booklet combined with a brief, face-to-face motivational session. Primary outcomes will be self-reported tobacco use at 12 and 24 month follow-up. Given that the Department of Defense is the world's largest employer, the potential of leveraging involuntary tobacco abstinence during BMT into extended abstinence has substantial public health significance.

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Keywords

tobacco; smoking; military; randomized controlled trial; smoking cessation intervention; relapse-prevention

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1. Introduction

Cigarette smoking is the leading preventable cause of morbidity and mortality in the United States [1, 2]. Sustained smoking cessation reduces mortality and morbidity, but most smokers who achieve short-term tobacco abstinence eventually relapse to smoking. Among smokers receiving a cessation intervention, at least 70% relapse [3]; among self-quitters, the relapse rate may be as high as 90% [4]. Consequently, behavioral treatments for tobacco dependence have for the past several decades incorporated strategies designed to reduce relapse [5].

The majority of smokers who try to stop smoking do so with little or no assistance [6], but surprisingly little research has been conducted on reducing relapse among self-quitters. Brandon and colleagues [7, 8] have demonstrated that a series of 8 printed “Forever Free” self-help booklets consistently improved point-prevalence abstinence rates among individuals who had recently quit smoking. A recent meta-analysis concluded that self-help interventions were the only empirically-supported relapse-prevention approach for smoking [9]. Given the enormous public health implications of this approach, more research on promoting long-term self-quitting is clearly needed.

Virtually all research to date on promoting self-quitting has been conducted in samples where participants have voluntarily stopped smoking prior to participating in the interventions [7, 8]. However, nothing is known about methods of preventing relapse following involuntary abstinence (e.g., during military training, hospitalization, or incarceration). With respect to the military, there are approximately 1.4 million active duty personnel, with nearly one quarter million young men and women entering service each year. All recruits receive 8.5 to 14 weeks of basic military training (BMT) during which tobacco (and alcohol) use is strictly forbidden at all times, with severe consequences for an infraction (e.g., repetition of BMT). Previous research [10, 11] has observed that involuntary cessation in the military with no other intervention is associated with non-trivial long-term cessation rates (15–20% at a one-year follow-up). However, the majority of smokers did resume tobacco use in the 12 months following the ban, and significant smoking initiation was observed among military personnel who entered the military as non-smokers. Additional work is needed to prevent relapse and smoking initiation following a comprehensive and total smoking ban.

This paper describes the design, intervention development, analysis plan, and baseline characteristics of the first 7495 participants of a randomized controlled trial taking place directly following BMT of the United States Air Force (USAF). The study compares tobacco use outcomes across three intervention arms: 1) a self-help manual designed specifically for Airmen (“Airman’s Guide to Remaining Tobacco Free”) distributed in a group setting (note: Air Force personnel are called Airmen regardless of gender or rank); 2)

the self-help manual combined with single face-to-face motivational counseling session; and, 3) a standard smoking-cessation booklet (“Clearing the Air,” published by the National Cancer Institute [NCI]).

2. Materials and Methods

2.1. Study Design

The initial year of the current project was dedicated to the development of a targeted booklet for Airman, followed by a three-arm group randomized trial. The treatment groups vary in the degree of intervention targeting and tailoring: a standard smoking cessation booklet (Standard condition), the targeted guide (Targeted Guide Condition), and the targeted guide plus a brief tailored intervention delivered face-to-face (Face-to-Face Condition). The primary dependent variables are both point prevalence and continuous abstinence smoking status at one-year follow-up following a forced tobacco use cessation of 8.5 weeks during BMT. Out of logistical necessity, Airmen were randomly assigned at the squadron level, rather than the individual level, on a weekly basis. A block randomization scheme was used to assign the Airmen from 1 out of 4 squadrons to the Standard intervention, 2 out of 4 to the Targeted Guide intervention and 1 out of 4 to the Face-to-Face intervention. The ratio of Targeted Guide to Face-to-Face is 2:1 to facilitate actual delivery of the more labor-intensive latter intervention.

2.2. Intervention Development: *Airman’s Guide to Remaining Tobacco Free*

Although the original intent was to modify the existing *Forever Free* booklets to adapt them for use with military personnel, we soon recognized that young military recruits who were experiencing forced tobacco abstinence would require substantially different messages and format than had been shown efficacious for older civilian smokers who had voluntarily quit smoking [7, 8]. For example, unlike the general population of smokers whose relapse risk tends to diminish monotonically over time, airmen have four distinct “high risk” periods (identified via formative assessment) for tobacco relapse (or initiation): (1) The first the first time they are allowed to use tobacco, approximately two weeks after the initiation of Technical Training; (2) first leave after graduating from Technical Training School; (3) first duty station,; and (4) if and when they deploy outside the continental U.S. [12].

Based on the unique characteristics of military recruits and their patterns of smoking, we developed new targeted intervention material for this population. The guiding principles underlying the intervention were derived from the Theory of Planned Behavior [13] and Relapse Prevention Theory [14]. To develop content, we first evaluated numerous anti-smoking web sites (e.g., American Cancer Society, American Lung Association, <http://www.trinketsandtrash.org/>) to seek input and look for themes that would be appropriate for young Airmen. We also searched interventions and web sites that have had large anti-smoking campaigns (e.g., Florida, California). Finally, we consulted with experts in tobacco cessation and relapse prevention.

From these initial formative discussions, we developed vignette mock-ups that included photographs, graphs, and verbal anti-smoking messages of special relevance to Airmen.

Following approval by the Institutional Review Board, we conducted five focus groups (N = 49) with active duty Airmen in Technical Training School at Lackland Air Force Base. Using a 5-point Likert scale, participants were asked to rate each of the vignettes on how persuasive they were in conveying an anti-smoking message. Comments on each of the vignettes were solicited from the Airmen as well.

The results were tallied and the vignettes were then submitted for comments to tobacco experts before a final set of vignettes and text was selected. When existing photos were unavailable to illustrate vignettes, new photos were taken using actual Airmen who volunteered as models. We obtained permission to reproduce copyrighted or proprietary material whenever possible. When it was unclear whether certain photos or anti-smoking ads were copyrighted or not (which is often the case with widely distributed materials), we created new material with a similar message but different images.

The resultant booklet, targeted to Airmen and their unique relapse risks, was arranged in a flip-book style, similar to the “Airman’s Manual,” a flip-book containing a wide range of survival and other useful information that Airmen are required to carry with them at all times. After the final version was complete, the booklet was submitted to Wilford Hall Ambulatory Surgical Center Public Affairs, Air Education and Training Command, and medical law consultants (to ensure compliance with copyright and reproduction laws) for review. Minor changes were suggested and incorporated.

Finally, we received permission from the Air Force Branding Office (Air Force Personnel Center) to use the Air Force “wings” logo on the finalized booklet with the intent of enhancing perceived credibility of the intervention. To our knowledge, this booklet is the only civilian-generated material that has ever been allowed to use the Air Force logo.

The development, testing, and approval process took approximately 13 months. Overall, 11 versions of the booklet were generated, reviewed, and edited. The final version is 5×7 inches, 46 pages, with text and color illustration. The text covers the advantages (i.e., health, financial) of remaining tobacco-free after basic training, and the opportunity that the tobacco ban provides to begin a lifetime without tobacco. Additional information is included about challenges and coping suggestions for the four times that Airmen are at particular risk of smoking. The text is supplemented by 22 provocative color images (primarily photographs) created specifically for Airmen and designed to reinforce the messages that smoking: 1) is responsible for more fatalities than combat; 2) conveys a negative image to civilians; and 3) impedes military readiness and promotion through the ranks. A copy of this manual can be found on at <http://www.uthsc.edu/airmansguide>.

2.3 Participants

Participants in this study are Airmen who recently completed 8.5 weeks of BMT with involuntary tobacco abstinence. At the time of enrollment, participants were in their first week of Technical Training School, which follows BMT, at either of two locations in San Antonio, Texas: Lackland Air Force Base or Fort Sam Houston, both in San Antonio, TX. They are still required to be alcohol and tobacco free for the first two weeks of Technical Training. Given that large numbers of Airmen initiate, as well as relapse to, tobacco use

after joining the Air Force [10, 11], the current investigation was directed toward all Airmen, rather than only those who were using tobacco prior to basic training. Because we are interested in intervention effects upon both initiation and relapse to both smoking and smokeless tobacco, the sample size has been set at 23,000 participants.

2.4. Assessments

2.4.1. Baseline Questionnaire—The Tobacco Use Questionnaire collects information on demographics, tobacco use, exposure history, and tobacco dependence. Demographics collected include height and weight, gender, ethnicity, age, occupation, income, marital status, and education level. Assessment of tobacco use and exposure includes questions relating to use of cigarettes, smokeless tobacco, cigars, and waterpipes (Hookah). Family members who smoke, age at onset of smoking, number of previous quit attempts, and cigarettes per day prior to entering BMT are also collected because of their possible influence on the primary outcomes. Tobacco dependence is assessed retrospectively (tobacco use prior to Basic Military Training), using a modified version of the Fagerström Test for Nicotine Dependence (FTND; [15]) because Airmen are abstinent from tobacco at the time of completion of the baseline survey. Questions were modified to assess all tobacco use.

2.4.2. Follow-up—One and two year follow-ups for participants are collected via an online questionnaire located on the University of Tennessee Health Science Center (UTHSC) webserver. A message is sent to the Airmen via their military email account reminding them that it is time to complete the follow-up questionnaire. The email provides completion instructions including a unique username and password with a link to the questionnaire login portal. If three attempts to contact an Airman are unsuccessful, the research staff attempts to call the participant and complete the follow-up questionnaire via telephone.

Follow-up information collected includes smoking status, if they relapsed, when they relapsed (e.g., Tech Training, while deployed) and environmental factors that may predict smoking status. Environmental factors include deployment status, deployment location (i.e., peaceful or combat zone, and, if in a combat zone, the relative degree of personal vulnerability [on base or “outside the wire”]). We also track Technical Training assignment, length of the absolute smoking abstinence that their training site employs, and program adherence.

Our primary outcomes are self-reported continuous and seven-day point prevalence tobacco abstinence at 12- and 24-month follow-up [16]. Continuous abstinence is defined as no tobacco use from the start of BMT to the 12-month follow-up (with the exception of a traditional celebratory cigar before deployment). Point prevalence abstinence requires complete tobacco abstinence for the seven days prior to each follow-up point. Biochemical verification is not possible because Airmen are stationed around the world.

2.5. Intervention Conditions

We are comparing three intervention arms varying in the degree of tailoring to the specific needs and conditions of Airmen who recently completed 8.5 weeks of BMT that included involuntary abstinence from tobacco use. Airmen are housed in squadrons within the various Technical Training Schools, and we chose randomization by squadron to decrease the risk of treatment contamination and to facilitate delivery of the interventions that all contain an interactive presentation of some written material in a group setting. The squadron is the “natural” group structure during Technical Training, and typically include 40–50 Airmen, although the 190 squadrons included to date ranged in size from 1 to 95 Airmen, reflecting the needs for the various Technical Training programs. The written materials in each condition were distributed to those who consented to the intervention.

2.5.1. Standard Condition—Squadrons randomized to this condition receive the *Clearing the Air* booklet [17]. This booklet is a 36-page, comprehensive guide for quitting smoking with 7 pages dedicated to relapse-prevention. This condition represents a credible, didactic written intervention not tailored to a military population. As such, it served as a standard comparison for evaluating the incremental benefits of a more targeted written intervention and a tailored face-to-face intervention, as represented by the two other study arms. This booklet has been used as a credible comparison condition in the past [18].

2.5.2. Targeted Guide Condition—Airmen in this condition receive the *Airman’s Guide to Remaining Tobacco Free*, the development of which was described above. This condition represents the primary intervention under study in that it specifically targets Airmen who have just completed an involuntary smoking ban during BMT. It uses provocative imagery and text designed to appeal to the age, education, and personal characteristics of this population of interest, while conveying key themes adapted from relapse prevention therapy [19]

2.5.3. Face-to-Face Condition—Airmen in this condition receive the *Airman’s Guide to Remaining Tobacco Free* as well as a 15–20 minute motivational intervention delivered during face-to-face meetings that usually occur the day after recruitment and baseline assessment. This condition was included because it was unknown whether the *Airman’s Guide* alone would be sufficiently salient and potent to prevent tobacco use relapse or initiation, given the high risk situations that Airmen encounter. The meeting between the Airman and an Interventionist takes place at a central location on the base. The brief intervention is based on the tenets of Motivational Interviewing (MI; [20]), and it includes MI strategies such as decisional balancing, normalizing, and the readiness to change ruler. Additionally, it includes techniques from Relapse Prevention Therapy [19], including the identification of high-risk situations (specifically the four time-points, described above, associated with smoking among graduates of BMT) and possible cognitive and behavioral coping strategies. The Interventionist utilizes the *Airman’s Guide* booklet to illustrate and reinforce the discussion points, and the entire intervention is heavily adapted for Airmen, including the relevance of smoking in the USAF with respect to relative health risk (e.g., that Airmen are more likely to die from smoking than from combat), troop readiness (i.e., that the physical effects of smoking impair military readiness), and career advancement

(e.g., that prevalence of smoking is inversely related to military rank). It is also tailored to each Airman with respect to their history of tobacco use (i.e., cigarette smoker, smokeless tobacco user, or tobacco non-user), intentions regarding future use (i.e., planning to abstain, planning to initiate or resume use, or ambivalent), as indicated on the baseline questionnaire, and their own concerns and perceived barriers to tobacco abstinence.

The Interventionists are paraprofessional Research Specialist staff. Most of the staff are retired Airmen, so they are familiar with the environment and challenges of Technical Training. The Interventionists received an initial 3-hour training on the specific face-to-face intervention, including its coordinated use with the *Airmen's Guide*. Basic MI techniques were taught during a two-day workshop, including a general scripted outline designed to evoke verbal behavior from the Airmen that would be consistent with remaining tobacco free. In addition to the 3-hour initial training, staff participated in weekly group supervision and practice sessions. Finally, interventionists periodically observe, and are observed by, a staff member who is a member of the Motivational Interviewing Network of Trainers, during face-to-face interviews with Airmen.

2.6. Procedure

2.6.1. Recruitment and Randomization—Due to the unique nature of this study requiring that randomization to intervention condition occur at the group (squadron) level rather than individual (Airman) level, the randomization of the squadrons must occur prior to the consenting and baseline data collection meeting in which Airmen receive their intervention materials. At the beginning of each week, following communication with the Military Training Leaders to determine logistics of meeting with each of the squadrons, the research staff performs the randomization procedure utilizing an automated macro built into the data management system. The group assignment is accomplished via computerized block design that allows study staff enrolling participants to remain blinded to group assignment until the randomization process is complete. Squadrons are randomized to one of the three aforementioned intervention conditions via this blinded process performed using FileMaker Pro v12.03 (FileMaker Inc., Santa Clara, CA, 95054). Specifically, blocking is applied to assure an assignment of one squadron to the standard condition, one squadron to the face-to-face condition, and two squadrons to the targeted guide condition, each week throughout the duration of the study. This blocking process allows that one of the 12 possible ways to consecutively assign four squadrons to these three conditions is randomly selected and determines the assignment of the of four squadrons to an intervention condition. Each new briefing cycle week initiates a new random determination of a block. Study staff remains blinded toward which random block has been selected and consequently cannot predict upcoming squadron assignments.

Once the computerized random assignment is completed, study staff carries out the appropriate intervention condition with the participants in each of the squadrons during orientation week. At the meetings with squadrons, Airmen are introduced to the study, read the informed consent document, and encouraged to ask questions regarding participation. Those Airmen who choose to participate complete the informed consent and begin completing the baseline Tobacco Use Questionnaire. After completing the questionnaire,

Airmen in squadrons randomized to the Standard or Guide conditions are provided with the appropriate intervention materials along with a brief (3 minute) explanation of the booklet contents. Those in the Face-to-Face condition receive another copy of the Airman's Guide during their one-on-one meeting, which is usually scheduled for the following day.

2.7. Data Collection and Processing

Baseline data are collected on scannable paper forms specially designed to facilitate automated data entry. Once complete, each form is scanned at the study site, encrypted, and transmitted to the UTHSC server in Memphis, TN, for processing. Processed data are automatically entered into the study database, where it is available to the San Antonio-based study staff for quality assurance checks.

For the follow-up assessment, research staff at UTHSC generate a roster each quarter of those participants due for follow-up and upload it to a secured UTHSC server where Defense Manpower Data Center (DMDC) personnel access it and return to the server a new encrypted dataset that includes the contact information and current duty assignment of the Airmen. Research staff at UTHSC then merge these new data to the study database, where the study staff at Lackland AFB may retrieve the information in order to send an email to each participant at their 12-month post-enrollment date. Follow-up data are stored in the same secure database as the baseline data located at UTHSC.

2.8 Statistical Analysis

The primary outcome measures in this study are point prevalence and continuous abstinence of tobacco use. These are dichotomous outcomes and we will use logistic regression as our main analytical approach, adjusting for known covariates (gender, age, etc.), as well as controlling for the grouping structure created by randomizing all Airmen in a single squadron to the same intervention by utilizing indicator variables for individual squadrons (capturing how strongly Airmen of the same squadron resemble each other).

That is, we will test the relative success of the interventions at 12 month using pairwise comparisons of Standard to Guide, Guide to In-Person, and Standard to In-Person interventions, with Bonferroni-corrected cut-off values to maintain the type I error rate for the family of three comparisons at 5%. The secondary outcome concerns the context in which Airmen initiate tobacco usage or relapse post BMT (during Technical Training, their first deployment, etc.), and we intend to analyze this aspect utilizing multinomial logistic regression that allows for a discrete outcome with more than two categories.

We are concerned with attrition at follow-up and would like to emphasize that avoiding missing data as much as possible is the best line of defense [21]. Regardless, we do expect some attrition and find it conceivable that the propensity to collect data successfully might be confounded with factors possibly leading to a change in tobacco usage (e.g., deployment of an Airman during time of follow-up might affect data collection as well as the tobacco usage of the Airman). We plan to use the well-established methods of inverse probability weighing as well as imputation-based approaches including multiple imputations [22] to address inference under this assumption.

The sample size is sufficient to allow for testing of moderator variables, followed by subgroup analyses. For example, because the intervention was designed to prevent smoking relapse per se, we will test whether smoking status upon enrollment moderates any treatment effects. Given that about 72% of Airmen were none-cigarette smokers at the beginning of BMT we will have a detectable effect size of approximately 4.5 percentage point differences with respect to 12 month smoking rates between the three intervention groups (based on Bonferroni-corrected type I error rate of 5%, 80% power, 20% attrition).

3. Baseline Results

3.1. Accrual and Retention

Through January 23, 2013, we have enrolled 7,495 of 9,998 approached Airmen (75%). See Figure 1 for study flow. The sample is slightly less than 7500 because the 7500th enrollee was in the middle of a squadron and randomization is by squadron. Thus, the slightly smaller number represents intact squadrons.

3.2. Description of Sample

Table 1 lists the demographic characteristics collected at baseline from the first 7495 Airmen enrolled into the study. As expected for this population, the sample was predominately young, male, and single. The largest ethnic minority group was African American (15%), and 15% of the sample identified as Hispanic. The majority of the sample had no formal education after high school, although over one-third had some college. The p-values in Table 1 are intended to provide an index of how well our randomization process worked despite the utilized squadron randomization. The values are based on ANOVA and chi-square tests and would be accurate if individual randomization of Airmen would have been conducted. Therefore, a large p-value indicates that the balancing of covariates has worked just as well as would be expected under individual randomization, whereas small p-values indicate that balancing of covariates was not optimal. This was especially the case for gender and education, but we expected this because squadrons attract certain education-levels and genders selectively due to different requirements for the associated training. Consequently, the limited number of exercised randomizations (190 squadrons) did not lead to the same balancing of these covariates that would have been expected through individual randomization of Airmen. All models during data analysis will be adjusted for these covariates and will account for the grouping structure due to randomization on the squadron-level.

With respect to tobacco use, Table 2 shows the sample's history of cigarette, smokeless tobacco, cigar, and hookah use prior to the involuntary tobacco abstinence required during BMT. Cigarettes were used at least monthly by 16%, whereas approximately 10% each reported using smokeless tobacco, cigars, and hookah at least monthly. Together 29% of the sample reported using some tobacco product at least monthly. (Note that this is less than the sum of the categories in Table 2 as there is considerable dual/multiple use in this cohort.) Whereas 79% of Airmen intend to remain tobacco-free after Technical Training, 15% reported "thinking about" resuming tobacco, and only 6% "definitely" planned to return to tobacco use. Note that there are significant differences in the relative distribution of these

intentions among the three intervention arms compared to what would be expected under individual randomization of Airmen. We find it quite possible that these intentions are, to some degree, gender and education-dependent (at least indirectly through confounding) and, therefore, see the possibility that this observed “imbalance” between the groups is a consequence of the observed “imbalance” of education and gender as noted for Table 1. Again, all models during data analysis will be adjusted for these covariates and will account for the grouping structure due to randomization on the squadron-level.

4. Discussion

This paper describes the design, intervention development, baseline participant demographics, and study flow to date of the ongoing “Preventing Relapse Following Involuntary Smoking Abstinence” trial that compares three minimally intensive interventions for preventing smoking following an 8-week involuntary ban for recruits in the United States Air Force.

The primary innovation of this study is the focus on preventing smoking relapse following a period of involuntary tobacco abstinence. Although this study addresses involuntary abstinence associated with military training, other examples include incarceration, inpatient medical and psychiatric care, and in less comprehensive manners, certain employment and residential settings. In some sense, even certain life events that extrinsically motivate many to suspend their smoking—such as pregnancy—can be conceptualized as close to the involuntary pole of smoking cessation volition. Yet BMT is unique in the scope of its smoking ban with respect to both the comprehensiveness of the ban (i.e., no forms of tobacco are allowed at any time under any circumstances during BMT) and the size of the affected population (approximately 250,000 recruits across the Department of Defense annually). Regardless of the setting, instances of induced tobacco abstinence can potentially serve as opportunities to encourage long-term tobacco abstinence. An intervention focused on relapse prevention does not need to confront all of the challenges facing a conventional smoking cessation intervention, such as achieving the initial day of abstinence, coping with nicotine withdrawal symptoms, and short-term maintenance of abstinence. Instead, it must motivate the former smoker to seek long-term abstinence, and prepare him or her for the high-risk situations that threaten such a goal.

The smoking ban during BMT is also unique because the population it affects (military recruits) may be over-represented by individuals who, as a whole, are at high risk of initiating and maintaining smoking, based on characteristics such as male gender, low socio-economic status, and perhaps personality traits such as sensation-seeking and risk-taking [11, 23]. Moreover, following their military training, these individuals are usually thrust into situations characterized by both long stretches of boredom and periods of intense stress. In summary, it would be difficult to conceive of the combination of individuals and environment that would be more prone to smoking relapse after the termination of a tobacco ban. As such, the post-BMT period represents an extreme test for any relapse-prevention intervention, let alone a minimal, self-help intervention.

A recent study of relapse prevention following involuntary abstinence (during incarceration) found that 6 weeks of face-to-face counseling using MI and cognitive-behavioral therapy led to substantially less relapse than a control condition 3 weeks after release [24]. These results suggest that involuntary abstinence may indeed be leveraged into longer voluntary abstinence via motivational techniques. However, such a time-intensive intervention would not be possible during BMT or Technical Training where virtually all training and education is at the squadron (group) level. The present study is testing a much more minimal intervention over a much longer follow-up period.

The study itself has several strengths. Most obvious is the extremely large sample size (target $N = 23,000$), which should yield small confidence intervals around the outcome results, and the statistical power to test a range of mediating and moderating variables. The study is also a unique example of Community-Based Participatory Research (CBPR; [25]) in that it is the product of a long-standing and active collaboration between the USAF and academic researchers. Through this collaboration, we were able to overcome multiple challenges associated with providing an intervention and conducting a study during Technical Training. These challenges included limited available time within the full Technical Training schedule, working within military regulations, recruiting and consenting very large numbers of participants, and the dispersion of participants throughout the world during the follow-up period. For example, our research offices are located in the Headquarters Building at Lackland AFB, which communicates our perceived value to the USAF. Despite these challenges, results to date indicate that recruitment and intervention provision has been highly successful.

Despite these strengths, several limitations must be acknowledged. First, the interventions vary along multiple dimensions. They differ in terms of the amount of didactic information provided, the inclusion of motivational components, and their duration and intensity, especially when comparing the written materials with the face-to-face counseling components. Because of these differences, it will be difficult to identify exactly which components are responsible for any outcome differences that we find across conditions. At this point in the intervention development plan, our goal was simply to identify any efficacious intervention for this challenging population. Should any of the treatment arms prove to be efficacious, future research can disassemble and parse the intervention to identify the potent components with the goal of further increasing its efficacy.

Another limitation is that we did not include a true no-treatment or usual care control condition. Instead, the comparison condition received an NCI booklet that was not written for the military and that minimally addressed tobacco relapse. However, the booklet appears to be a credible, high quality intervention. Our intention was to pit our novel interventions against a credible but non-targeted comparison condition. However, without a no-treatment control, we will be unable to evaluate the efficacy of the NCI booklet itself, especially if it performs comparably to the two novel interventions.

For logistical reasons, as well as to minimize participant burden and possible reactance effects, we have limited the follow-up contacts to 12 and 24 months. Thus, follow-up is less frequent, but of longer duration, than many clinical trials for smoking cessation. We believe

that this trade-off is appropriate for a minimal intervention delivered in a real-world setting. For similar reasons, we are not collecting biosamples (e.g., expired carbon monoxide or serum cotinine) to verify self-reported abstinence during follow-up. Doing so would present substantial logistical barriers, given the wide dispersal of Airmen. Moreover, evidence suggests that for low-intensity interventions without strong incentives to falsely report abstinence, there is little benefit derived from inclusion of biochemical verification measures [26, 27]. Outcome differences between study arms tend to be similar with or without biochemical verification.

Finally, our study involves only one of the four branches of the U.S. military, although the USAF is the second largest military branch (behind the Army). There are some differences between branches in terms of the demographic characteristics of recruits, the duration and content of BMT and subsequent technical training, and the nature of military deployment after training. These differences could conceivably affect the generalization of our findings to the other three military branches. However, these differences pale in comparison to the commonalities across military branches, and the difference between military and civilian smokers and their environments. Thus, we deemed generalizability to be only a minor concern.

In summary, the ongoing study is a large-scale effort to identify a cost-effective and easy-to-disseminate, minimal intervention developed specifically for military personnel after they complete BMT with an involuntary ban on tobacco use. To date we have recruited a large, diverse sample with outstanding rates of compliance. The study has the potential to leverage the BMT smoking ban to improve the health outcomes of a substantial population far beyond the length of their military training or careers.

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Figure 1.
Flow chart for enrollment and intervention assignment.

Table 1

Demographic Statistics for the Full Sample (to date), and by Study Arm.

	Full Sample (n=7495)	Study Arm			p-value*
		Standard (n=2189)	Targeted Guide (n=3611)	Face-to- Face (n=1695)	
Age (yrs.; M, SD)	20.50, 2.65	20.39, 2.62	20.52, 2.65	20.62, 2.69	0.0226
Gender (% Female)	25.11	24.53	23.76	28.73	0.0004
Marital Status (%)					
Single	88.93	88.85	88.87	89.14	0.4106
Separated/Divorced	0.91	0.59	1.02	1.06	
Married/Living as Married	10.11	10.51	10.05	9.73	
Ethnicity (%)					
Hispanic	14.64	14.25	14.93	14.51	0.7745
Not Hispanic	84.75	85.20	84.52	84.66	
Missing	0.61	0.55	0.55	0.83	
Race (%)					
Native American	0.89	0.91	0.94	0.77	0.2614
Asian	2.63	0.72	1.07	0.84	
Hawaiian/Pacific Islander	1.48	1.46	1.47	1.53	
African American	14.94	15.08	14.40	15.93	
Caucasian	68.23	68.66	68.71	66.67	
More than one race	7.08	6.67	7.45	6.84	
Other	4.44	4.52	4.40	4.42	
Missing	0.29	0.23	0.42	0.12	
Education (%)					
High School Graduate/GED	52.81	55.14	52.84	49.73	0.0145
Post HS Vocational Training	1.56	1.42	1.55	1.77	
Some college/AA	38.25	37.09	37.97	40.35	
Bachelor's degree	6.34	5.12	6.87	6.78	
Some post graduate	0.55	0.59	0.42	0.77	

	Full Sample (n=7495)	Study Arm			p-value *
		Standard (n=2189)	Targeted Guide (n=3611)	Face-to-Face (n=1695)	
Postgraduate degree	0.31	0.37	0.19	0.47	
Missing	0.19	0.27	0.17	0.12	

* “Naïve” p-value ignoring the group-randomization scheme provided as a benchmark for how balanced our groups are compared to expected balancing if individual randomization would have been applied (in which case the shown p-values based on ANOVA and chi-square tests would be accurate – computations ignore missing values).

Table 2

Tobacco Use Prior to Basic Military Training, for the Full Sample (to date), and by Study Arm (Percentages except where noted).

	Full Sample (n=7495)	Study Arm			p-value*
		Standard (n=2189)	Targeted Guide (n=3611)	Face-to- Face (n=1695)	
Cigarettes					
Non-User	72.10	72.22	71.64	72.92	0.4074
Daily User	8.39	7.86	8.61	8.61	
Weekly User	4.06	4.80	3.90	3.42	
Monthly User	3.43	3.47	3.30	3.66	
< Monthly User	5.66	5.44	5.70	5.84	
Former User	6.20	6.03	6.70	5.37	
Missing	0.16	0.18	0.14	0.18	
Age of Cigarette Initiation (M, SD)	17.03, 2.21	16.86, 2.14	17.12, 2.27	17.07, 2.16	0.0632
Smokeless Tobacco (SLT)					
Non-User	83.48	82.96	82.72	85.78	0.2107
Daily User	5.99	6.53	6.04	5.19	
Weekly User	1.96	2.15	2.08	1.47	
Monthly User	2.09	2.38	2.16	1.59	
< Monthly User	3.92	3.56	4.24	3.72	
Former User	2.37	2.15	2.60	2.18	
Missing	0.17	0.27	0.17	0.06	
Age of SLT Initiation (M, SD)	16.99, 2.41	16.76, 2.27	17.10, 2.47	17.06, 2.46	0.0966
Cigars					
Non-User	73.44	75.24	72.69	72.68	0.0300
Daily User	0.73	1.05	0.55	0.71	
Weekly User	3.26	3.52	3.38	2.65	
Monthly User	5.82	5.30	6.20	5.66	
< Monthly User	15.05	13.16	15.65	16.22	
Former User	1.67	1.69	1.50	2.01	

	Full Sample (n=7495)	Study Arm			p-value*
		Standard (n=2189)	Targeted Guide (n=3611)	Face-to- Face (n=1695)	
Missing	0.04	0.05	0.03	0.06	
Hookah					
Non-User	72.47	75.00	71.70	71.40	0.0595
Daily User	0.77	0.51	1.04	0.43	
Weekly User	3.16	2.70	3.56	2.72	
Monthly User	5.99	5.47	5.91	6.81	
< Monthly User	15.68	14.65	15.58	17.11	
Former User	1.86	1.60	2.14	1.45	
Missing	0.07	0.07	0.07	0.09	
Intentions to Use Tobacco after Technical Training					
Plan to remain tobacco free	78.84	79.03	77.26	81.95	0.0029
Thinking about using	15.24	14.94	16.62	12.68	
Will definitely use	5.86	5.85	6.09	5.37	
Missing	0.07	0.18	0.03	0.00	

* “Naïve” p-value ignoring the group-randomization scheme provided as a benchmark for how balanced our groups are compared to expected balancing if individual randomization would have been applied (in which case the shown p-values based on ANOVA and chi-square tests would be accurate – computations ignore missing values).