

HHS Public Access

Author manuscript

Womens Health Issues. Author manuscript; available in PMC 2021 July 09.

Published in final edited form as:

Womens Health Issues. 2019 June 25; 29(Suppl 1): S15–S23. doi:10.1016/j.whi.2019.04.001.

Smoking Cessation among Female and Male Veterans before and after a Randomized Trial of Proactive Outreach

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Abstract

Introduction: Female veterans smoke cigarettes at high rates compared with both male veterans and nonveteran women. Proactive outreach (PRO) to smokers may reduce gender disparities in cessation care. The objectives of this study were to compare baseline experiences with VA smoking cessation care for men and women and to assess for gender differences in response to a PRO intervention.

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Methods: We conducted a post hoc subgroup analysis of a pragmatic, multisite randomized, controlled trial comparing PRO with usual care (UC). Baseline experiences included physician advice to quit, satisfaction with care, and past-year treatment use. At the 1-year follow-up, treatment use, quit attempts, and 6-month prolonged abstinence for women and men randomized to PRO versus UC were compared using logistic regression.

Results: Baseline and follow-up surveys were returned by 138 women and 2,516 men. At baseline, women were less likely than men to report being very or somewhat satisfied with the process of obtaining smoking cessation medications in the VA (47% of women vs. 62% of men), but no less likely to report having used cessation medications from the VA in the past year (39% of women vs. 34% of men). After the intervention, phone counseling and combined therapy increased among both women and men in PRO as compared with UC. At the 1-year follow-up, men in PRO were significantly more likely to report prolonged abstinence than those in UC (odds ratio, 1.65; 95% CI, 1.28–2.14); results for women were in the same direction but not statistically significant (odds ratio, 1.39; 95% CI, 0.48–3.99).

Conclusions: Satisfaction with cessation care in VA remains low. PRO to smokers was associated with an increased use of cessation therapies, and increased odds of achieving prolonged abstinence. A subgroup analysis by gender did not reveal significant differences in the treatment effect.

Female smokers experience unique health consequences of tobacco use, including increased cardiovascular disease risk relative to male smokers (Huxley & Woodward, 2011), as well as pregnancy complications, lower bone density, and elevated cervical cancer risk (U.S. Department of Health and Human Services, 2001). Although women have historically smoked cigarettes less than men, the gap has narrowed in recent years due to a slower rate of decline in smoking prevalence for women than men (Jamal et al., 2016). In 2015, 13.6% of adult U.S. women smoked, compared with 16.7% of adult men (Jamal et al., 2016).

Women veterans are a unique population of women for whom the prevalence of smoking has remained persistently elevated over recent years, despite decreasing for nonveteran women and veteran and nonveteran men (Brown, 2010). A higher proportion of women veterans smoke than nonveteran women (Weinberger, Esan, Hunt, & Hoff, 2016), and among women veterans who use the Veterans Health Administration (VA), current smoking rates exceed those of male veterans (23% - 29% of women smoked vs. 19% - 23% men; Duffy et al., 2012; Farmer, Rose, Riopelle, Lanto, & Yano, 2011). These differences are likely due, in part, to the younger mean age of women veterans as compared with male veterans (Barnett, Hamlett-Berry, Sung, & Max, 2015). The youngest cohort of women veterans (born 1985– 1989) in a recent national survey reported an alarmingly high smoking rate (44% of women smoked vs. 40% of men) that portends a growing problem (Brown, 2010). In addition to age, significant correlates of smoking that are highly prevalent among women veterans include the presence of mental health problems (Davis, Bush, Kivlahan, Dobie, & Bradley, 2003), including post-traumatic stress disorder (Dobie et al., 2004) and a history of sexual assault (Frayne, Skinner, Sullivan, & Freund, 2003; Surís & Lind, 2008). Although women veterans make up only 7% of current VA users, they are the fastest growing population of patients accessing VA care (Frayne et al., 2014), and smoking-related health care costs for women veterans totaled \$132 million in 2010 (Barnett et al., 2015). Consequently, decreasing the

prevalence of smoking among women veterans should be a priority for VA policymakers and clinicians.

Both biological (sex) and sociocultural (gender) factors contribute to smoking's slow decline among women, and women veterans in particular. According to the National Institute of Health's socioecological model for understanding tobacco-related health disparities, tobacco use is interrelated with life circumstances at social, educational, health, and economic levels (National Cancer Institute, 2017). For example, women who have experienced intimate partner violence have a higher smoking prevalence, and this relationship is influenced by pregnancy, ethnicity, and socioeconomic status. Women smoke fewer cigarettes per day than men on average, yet experience a high degree of nicotine dependence (Smith et al., 2015), which may be partially explained by higher menthol cigarette use (National Cancer Institute, 2017).

Most health care-based smoking cessation interventions, including those used in the VA, do not account for the complex sex and gender differences in smoking. Traditional clinical interventions rely on a reactive model: patients present to clinic and the clinician provides a brief "5As" intervention: ask about smoking, advise the patient to quit, assess readiness to quit, assist with quitting, and arrange follow-up care (Fiore, 2008). An analysis of organizational features in the VA could not identify any VA facility characteristics or variations that influenced sex or gender disparities in receipt of the 5As (Farmer et al., 2011). Recent advances in gender-sensitive primary care provision for women veterans have improved but not eliminated sex and gender differences in experiences of care in the VA. Some women, particularly those with a history of military sexual trauma, still report an unwelcoming environment for women at VA facilities (Kehle-Forbes et al., 2017). A proactive outreach (PRO) approach to smoking cessation may overcome sex and gender barriers to in-person and group care by contacting all smokers by telephone and offering assistance with quitting, either through in-person or telephone counseling and/or with cessation medications.

In 2005, we published an analysis of baseline data from a multisite, randomized, quality improvement project (conducted in 2000) to implement national VA tobacco cessation guidelines, in which we found comparable rates of receipt of advice to quit among female (64%) and male (66%) veteran smokers (Sherman, Fu, Joseph, Lanto, & Yano, 2005). However, we found significantly lower rates of smoking cessation medication prescriptions for women (16%) as compared with men (27%; age-adjusted odds ratio [OR], 0.6; 95% CI, 0.4–0.9). At the 1-year follow-up, only 2.7% of women had successfully quit smoking, as compared with 9.5% of men (age-adjusted OR, 0.3; 95% CI, 0.07–1.20; Sherman et al., 2005).

Since our prior study, the VA has taken steps to comprehensively address smoking cessation among veterans, including sponsoring a conference of national experts in 2004 to identify best practices for smoking cessation policy development in VA. In 2003, 2008, and 2014, the VA revised national policy directives to expand access to smoking cessation medications and counseling, and to designate a lead smoking cessation clinician at each VA facility (Institute of Medicine, 2009). Although these efforts have not been specifically tailored to women

veterans, we hypothesize that this population-based approach has improved smoking cessation care for both women and men.

The objective of the current study was to determine whether sex and gender (hereafter, gender) differences in smoking cessation care at VA that we observed in 2000 persisted in 2009 and 2010, and to test whether a PRO intervention affected female and male smokers differently. Specifically, we used baseline data from a multisite, randomized trial of proactive tobacco cessation outreach (conducted in 2009 and 2010) to describe female and male smokers' experiences with smoking cessation recommendations (physician advice to quit) and treatment (use of cessation medications and counseling, and satisfaction with treatment) in the year before study enrollment. We hypothesized that, unlike in our previous study using data from 2000, smoking cessation recommendations and treatment within the VA would no longer vary by gender. We then assessed for a differential response to PRO by gender. This aim was exploratory, to inform future research.

Methods

Study Design and Participants

Study participants were drawn from a multisite, prospective, randomized, controlled trial studying the effect of a PRO intervention versus usual care (UC) on smoking abstinence rates and use of cessation treatments. A sample of 6,400 current smokers (age 18–80 years) was identified via the VA electronic medical record at four VA medical centers (New York City, Jackson, Tampa, and Minneapolis). Sampling was stratified by site to include 1,600 participants per site, randomized 1:1 into the two study arms (randomized complete block [site] with subsampling study design). A baseline survey was sent to 6,400 potential participants, of whom 5,123 participants were included in the final study population and were also sent a follow-up survey 1 year later. Participants were recruited from October 2009 to September 2010; the study was completed in November 2011. For the current article, we performed a complete case analysis including the 2,654 (138 female and 2,516 male) veterans who returned both baseline and follow-up surveys. This study received ethical approval from the institutional review boards of all participating sites. More details on this study design and methods are available elsewhere (Fu et al., 2012).

Treatment

The PRO intervention combined counselor-initiated contact (mailed materials followed by telephone outreach) with an offer of telephone smoking cessation counseling or referral to in-person counseling. Telephone care included proactive calls from counselors at the Minneapolis VA who were trained in motivational interviewing. Counselors also facilitated access to smoking cessation pharmacotherapy through the participant's VA primary care provider. The UC group did not receive PRO, but did have access to smoking cessation services through their local VA and state (or insurance-based) telephone quitline.

Measures

Pre-intervention—The first objective of this analysis was to describe female and male veteran smokers' experiences with smoking cessation recommendations and treatment in the

year before enrollment (2009–2010) in this pragmatic trial. We focused on three experience domains related to successful smoking cessation that are susceptible to changes at the health care system level: VA physician advice, use of cessation treatments inside or outside the VA, and satisfaction with VA cessation care.

VA physician advice.: Physician advice to quit is a core component of the 5A's brief smoking cessation treatment model (i.e., ask, advise, assess, assist, arrange; Abrams et al., 2003), which has been included in VA guidance to providers. VA physician advice questions, adapted from standardized HEDIS measures (Davis, 1997), asked participants about advise/assist care received during at least one visit in the previous 12 months: "Did your VA doctor or health care provider say you should try to quit smoking? Did your VA doctor or health care provider talk about ways (other than medication) to help you with quitting smoking? Was medication talked about to help you quit smoking (for example: nicotine gum, patch, nasal spray, inhaler, prescription medication)?"

<u>Use of cessation treatments.</u>: Smokers were asked if they had used behavioral counseling (in person or telephone) or smoking cessation medications to try to quit smoking in the previous 12 months, either inside or outside the VA. Survey questions about prior treatment were adapted from the California Tobacco Surveys (California Department of Public Health) and the Centers for Disease Control and Prevention (2017) Behavioral Risk Factor Surveillance Survey.

Satisfaction with VA care.: Patient satisfaction with care is a multidimensional concept, influenced by patient, provider, and health care system characteristics, as well as patient expectations and preferences (Ware, Snyder, Wright, & Davies, 1983). Satisfaction with VA cessation care questions were designed to assess overall satisfaction with care, as well as practical concerns specific to obtaining smoking cessation care: "How satisfied were you with help received from your VA doctor or health care provider about quitting smoking? How satisfied were you with the process of obtaining medications from the VA to help you quit smoking?" The proportion of smokers who reported being very or somewhat satisfied was reported; patients who responded, "I never received help," were not included in the denominator.

Baseline Demographic and Smoking Characteristics

Additional measures described patient personal and smoking characteristics. Standardized sociodemographic questions were asked at baseline and covered race, ethnicity, marital status, education level, employment status, and income (Fu et al., 2012). We assessed nicotine dependence with the two-item Heaviness of Smoking Index (Heatherton, Kozlowski, Frecker, Rickert, & Robinson, 1989) and asked participants whether they had made at least one quit attempt (lasting at least 24 hours) in the previous year. Cognitive factors included self-efficacy to quit (Baldwin et al., 2006; Dijkstra & Vries, 2000), readiness to quit (Abrams et al., 2003; Biener & Abrams, 1991), and attitudes toward nicotine replacement therapy (Etter & Perneger, 2001). Environmental factors included whether smoking was allowed at home, whether the participant lived with other smokers, and/or perceived external pressure to quit from "people close to me." We obtained

information on age, gender, and comorbid mental health conditions (using *International Classification of Diseases* 9the edition, codes) from VA administrative data sources.

Postintervention

Six-month prolonged abstinence.: The primary postintervention outcome for this analysis was self-reported 6-month prolonged abstinence at the 1-year follow-up, and was assessed among all randomized, included participants, regardless of treatment use during the study. Quit attempts were self-reported intentional cessation for more than 24 hours. Use of smoking cessation therapies was self-reported use of any cessation medications, telephone counseling, or a combination of medication and counseling, including therapies from within the VA or from outside sources.

Analysis—Because the study design involved stratified sampling across four study sites, our estimations, testing, and modeling procedures are stratified analyses. A complete case analysis included only available survey responses. Baseline characteristics for women and men were compared using the Wald χ^2 test for categorical variables and the Wald F test for continuous variables. Because randomization was not stratified by gender, we tested for differences in baseline characteristics between treatment arms within each gender, to include imbalanced covariates in later models. Logistic regression analyses, taking into account the sampling design and imbalanced covariates (i.e., age), were conducted to test the effect of gender on baseline experiences with smoking cessation recommendations and treatment. We then used logistic regression modeling to test for an interaction of Gender \times Treatment (PRO vs. UC) with respect to prolonged abstinence at follow-up, again taking into account the sampling design and imbalanced covariates. The proportion of participants who used cessation treatments, as well as the proportion abstinent and treatment arm effect sizes (odds ratios [ORs] with 95% CI) were obtained separately for women and men in subgroup analyses.

Results

Of the 5,123 randomized veterans, baseline and follow-up surveys were returned by 138 women and 2,516 men (51.8% response rate). There was a differential response rate by gender in the PRO arm, but not in the UC arm. Among smokers randomized to PRO, women were less likely than men to complete both baseline and follow-up surveys (response rate 36.5% for women vs. 51.1% for men). In UC, the response rates did not differ by gender: 56.4% for women and 53% for men. Women comprised 5.2% of the study sample, proportionate to their representation in the VA at the time of enrollment (6%; Frayne et al., 2014). Age was the only covariate found to be imbalanced between treatment arms for any gender and, therefore, was included in subsequent models.

Pre-intervention

Baseline characteristics by gender—Compared with male smokers, female smokers were younger, less likely to be married, and were more likely to be employed (Table 1). Cigarettes per day and time to first cigarette did not differ significantly between women and men. Women began smoking at a slightly older age and were much more likely to smoke

menthol cigarettes. Men were more likely than women to use tobacco products other than cigarettes in addition to smoking cigarettes. Female and male smokers were equally likely to have tried to quit in the previous year and reported similar confidence and self-efficacy to quit, similar perceptions of the advantages and disadvantages of nicotine replacement therapy, and similar environmental pressures to quit (smoking allowed in the home or living with another smoker). Women were significantly more likely than men to strongly agree that "people important to me want me to quit smoking." Administrative data revealed significantly higher rates of depression and anxiety among female smokers, and higher rates of substance use disorder among male smokers. Post-traumatic stress disorder diagnoses did not differ by gender.

Prior Year Smoking Cessation Recommendations and Treatment

VA physician advice—Nearly all female (89%) and male (93%) smokers reported being advised to quit smoking by their primary care provider in the year before study enrollment (Table 2). There were no statistically significant differences in the proportions of women or men who reported that a VA provider discussed ways to quit other than medications (79% of women vs. 74% of men) or discussed medications to help with quitting (72% vs. 71%).

Use of cessation treatments—Few smokers reported having used behavioral counseling, either in person or over the phone, in the past year, either within or outside the VA. Most use did not differ by gender, with one exception: female smokers were more likely to have used non-VA telephone counseling (e.g., state or insurance-based quitline support) than male smokers (5% vs. 1%). More smokers reported receiving cessation medications from the VA (39% of women and 34% of men) than from outside the VA (11% of women and 12% of men); these proportions were not significantly different bygender.

Satisfaction with VA cessation care—Sixty-two percent of female and male smokers reported being very or somewhat satisfied with the help they received with quitting. Women were significantly less likely than men to report being very or somewhat satisfied with the process of obtaining medications to quit (47% of women vs. 62% of men).

Postintervention

Six-month prolonged abstinence—Overall, similar proportions of female and male smokers reported 6-month prolonged abstinence at the 1-year follow-up (12.3% and 10.9%, respectively; p = .61; Table 3; Figure 1). There was not a statistically significant interaction of Gender × Treatment (proactive vs. UC) with respect to smoking cessation (p = .75). Among 50 women randomized to proactive care, 7 quit smoking, as compared with 9 of the 88 randomized to UC (model-based prolonged abstinence estimates for women 13.9% in proactive care vs. 10.4% in UC; age-adjusted OR, 1.39; 95% CI, 0.48–3.99). Among 1,218 men randomized to proactive care, 161 quit, as compared with 110 of the 1,298 men in UC (13.6% in proactive care vs. 8.7% in UC; age-adjusted OR, 1.65; 95% CI, 1.28–2.14).

Quit attempts—More than one-half of female and male smokers made at least one quit attempt during the 1-year follow-up period, with no statistically significant difference by treatment arm or gender.

Use of smoking cessation therapies—Among women and men, randomization to the PRO intervention was associated with significantly higher use of telephone counseling (for women: 57.2% vs. 10.5%; OR, 11.36; 95% CI, 3.42–37.66; for men: 33.2% vs. 5.9%; OR, 7.92; 95% CI, 5.24–11.95) or combined therapy with counseling and medication (for women: 34.9% vs. 15.7%; OR, 2.88; 95% CI, 1.10–7.58; for men: 22.4% vs. 8.6%; OR, 3.08; 95% CI, 2.29–4.14), compared with UC. In contrast, PRO was not associated with significant increases in rates of in-person cessation counseling (for women: 14.3% vs. 15.8%; OR, 0.89; 95% CI, 0.27–2.90; for men: 9.2% vs. 8.4%; OR, 1.11; 95% CI, 0.80–1.55) or medication use (for women: 52.5% vs. 55.7%; OR, 0.88; 95% CI, 0.40–1.94; for men: 47.5% vs. 43.4%; OR, 1.18; 95% CI, 0.98–1.41).

Discussion

In a large, multisite, randomized trial of a PRO smoking cessation intervention, we analyzed baseline experiences of smoking cessation care in the VA as well as postintervention outcomes by gender. Baseline experiences did not vary significantly by gender with respect to advice to quit or use of cessation medications for recent quit attempts. However, women were less likely than men to be satisfied with the process of obtaining cessation medications. After a PRO intervention, female and male smokers were both more likely to use telephone counseling and combined therapy with counseling and medication, but only male smokers were significantly more likely to achieve prolonged abstinence if randomized to PRO rather than UC. Prolonged abstinence outcomes for women were of a similar magnitude and direction, but did not reach statistical significance.

Baseline Experiences with Smoking Cessation Recommendations and Treatment in VA

Compared with our parallel analysis, based on data from 2000, rates of advice to quit improved for both women and men in the VA from approximately two-thirds of women and men to approximately 90% of each a decade later. This rate is far higher than the range seen in surveys of nonprofit health maintenance organization or Medicare patients (71%–76%) (Shadel et al., 2015; Stevens et al., 2005; Quinn et al., 2005) and the range from national population-based surveys of smokers with a health care visit in the past 12 months (57%-66%; Babb, 2017; Kruger, O'Halloran, Rosenthal, Babb, & Fiore, 2016). Recommendations for medications and behavioral counseling to quit increased substantially for both women and men, and the gender disparity related to medication prescriptions that we previously identified was no longer evident. Our findings build on intervening work by Farmer et al. (2011), which revealed progressive improvement in levels of advice to quit (87% of women, 83% of men) and cessation assistance (63% and 62% with medications; 61% and 60% other treatments) for female and male smokers in the VA, respectively. Some credit for these improvements for both women and men over time may be attributable to VA policy directives that have made cessation medications and counseling more readily available to all patients, such as the elimination of copayments for individual or group cessation counseling sessions in 2005 (Petzel, 2014).

Despite these improvements in physician advice to quit, baseline satisfaction with cessation care was relatively low for both women and men. System-level changes to create a more

streamlined, accessible process for obtaining cessation medications have been shown to increase use of cessation medications (Ku, Brantley, Bysshe, Steinmetz, & Bruen, 2016). Satisfaction with the process of obtaining cessation medications was significantly lower for women than men; the reason for this disparity was unclear from our data. No other studies have examined this specific disparity, but several surveys have compared female and male veterans' satisfaction with VA pharmacy services more broadly, with mixed results. In a 2004 survey, women reported lower satisfaction than men with respect to VA pharmacy pickup and mail services in unadjusted analyses, but the differences became insignificant after accounting for demographic and health factors (Wright, Craig, Campbell, Schaefer, & Humble, 2006). In contrast, a more recent survey found very high satisfaction with pharmacy services for both female and male veterans, but described some disparities by race and gender for satisfaction with pharmacy services and related measures such as cost and respect (Zickmund et al., 2018). Future efforts to study and improve smoking cessation in VA should include attention to potential gender differences in experiences obtaining cessation medications.

At baseline, most smokers had not used behavioral counseling to try to quit smoking during the past year: 10%-12% of all smokers reported use of VA behavioral counseling, regardless of reporting a formal quit attempt. Population-based surveys show that relatively few U.S. smokers use behavioral counseling during a quit attempt (4%-9%; Curry, Sporer, Pugach, Campbell, & Emery, 2007; Shiffman, Brockwell, Pillitteri, & Gitchell, 2008). Although comparable data from other health care systems are lacking, rates in this study also exceeded behavioral counseling use by insurance status for privately insured (2.6%), Medicare (0.9%), and Medicaid (0.9%) populations (Cokkinides, Ward, Jemal, & Thun, 2005). Women were more likely than men to have used telephone counseling, although the absolute numbers were small. This finding is consistent with analyses of telephone quitlines worldwide, which universally demonstrate higher use by female smokers (Abdullah, Lam, Chan, & Hedley, 2004; Gilbert, Sutton, & Sutherland, 2005; Miller, Wakefield, & Roberts, 2003; Swartz, Cowan, Klayman, Welton, & Leonard, 2005). The rate of telephone counseling use among male veteran smokers at baseline mirrored the national average of 1% of smokers (Cummins, Bailey, Campbell, Koon-Kirby, & Zhu, 2007). Higher baseline use of phone counseling among female smokers highlights the potential of phone-based PRO interventions for women.

Gender Differences in Response to PRO

After PRO, both female and male smokers were more likely than those randomized to UC to use telephone counseling and combined therapy with counseling and medication. For male smokers, a small, statistically significant effect of PRO on prolonged abstinence was seen. This small effect of a population-level intervention could translate to a meaningful public health impact. A small effect on prolonged abstinence was also observed among women, but the confidence interval was wider and included 1. These post hoc subgroup findings add to the limited, mixed evidence on gender differences in response to proactive smoking cessation interventions.

Some prior research with female smokers has not demonstrated a significant benefit from PRO interventions. Several randomized trials proactively identified and recruited female smokers in specific populations, such as pregnant women (Rigotti et al., 2006; Solomon, Secker-Walker, Flynn, Skelly, & Capeless, 2000) or women with abnormal pap test results (McBride et al., 1999; McClure, Westbrook, Curry, & Wetter, 2005). Women in those trials were randomized to a proactive telephone counseling intervention or to a UC/best practice control. Three of four studies found no statistically significant improvement in abstinence rates at any time point for proactive counseling as compared with UC; one found short-term improvement at 6 months but not at 12 months. Compared with our study population, each of these women-only trials included more women (n = 151-580) with a younger mean age (23–36 years vs. 51 years in our study). A gender gap in long-term efficacy outcomes may not be specific to PRO interventions: a recent review of sex/gender differences in smoking cessation reported that, in general, women and men attempt to quit at similar rates, but women are less likely to maintain abstinence in studies with longer follow-up (Smith, Bessette, Weinberger, Sheffer, & McKee, 2016).

In contrast, several studies have shown a benefit of proactive cessation care for long-term abstinence in female smokers. Recently, Haas et al. (2015) conducted a randomized, controlled trial using interactive voice response technology to proactively offer cessation support to a group of low-income smokers. In a subgroup analysis, women had significantly higher odds of abstinence at the 9-month follow-up when randomized to PRO versus UC; the result for men was in the same direction but was not statistically significant. That study was smaller than ours overall (n = 707), but included many more women (68% female). Similarly, we recently completed a large trial of PRO to low-income (non-VA) smokers in Minnesota (Fu et al., 2016) and in an unpublished subgroup analysis found a statistically significant intervention effect among a large sample of female smokers (n = 1,250 women; 15.7% in PRO reported 6-month prolonged abstinence at the 1-year follow-up, compared with 11.9% in UC; p = .04), with results in the same direction but not statistically significant among a smaller sample of male smokers (n = 507 men; 18.3% vs. 12.4% reported prolonged abstinence in PRO vs. UC; p = .06; unpublished results provided via personal communication with Patrick Hammett, February 20, 2018). Compared with the smaller, women-only trials discussed, more recent studies likely benefit from increased availability of effective cessation medications and contemporaneous public health interventions (such as smoke-free policies). Taken together with our results, these larger, more recent trials suggest that PRO is an effective smoking cessation intervention for women.

Limitations

Women veterans are a unique subpopulation, and these results are not necessarily generalizable to other groups. The study sample, from four VA sites, was not designed to be representative of all VA smokers. Only current smokers were enrolled, so baseline experiences with smoking cessation recommendations and treatment in the VA were likely biased by the fact that participants had not achieved abstinence. Prolonged abstinence is a self-reported measure that may be subject to social desirability bias. Although multiple studies have validated smoking self-report (Patrick et al., 1994; Yeager & Krosnick, 2010), including among VA smokers (Noonan, Jiang, & Duffy, 2013), self-report may be less

reliable among populations for whom smoking is particularly socially undesirable, such as pregnant women (Florescu et al., 2009). However, overall rates of smoking status misclassification by self-report do not seem to vary significantly by gender (Caraballo, Giovino, Pechacek, & Mowery, 2001).

Response rates were lower for women (but not men) assigned to PRO, as compared with UC. We doubt that this finding represents a negative reaction to the intervention by women because the difference in response rates was present at baseline, before receipt of any outreach. We suspect the differential response rate represents a combination of chance and a smaller sample size in the PRO arm. Randomization was not stratified by gender, which may have contributed to the lower number of women assigned to PRO rather than UC. Future trials should oversample women veterans, to increase sample size, and consider blocking randomization by sex, to ensure matched treatment groups.

Owing to the relatively small number of women enrolled, we lacked power to show an interaction between gender and treatment with respect to prolonged abstinence.

Additionally, we report a complete case intent-to-treat analysis that is subject to bias from missing data that is not missing at random. Post hoc subgroup analyses provide descriptive data about experiences with PRO for female and male smokers separately, but results require replication in a larger sample to be conclusive.

Implications for Practice and/or Policy

VA providers and policymakers must address patient satisfaction with tobacco cessation care, particularly with respect to obtaining cessation medications. PRO to smokers helps to facilitate treatment use among female and male veterans and can be considered a tool for improving access to care. Future cessation trials should oversample women veteran smokers.

Conclusions

VA smoking cessation care has improved substantially in the past decade for both women and men. Research on smoking cessation interventions for women veterans remains limited despite high smoking rates among women veterans. This study adds to the evidence that PRO can be an effective intervention for both female and male smokers.

Acknowledgments

Dr. Danan had full access to all the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis.

Supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, and Health Services Research and Development (IAB-05-303). The views expressed in this article are those of the authors and do not represent the views of the VA or the US Government. This trial is registered in clinicaltrials.gov (NCT00608426).

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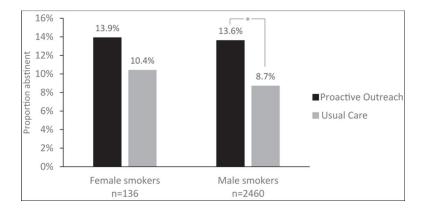


Figure 1.Proportion of female and male smokers who report 6-month prolonged abstinence at the 1-year follow-up, by treatment arm.

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Table 1

Baseline Sample Characteristics by Gender*

	Female Smokers. n (%) or Mean (SE)	Male Smokers. n (%) or Mean (SE)	" Value
			L man
All participants	138	2,516	1
Treatment group			
Usual care	88	1,298	
Proactive outreach	50	1,218	
Sociodemographic characteristics			
Age (y)	51.2 (0.9)	59.0 (0.2)	<.01
Race			
White	72 (57%)	1,533 (67%)	.17
Black	48 (32%)	672 (23%)	
Hispanic	8(5%)	158 (5%)	
Other	10(7%)	153 (6%)	
Married or cohabiting	46 (36%)	1,245 (52%)	<.01
Currently employed	61 (46%)	715(29%)	<.01
Annual income \$20k	56 (40%)	1,172 (48%)	90.
Smoking behaviors			
Cigarettes per day			
10	61 (40%)	877 (32%)	.12
11–20	54 (42%)	1,049 (44%)	
21	23(18%)	546 (24%)	
Time to first cigarette (min)			
>31	39 (29%)	689 (26%)	.27
6–30	66 (47%)	1,308 (54%)	
<5	33(25%)	499 (20%)	
Age of smoking initiation (y)	18.8 (0.5)	17.2 (0.1)	<.01
Menthol cigarette user	81 (56%)	881 (31%)	<.01
Use other tobacco products	28(21%)	1,124 (47%)	<.01
Cessation attitudes and attempts			
Quit attempt in past 12 mo	78 (56%)	1,392 (54%)	.73

	Female Smokers. n (%) or Mean (SE) — Male Smokers. n (%) or Mean (SE)	Male Smokers. n (%) or Mean (SE)	p Value
			,
Readiness to quit	5.8 (0.2)	5.7 (0.0)	.55
Global confidence to quit (0–5)	2.2 (0.1)	2.3 (0.0)	.24
Self-efficacy to quit			
Emotional subscale	-0.7 (0.2)	-0.4 (0.0)	90.
Skill subscale	0.4 (0.1)	0.1 (0.0)	90.
Social subscale	-0.2 (0.2)	-0.2 (0.0)	.94
Perceptions of NRT			
Advantages subscale	29.1 (0.5)	28.4 (0.1)	.16
Disadvantages subscale	11.6 (0.3)	11.9 (0.1)	.49
Smoking not allowed in home	48 (37%)	937 (41%)	4.
Another smoker lives in home	60 (44%)	1,043 (42%)	69.
People important to me want me to quit smoking			
Strongly disagree to neutral	22 (16%)	493 (22%)	<.01
Somewhat agree	19(15%)	554 (24%)	
Strongly agree	88 (68%)	1,309 (55%)	
Mental health diagnoses			
Depression	53 (40%)	493 (19%)	<.01
Anxiety	21 (16%)	219 (9%)	.03
PTSD	12 (9%)	200 (7%)	.46
Substance use disorder	17 (12%)	499 (19%)	.02

Abbreviations: NRT, nicotine replacement therapy; PTSD, Post-traumatic stress disorder; SE, standard error.

 $[\]sp{*}$ Summary statistics adjust for study design with stratified sampling by site.

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Table 2

Baseline Experiences with Smoking Cessation Recommendations and Treatment, by Gender, Within the Past 12 Months

	Female Smokers, $n\left(^{9/6}\right)^*$	Male Smokers, $n\left(\%\right)^{*}$	Age-Adjusted Odds Ratio* (95% CI)
N	138	2,516	
VA physician advice			
VA provider advised to quit	113 (89%)	2,200 (93%)	0.63 (0.36–1.13)
VA provider discussed nonmedical ways to quit	100(79%)	1,748 (74%)	1.31 (0.84–2.05)
VA provider discussed medications to quit	90(72%)	1,669(71%)	1.05 (0.71–1.56)
Use of cessation treatments			
Behavioral counseling from VA, any	16(12%)	262 (10%)	1.19 (0.69–2.07)
In-person counseling	16(11%)	240 (9%)	1.26 (0.72–2.19)
Phone counseling	0(0%)	29(1%)	Not estimable
Behavioral counseling from outside VA, any	15(12%)	153 (6%)	2.09 (1.17–3.73)
In-person counseling	11 (8%)	127 (5%)	1.68 (0.87–3.27)
Phone counseling	6 (5%)	30(1%)	5.23 (1.99–13.74)
Cessation medication use from VA	52 (39%)	867 (34%)	1.22 (0.84–1.75)
Cessation medication use from outside VA	16(11%)	305(12%)	0.96 (0.56–1.67)
Satisfaction with VA cessation care [†]			
N	96	1,787	
Very or somewhat satisfied with help received to quit	57 (62%)	1,106 (62%)	0.99 (0.65–1.52)
N	75	1,401	
Very or somewhat satisfied with process of obtaining meds to quit 33 (47%)	33 (47%)	874 (62%)	0.54 (0.33–0.87)

Abbreviations: SE, standard error; VA, Veterans Health Administration.

 $^{^*}$ Proportions and odds ratios are model based. The model adjusts for study design and age.

 $^{^{\}not\uparrow} Denominator \ for \ satisfaction \ questions \ excludes \ participants \ who \ reported \ that \ they \ never \ received \ help \ with \ smoking \ cessation$

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Table 3

Postintervention Outcomes: Six-Month Prolonged Abstinence, Quit Attempts, and Treatment Use by Treatment Arm and Gender

	Proactive Outreach, n (%) Usual Care (Ref), n (%) *	Usual Care (Ref), n (%)*	Age-Adjusted Odds Ratio* (95% Cl)
N	1,268	1,386	
Six-month abstinence			
Female smokers	7 (13.9%)	9 (10.4%)	1.39 (0.48–3.99)
Male smokers	161 (13.6%)	110(8.7%)	1.65 (1.28–2.14)
Quit attempts			
Female smokers	28 (54.6%)	49 (54.6%)	1.00 (0.45–2.21)
Male smokers	667 (57.6%)	699 (54.6%)	1.13 (0.94–1.35)
Use of in-person counseling			
Female smokers	5 (14.3%)	9(15.8%)	0.89 (0.27–2.90)
Male smokers	77 (9.2%)	76 (8.4%)	1.11 (0.80–1.55)
Use of phone counseling			
Female smokers	17 (57.2%)	4 (10.5%)	11.36 (3.42–37.66)
Male smokers	174 (33.2%)	29 (5.9%)	7.92 (5.24–11.95)
Cessation medication use			
Female smokers	26 (52.5%)	43 (55.7%)	0.88 (0.40–1.94)
Male smokers	528 (47.5%)	510 (43.4%)	1.18 (0.98–1.41)
Combined therapy			
Female smokers	13 (34.9%)	9(15.7%)	2.88 (1.10–7.58)
Male smokers	174 (22.4%)	70 (8.6%)	3.08 (2.29–4.14)

* Proportions and odds ratios are model based. The model adjusts for study design and age, and baseline measures when applicable