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Expanding the reach of a validated smoking-cessation intervention: A Spanish-language trial.

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Tobacco smoking is the leading preventable cause of cancer mortality. Pharmacotherapy and behavioral counseling have demonstrated independent and additive effects toward aiding smoking cessation; however, counseling is rarely chosen by smokers. In contrast, minimal self-help interventions, such as smoking cessation pamphlets or booklets have much wider potential reach, yet their efficacy has been largely disappointing, with incremental abstinence rates averaging only 1%. Given the high dissemination potential, any significant improvement in the efficacy of self-help would have large public health impact with respect to smoking and smoking-related illness and mortality.

A notable exception to the historically poor efficacy of self-help has been the extended self-help smoking interventions developed by our research team. Originally developed to prevent post-cessation relapse to smoking, these booklets entitled, *Forever Free*, significantly reduced smoking relapse through two years of follow-up among individuals who had recently quit smoking. In addition, the intervention was found to be extremely cost-effective. Based on its efficacy and cost-effectiveness, we expanded the intervention to include initial smoking cessation as well as relapse prevention, 18 months of contact, and a written social support component. Results of a recently completed National Cancer Institute (NCI) funded trial of this intervention, *Forever Free: Stop Smoking for Good*, revealed high efficacy throughout the 24-month follow-up period, further supporting the utility of extended self-help for promoting and maintaining tobacco abstinence. We recognize, however, that wide-scale implementation, and therefore public health impact, would be enhanced the availability of a Spanish-language version to reach the largest and fastest growing ethnic minority population of smokers.

The current smoking prevalence among Hispanic/Latino adults varies by cultural subgroup, with highest prevalence among those of Puerto Rican (35%, men; 33% women) and Cuban origins (31%, 30%) and lowest among Dominicans (11%, 12%). Greater smoking prevalence is also associated with lower income and education, and greater US acculturation. Prior work by our research team and others has demonstrated that Hispanic/Latino smokers face unique challenges such as lower awareness and acceptability of nicotine replacement therapies and receiving less assistance with smoking cessation from their health providers. As highlighted in the Clinical Practice Guidelines for Treating Tobacco Use and Dependence, additional research is needed to develop and validate interventions for racial and ethnic minority smokers.

The goal of this study is to address this gap by testing a Spanish-language version of the validated self-help smoking cessation intervention. If demonstrated effective, the proposed intervention would represent an easily disseminable and low-cost intervention with significant public health impact for Hispanic/Latino smokers throughout the United States. The aims of this project are to test the efficacy of a Spanish-language version of a validated, extended self-help intervention for smoking cessation among Spanish-speaking smokers against usual care control. Participants (N = 1400) recruited nationally will be randomized to the two arms.

Specific Aim 1: To test the efficacy of a Spanish-language extended self-help intervention compared to usual care.

Participants in the first arm will receive the Spanish-language version of the *Stop Smoking for Good* (SS-SP) intervention distributed over 18 months. Those in the second arm, Usual Care (UC), will receive a single, credible, NCI-produced Spanish-language self-help booklet. Outcomes will be assessed through 24 months.

Hypothesis 1: The SS-SP booklets, compared with UC, will produce higher rates of tobacco abstinence that

will be maintained through the 24-month assessment.

Secondary Aim: To evaluate moderator variables that may aid in refining and targeting of the intervention to maximize impact.

Demographic moderator variables include gender, age, income, *country of origin*, and generational status. Psychological moderators include nicotine dependence, acculturation, cessation motivation, *trait affect*, and cessation self-efficacy. Moderator analyses will be exploratory, without strong a priori hypotheses.

Public Health Significance: This would be the first study to test a Spanish-language adaptation of a validated and easily implemented self-help smoking cessation intervention in a nation-wide RCT, with the potential to reduce ethnic health disparities associated with tobacco smoking.

B. SIGNIFICANCE

B1. Smoking Burden and Cessation

Tobacco smoking is responsible for approximately 400,000 premature deaths annually in the United States, and 5 million worldwide, with causal links to cancers at 18 different organ sites, as well as coronary heart disease, chronic obstructive pulmonary disease, cardiovascular disease, and stroke (CDC, 2008; Rostron, 2013; USDHHS, 2014). Despite the well-known health consequences of smoking and the benefits of quitting (Jha et al., 2013), 18% of American adults continue to smoke (CDC, 2014) primarily because they have developed dependence to nicotine, the major psychoactive substance in tobacco. Smoking-related mortality is a distal consequence of this substance dependence. Therefore, the treatment of tobacco (nicotine) dependence remains a public health priority of paramount significance. The U.S. Public Health Service (USPHS) Clinical Practice Guidelines for Treating Tobacco Use and Dependence (Fiore et al., 2008) and the CDC's Healthy People 2020 (USDHHS, 2014) draw greater attention to key risk factors for tobacco use and associated disease and mortality, including race/ethnicity and socioeconomic status. There is need for the development and delivery of smoking cessation interventions for special populations of smokers, including ethnic and racial minority groups, who incur high mortality rates related to smoking-related diseases.

B2. Self-Help Approaches to Smoking Cessation

Self-help refers to very minimal intensity types of interventions, such as print and electronic media provided to smokers. Because few smokers seek more intensive interventions, self-help materials have the potential for high public health impact if they can reach large numbers of smokers and aid them in achieving cessation. Their ease of administration and distribution maximizes the Adoption, Implementation, and Maintenance variables within the RE-AIM model of implementation (Glasgow et al., 1999; Glasgow, Lichtenstein, & Marcus, 2003). Curry et al. (2003) summarized the appealing features of self- help manuals, including: (1) They package state-of-the-art, cognitive-behavioral intervention components in a format that can be disseminated. (2) Distribution can occur through a variety of channels at a relatively low cost. (3) Smokers can customize program recommendations to their specific needs and interests. (4) Written materials are easy to keep so that smokers can refer back to them or use them again in a future quit attempt. Unfortunately, recent meta-analyses indicate little efficacy for self-help interventions. Both the Clinical Practice Guidelines (Fiore et al., 2008) and a Cochrane Review (Hartmann-Boyce et al., 2014) concluded that self-help materials have at best marginal efficacy, improving cessation rates by about 1% compared to no-treatment controls.

In summary, self-help interventions have potential for vast reach, but their public health impact has been limited by low efficacy. This contrasts with greater efficacy, but much poorer reach, of intensive behavioral interventions (Fiore et al., 2008). A logical goal is to develop self- help interventions with high reach that draw upon cognitive-behavioral counseling to enhance their efficacy. Toward this goal, our team has developed several efficacious self-help tobacco interventions over the past decade, as described in section B3.

B3. The "Forever Free" Self-Help Interventions

B3.1. Smoking Relapse Prevention. To achieve the goal of increasing the efficacy of self-help, our research team made two very significant changes to the typical self-help approach. First, we initially focused on the prevention of smoking *relapse*. Second, rather than a single brief self-help intervention (e.g., a pamphlet), we developed an extended self-help intervention—specifically, an evidence based, eight booklet series entitled, *Forever Free,* delivered over the course of a year. The content of these booklets was based on cognitive- behavioral theory (e.g., Bandura, 1977; Marlatt, 1985) and empirical evidence regarding the nature of tobacco dependence, cessation, and relapse (e.g., Baker et al., 2004). The booklets were conceptualized as a means of translating the cognitive-behavioral counseling that occurs in a clinic into a written format that would be much more accessible to smokers. The booklets were sent over an extended period of time (12 months) to maintain abstinence motivation.

Across three randomized controlled trials (RCTs), this intervention was found to be highly efficacious and cost-effective among self-quitting smokers (Brandon et al., 2000, 2004; Chirikos et al., 2004), and among low-income pregnant and postpartum women, using a modified version (Brandon et al., 2012). Moreover, a recent meta-analysis found self-help to be the only efficacious relapse-prevention modality (Agboola et al.,

2010). Based on the results of our prior studies, the booklets have been adopted by NCI (distributed by the Cancer Information Service, available for free download at www.smokefree.gov, and identified as a Research Tested Intervention Program on cancercontrolplanet.cancer.gov), as well as by hospitals and health departments throughout the country. Additionally, an anglicized version of the booklets is currently being tested in Great Britain for possible adoption by the National Health Service.

B3.2. Smoking Cessation. Based on the success of extended self-help for preventing smoking relapse, we have since developed a version, *Forever Free: Stop Smoking for Good,* to assist current smokers with both initial cessation and maintenance of abstinence. We recently completed an NCI-funded RCT testing this English-language intervention (described further in D1.2.3 below**)**. Compared to Usual Care, our intervention produced significantly greater smoking abstinence rates through the 24 months of follow-up. Additional details regarding these studies are presented in the *Preliminary Studies* section (D1.2). **In summary, this line of research supports that extended self-help is an efficacious tool for promoting and maintaining tobacco abstinence.**

B4. Hispanic/Latino Smokers

Hispanic/Latinos are the largest and fastest growing minority group in the United States (Ennis, Rios-Vargas, & Albert, 2011). The current smoking prevalence among Hispanic/Latino adults varies by cultural subgroup, with highest prevalence among those of Puerto Rican (35%, men; 33% women) and Cuban origins (31%, 30%) and lowest among Dominicans (11%, 12%) (Kaplan et al., 2014). Higher prevalence of smoking is also observed within medically underserved communities and low SES communities (Báezconde-Garbanati et al., 2007). In addition to language limitations due to scarce Spanish-language smoking resources (Santisteban et al., 2006), Hispanic/Latinos are disproportionately represented in the lower SES groups. Low income and financial strain can operate as distracters from efforts at self-directed health behavior change and are associated with poorer success rates among those attempting to quit smoking (Barbeau et al., 2004; Kendsor et al., 2010; Sheffer, 2012). Low-income smokers may be hampered in their quitting attempts because of the practical limitations (e.g., cost and transportation) of attending smoking cessation programs and lack of availability of self- help interventions that are salient with respect to their everyday concerns and realities.

Hispanic/Latino smokers also appear to have less access to the full range of smoking cessation assistance. For example, Hispanic/Latinos are less likely to receive tobacco screening and counseling from their physicians (Lopez-Quintero et al., 2006; Sonnenfeld et al., 2009). Access to evidence-based smoking cessation treatments is further restricted for individuals with limited or no English proficiency (Wetter et al., 2007). A recent study conducted with bilingual Hispanic smokers demonstrated higher intended utilization of smoking cessation intervention materials if they were received in their preferred language, supporting the need for the availability of Spanish-language materials for bilingual smokers as well (Rodriguez-Esquivel et al., 2015).

Among underserved populations, the absence of readily available Spanish-language evidence- based materials has been cited as a key barrier to primary care providers assisting with smoking cessation (Blumenthal, 2007). More generally, there is very little research evaluating smoking cessation interventions for Hispanic/Latinos (Doolan & Froelicher, 2006). In fact, only a handful of randomized trials have been conducted testing the efficacy of targeted interventions for Hispanic/Latino smokers (Webb et al., 2010). Therefore, the USPHS Clinical Practice Guidelines called for more research on the development and validation of interventions for racial/ethnic minority smokers, with attention to appropriate language and sociocultural factors such as acculturation and socioeconomic status (Fiore et al., 2008). Moreover, extending the reach of smoking cessation interventions to Hispanic/Latino smokers aligns with NCI priorities for reducing health disparities. **In summary, there is a critical need for evidence-based smoking-cessation interventions for Hispanic/Latino smokers—interventions that are culturally-sensitive, relevant and responsive to the sociocultural needs of diverse subcultural groups of Hispanic/Latinos** (**Barrera et al., 2011).**

B5. Culture, Language, and Linguistics: Spanish Transcreation

Reducing tobacco use among minority populations is an essential step for eliminating cancer health disparities. Toward this end, extending the reach of validated smoking cessation interventions to the largest and fastest growing minority population is paramount.

Direct translations of health education materials from English to Spanish, without appropriate linguistic, literacy and cultural considerations, can result in the development of interventions that contain

inaccuracies, awkward language, and mismatched cultural content, consequently reducing acceptability and impact (Solomon et al., 2005). Because simple translation is insufficient, we intend to "transcreate" the existing English-language intervention components (10 Stop Smoking for Good Booklets and 9 supportive My Story pamphlets) for Hispanic/Latino smokers. Transcreation involves both translating and culturally adapting materials for a Spanish-speaking Hispanic/Latino audience (Marcario & Boyt, 2008; Solomon et al., 2005; Castro, Barrera, & Steiker, 2010). With transcreation, the text is not merely translated into another language, but reconstructed to meet the informational needs and health literacy of the target audience (Quinn et al., 2006). Research suggests that health education efforts focused on encouraging behavior change are more successful when transcreated and available to the intended population in their native language (Bender, Harbour et al., 2001), and with message content that is relevant and engaging for members of the targeted cultural group.

Importantly, research indicates that, when culturally tailored, cognitive-behavioral interventions are equally effective for Hispanic/Latino populations (e.g., Miranda et al., 2005; Muñoz & Mendelsen, 2005).

Our research team has been successful in utilizing transcreation processes to adapt self-help relapse-prevention interventions that were linguistically and culturally suitable for heterogeneous Hispanic/Latino, Spanish-language preferring populations (Simmons et al., 2011a, 2011b; Litvin et al., 2011). Key findings from our transcreation work are summarized in the *Preliminary Studies* section (D1.3.1).

In summary, the creation of effective interventions for Hispanic/Latino populations requires not only quality translation, but systematic adaptation informed by the unique cultural context and informational needs of the target audience, followed by empirical validation via an RCT.

C. INNOVATION

The proposed research has several innovative features. First, the study continues the team's expansion of the definition of self-help interventions by increasing the "dose" of self-help in return for potentially large gains in efficacy, while obtaining very favorable cost-effectiveness, as seen in our previous research (Brandon et al., 2000, 2004, 2012). It adapts a common communication channel to deliver a more intensive and focused intervention—one that is highly accessible to underserved populations. Second, by testing a Spanish-language smoking cessation resource, our intervention has the potential to reach the largest and fastest growing underserved population of smokers, one for which few evidence-based cessation resources exist. Moreover, the US Census data indicate that 45.7% of Spanish-speaking individuals speak English less than "very well." This percentage is higher among the low SES individuals most likely to smoke (Ryan, 2013). Therefore, the need is great for novel and efficacious cessation interventions to reach this sector of the Hispanic/Latino population. We will be the first to test the efficacy of a "transcreated" and evidence-based self-help intervention for a diverse Hispanic/Latino population. Third, the study represents an advance in translational research by increasing the reach of smoking cessation interventions to an underserved population (Spoth et al, 2013). Importantly, if shown to be efficacious, a written self-help intervention modality would be especially beneficial for low-income and underserved populations who experience unique barriers to obtaining smoking cessation treatments or medications (e.g., cost, transportation issues), and it would be ready for immediate dissemination.

D. APPROACH

D1. Preliminary Studies

D1.1. The Research Team (see biosketches for relevant citations) D1.1.1. The Investigators

We have assembled a team of investigators with significant expertise and experience in all aspects of the proposed: study conceptualization, the development and evaluation of smoking interventions for special populations (Brandon, Simmons), health disparities, health communication and literacy, and development and adaptation of multi-language educational interventions (Meade, Simmons), community-engaged research (Simmons, Meade), health disparities and tobacco (Simmons), and statistical methods (Sutton). The two PIs, Vani Nath Simmons, Ph.D., and Thomas Brandon, Ph.D., are longstanding collaborators on the development of self-help interventions for tobacco dependence, with attention to the specific needs of special populations of smokers. Cathy Meade, R.N., Ph.D., F.A.A.N., is a nationally recognized expert in the areas of health literacy and communications, and she has collaborated on our

previous self-help interventions. Drs. Brandon, Simmons, and Meade are members of the Outreach Research Program for an NCI-funded U54 Comprehensive Partnerships to Reduce Cancer Health Disparities grant between Moffitt Cancer Center and the Ponce School of Medicine in Puerto Rico. In addition, Dr. Meade leads an NCI-funded U54 Community Network Program Center, of which Dr. Simmons is the Community Outreach co-director. Thus, they have substantial experience working with community stakeholders and Spanish-speaking populations. Steven Sutton, Ph.D., has expertise in data management and statistical analyses of tobacco-intervention trials. Marina Unrod, Ph.D., has been a co-investigator on our prior self- help tobacco studies and has managed RCTs at TRIP for the past 8 years.

D1.1.2. Cultural Advisory Board

We have supplemented and expanded the expertise and reach of the primary investigators by assembling a Cultural Advisory Board (CAB) comprising researchers from our key focused recruitment areas. Each of these investigators has relevant experience developing interventions for the Hispanic/Latino community and recruiting Hispanic/Latino participants into research protocols. Members of the CAB include: Dr. Maria Fernandez (University of Houston), Dr. Felipe González Castro (University of Texas, El Paso), Dr. Monica Hooper (University of Miami), Dr. Julio Jimenez (Ponce School of Medicine, Puerto Rico), Dr. Kristen Wells (University of California, San Diego), *and Dr. Anita Kinney (University of New Mexico).* The CAB will use their local established community networks to assist in recruiting participants in their respective regions and will advise and provide feedback regarding the language and cultural appropriateness of the study instruments (See Letters of Support).

D1.1.3. Community Advisory Panel

In addition to our CAB described above, we will also seek input from Hispanic community members on the proposed assessments, recruitment strategies, and clinical trial procedures, as needed. We are fortunate to have access to two existing partnerships that will facilitate and support this process. Dr. Meade leads an NCI-funded U54 Community Network Program Center (Tampa Bay Community Cancer Network; TBCCN), of which Dr. Simmons is the Community Outreach co-director. TBCCN is comprises 20 community-based organizations that serve medically underserved communities. Importantly, we will be able to seek feedback from several of the partners included within TBCCN that represent Hispanic-serving organizations (e.g., Farmworkers self-help, Multicultural Resource Center, Latinos United for New Beginnings).

Additionally, as noted above,, Drs. Brandon, Simmons, and Meade are members of the Outreach Research Program of the Ponce School of Medicine and Moffitt Cancer Center U54 Partnership. Within the context of this partnership, we will work closely with our established Hispanic Community Advisory Panel (CAP). The CAP has offered their support of our project goals and will be able to provide valuable input on effective recruitment strategies for reaching Hispanics as well as our assessments. The CAP currently comprises 10 members with diverse sub-ethnic backgrounds (Colombian, Puerto Rican, Venezuelan,Mexican). (See Letter of Support).

D1.2. Prior Research on Self-Help Smoking Interventions

Our team has conducted and published descriptive, intervention, and laboratory-based studies to investigate the nature of smoking cessation and to develop intervention strategies. Most relevant to the current proposal, three RCTs testing the efficacy of our self-help interventions are described below.

D1.2.1. Relapse Prevention I. The first of these studies (Brandon et al., 2000) involved a 2 X 2 factorial design to test the independent and combined efficacy of two types of a minimal intervention that had been identified in an earlier feasibility study (Brandon & DeMichele, 1995):
(1) access to a year-long relapse prevention hotline and (2) a series of eight empirically based relapse-prevention booklets mailed to participants over the course of a year. We found that the repeated mailings of booklets significantly reduced 12-month relapse rates of recent quitters by two-thirds (12% vs. 35%, p = .001).

D1.2.2. Relapse Prevention II. A second clinical trial (R01 CA80706; Brandon et al., 2004) parsed the effects of repeated contact and booklet content, and extended follow-up to 2 years. The main findings were that the multiple booklets continued to produce reductions in smoking relapse through 2-year follow-up compared to a single-booklet control condition (22% vs. 32% relapsed, p = .02), and that booklet content was more potent than contact. The intervention was also highly cost-effective; cost per quality-adjusted life-year (QALY) gained was estimated as low as $83 in the sample (Brandon et al., 2004;

Chirikos et al., 2004).

D1.2.3. Cessation. The most relevant study (R01 CA134347) ended data-collection in May, 2014. This study was based on preliminary data suggesting that the *Forever Free* booklets, although developed to prevent relapse, were efficacious for current smokers. This contrasts with the general finding that self-help is minimally effective (1% additional cessation) for smoking cessation (Hartmann-Boyce et al., 2014). We modified the original *Forever Free* booklets to include instruction on smoking cessation, per se, creating a new version for current smokers titled, *Stop Smoking for Good*. We randomized 1874 current smokers to three conditions: (1) Usual Care (a standard smoking cessation booklet, *Clearing the Air,* published by NCI [NCI, 2008]); (2) Standard booklets (8 *Stop Smoking For Good* booklets mailed over 12 months); or (3) Enhanced booklets.

The Enhanced intervention comprised 10 *Stop Smoking for Good* booklets and 9 supportive pamphlets. The *Stop Smoking for Good* booklets were sent separately upon enrollment and at 1, 2, 3, 5, 7, 9, 12, 15, and 18 months. The first booklet provided a general overview about quitting smoking, and each of the remaining nine booklets included more extensive information on a topic related to quitting smoking maintaining abstinence: *Smoking Urges; Smoking and Weight; What if You Have a Cigarette?; Your Health; Smoking, Stress, and Mood; Lifestyle Balance; Life without Cigarettes, The Benefits of Quitting Smoking,* and *The Road Ahead*.

In addition to the 10 booklets, we also made contact during non-booklet months to enhance perceived social support via 9 tri-fold color pamphlets (*My Story: How I Quit Smoking*) that reinforced key messages about quitting smoking (e.g., dealing with stress, keeping weight gain in perspective, finding other forms of positive reinforcement). To further approximate a sense of social support, the message was communicated via a first-person narrative from a former smoker, incorporating photographs of the purported speaker. All materials were written at the 5-6 grade reading level so as to maximize their accessibility to a wider range of smokers (Meade & Byrd, 1989). The existing English-language 10 *Stop Smoking for Good* booklets and 9 supportive pamphlets are accessible to reviewers at www.moffitt.org/PQ.

We recently completed analyses of 7-day point-prevalence abstinence rates through 24 months following multiple imputation to manage missing data (Brandon et al., 2015). As seen in Table 1 below, the Enhanced Booklet condition produced consistently higher abstinence rates at all follow-up points compared to Usual Care. Even at 24 months, the differential abstinence rates were over 11%. Given the low cost of the intervention, these differences represent high clinical and public health significance and potential impact. In terms of cost per quitter, preliminary economic analyses indicate that the incremental cost-effectiveness ratios (i.e, the difference in cost between an intervention and Usual Care, divided by the difference in abstinence at 24 months) of the Standard and Enhanced conditions were $560 and $361, respectively—both far lower than most other smoking-cessation interventions, which tend to yield cost per quitter estimates between $1000 and $10,000 (e.g., Cromwell et al., 1997; Curry et al., 1998; Nohlert et al., 2013; Ronckers et al., 2005; Smit et al., 2013; Smith et al, 2007; Song et al., 2002). **This study demonstrates that a minimal, but extended, self-help intervention can significantly, and cost-effectively, improve smoking cessation rates, and it supports our plan to increase the reach and impact of this intervention by creating a Spanish-language version.**

Table 1: 7-Day Point Prevalence Abstinence Rates (%) at 6, 12, 18, and 24 Months in Cessation Study

	Percent Abstinent			Follow-Up	Usual
	Standard Condition	Enhanced Condition		*p*	6 Months Care
	11.54	13.85	16.09	.03	
12 Months	14.34	19.40	24.12	.0001	
18 Months	18.19	20.25	28.01	.0002	
24 Months	18.88	24.35	29.96	<.0001	

Note:. p-values are for comparison of the Enhanced vs. Usual Care conditions.

D1.3. Interventions for Special Populations

Our team has substantial experience creating interventions for special populations of smokers. Using formative research, we adapted the *Forever Free* intervention for pregnant women (Quinn et al., 2006). In an RCT (R01 CA94256), we compared the *Forever Free: For Baby and Me* booklets against standard, booklets (Brandon et al., 2012). We found both main effects and moderation by SES. For

example, by 12 months postpartum, low-income women were particularly likely to benefit from the new intervention compared to standard booklets (72% vs 51% abstinent at 12 months postpartum, p = .003).

Moreover, based on an analysis of predictors of post-treatment smoking among cancer patients (Simmons et al., 2013), we have adapted the *Forever Free* intervention for cancer patients by creating a supplemental informational and motivational video, *Surviving Smokefree*, and we are currently testing the combined intervention in an RCT (R01 CA154596). Also, in an ongoing study, we are collaborating with Robert Klesges, Ph.D., to test booklets inspired by *Forever Free* for preventing smoking relapse among US Air Force recruits following involuntary cessation during basic military training (R01 HL095785; Brandon et al., 2014). Finally, following systematic laboratory research (e.g., Simmons et al., 2004), we have developed a highly- interactive web-based intervention for college student smokers, who are loathe to participate in live, face-to-face counseling (Simmons, Heckman et al., 2013).

D1.3.1. Interventions for Hispanic/Latino Smokers. Our research team also has prior experience adapting and translating (i.e., transcreating) evidence-based self-help interventions for Hispanic/Latino smokers. Both the original relapse-prevention and pregnancy-related *Forever Free* booklets were transcreated for Spanish-speaking smokers. Our work resulted in a Spanish-language series titled, *Libres Para Siempre* (Simmons et al., 2011b) for prevention of smoking relapse among recent quitters and a second series titled, *Libres Para Siempre..por mi bebé y por mí*, (Simmons et al., 2011a) for reducing relapse among pregnant women. Both series of Spanish-language booklets have been adopted by NCI for dissemination and are available for free download at www.espanol.smokefree.gov.

Findings from the formative data we collected (Simmons et al., 2011a, 2011b) were used to inform the transcreated versions based on reported cultural experiences. For example, specific stressors mentioned by the Hispanic/Latino participants included difficulties with the immigration experience, feelings of isolation, lack of understanding of the health care system, and the use of coping strategies that often included prayer or family-oriented activities.

Therefore, these concerns and barriers were integrated into the content of the booklets. In addition, our findings were consistent with the conceptualization of cultural sensitivity-guided adaptations made at both deep and surface levels as outlined by Resnicow et al. (1999). For example, *familismo*, defined as a strong identification and attachment to the nuclear and extended family (Marin & Marin, 1991), was evident in our formative work. Specifically, participants' expressed concerns for how their smoking behavior negatively affects family members, and how quitting could be beneficial for their family (Simmons et al., 2011a). This finding was consistent with prior work revealing "family's health" as a primary motivator for quitting among Hispanic/Latino smokers (Sias et al., 2008). Thus, to enhance the cultural salience and relevance of the information presented, emerging themes such as these were used to modify the personal stories/vignettes throughout the booklets. Another finding that impacted the visual appeal and acceptability of the booklets was the suggestion to include graphics that encompass a diversity of individuals from different countries of origin (e.g., Puerto Rico, Columbia, Mexico, Cuba). Overall, the qualitative research revealed great enthusiasm and interest in the Spanish-language relapse prevention materials; however, a common theme emerged in our prior research, in which Hispanic/Latino participants expressed the value and need for personal contact (i.e., personalismo) to be made part of the intervention delivery process (Menzie, Simmons et al., in press; Simmons et al., 2011b; Litvin, Rojas, Simmons et al., 2011; Bejarano et al., 2013).

D2. Ongoing Transcreation Study

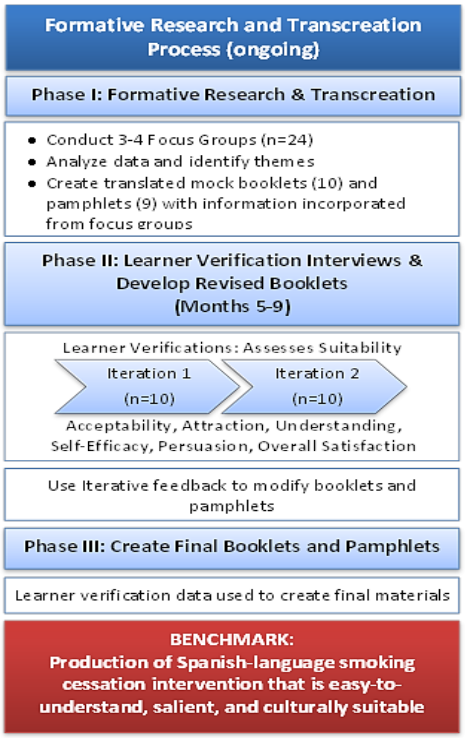
Since the original submission, we have received research funding form the Florida Biomedical Research Program which is allowing us to conduct our original Aim 1: To develop a culturally appropriate self-help intervention for racially and ethnically diverse Spanish-speaking smokers, based on the successful Stop Smoking for Good *intervention described above in*
D1.2.3. Funding began in May, 2015, and the process described below should be complete by April, 2016

The process of taking materials originally intended for an English-language audience and translating and adapting them for a Spanish-speaking Hispanic audience has been termed "transcreation" (Marcario & Boyte, 2008; Card et al., 2012; Soloman et al., 2006; Buki et al., 2009). In the development of the new Spanish-language intervention, this involves translating the existing English-language *Stop Smoking for Good* materials into Spanish and adapting the intervention for a Hispanic/Latino audience using a series of iterative procedures.

Importantly, our ongoing iterative process to transcreate the intervention parallels our previously employed methods used to develop the materials described above, and is guided by NCI's Stages in Health Communication Model (USDHSS, 2008) and the ADAPT-ITT Model (Wingood et al. 2008). We are further guided by published recommendations for the linguistic, literacy, and cultural adaptation of evidence-based interventions (Marcario & Boyte, 2008; Soloman et al., 2005; Castro et al., 2010; Barrera & Castro, 2006). For example, Resnicow et al.'s (1999) conceptualization of cultural sensitivity is guiding adaptations made at both surface and deep levels.

We are not developing a *de novo* intervention. Rather, the Spanish-language smoking cessation intervention that we are in the process of transcreating is building upon content of the existing

Figure 1



efficacious English-language intervention (10 booklets + 9 pamphlets), which is based on cognitive behavioral theory. We believe that the success of the existing intervention is largely due to its theoretical and empirical basis, so we are maintaining that evidence base for the new booklets. However, we recognize the importance of cultural adaptation to enhance receptivity and the likelihood that the materials will be used (Barrera et al., 2013).To achieve this goal, we are employing a multi-phase process to create a usable, understandable, and acceptable intervention by engaging users. (See Figure 1.)

Phase I involves formative research via focus groups to gather data on culturally relevant impediments and facilitators to achieving smoking abstinence among a diverse group of Hispanic/Latino individuals. Findings are then being used to improve the saliency of the intervention among a new group, Hispanic/Latino smokers. Consistent with our prior work, and adapted from the Brislin Model of Translation (1970), the initial development of the materials involves a bilingual/bicultural team and CAP engaging in an extensive iterative process to identify possible concepts and words that may not translate well, might be misunderstood, or be inappropriate. This entails translating the documents from the source language (English) to the target (Spanish) language, and having a second bilingual expert blindly back-translating the documents. Next, the research team and the investigators meet to discuss any differences or inconsistencies identified through the translation and back-translation processes. As a group, changes are made to ensure that the translated documents reflect cultural congruence and comparability in terms of meaning. The intervention then begins to take shape and becomes infused with the thematic findings from our qualitative work as well as relevant literature on smoking among Hispanic/Latinos.

Then, in Phase II, initial drafts of the Spanish-language materials undergo learner verification, a process to assess suitability. This approach, modeled after the work of Doak et al., (1996) strives to reduce miscommunication of messages. It involves verifying the newly translated and revised materials with the intended audience in relation to acceptability, attraction, understanding, self-efficacy, and persuasion via a series of questions relating to the elements to be verified. This procedure allows us to obtain reactions to the developing intervention materials (booklets and supportive stories) in terms of tone, character development and messaging design style so that we can make suitable adjustments. *In consideration of regional variations in language and culture, our sample will include individuals from various ethnic backgrounds and countries of origin (e.g., Puerto Rico, Guatemala, Cuba, Dominican Republic, Mexico, and Columbia).*

Through the booklets and pamphlets, we will attend to the diverse cultural backgrounds of our Hispanic/Latino audience by conveying stories and experiences with proper attention to diversity in age, generational and acculturation status, gender, and country of origin. For example, unique stressors and relapse risk factors that are revealed are incorporated into the existing content. In addition, the stories conveyed in the booklets and pamphlets (i.e., first-person narratives) develop around the cultural relevant content and areas discovered during the focus group discussions. Revisions are evaluated by the team and advisors on *importance* (degree it can enhance effectiveness), *feasibility* (ease/burden of suggestion), and *congruence* (fit with core evidence-supported components) (Chen, 2013). In summary, the transcreation process helps us achieve a balance between preservation of essential, evidence-based intervention core elements that are crucial to the intervention's effectiveness (e.g., cognitive-behavioral coping strategies) while infusing cultural relevance, and thereby enhancing appeal for the intended audience (Castro et al., 2004). The research team brings extensive experience and skill in these methods.

As when it was an aim of the original submission, the transcreation process is projected to take 12 months, with a target completion date of April, 2016. This coincides perfectly with the earliest funding start date of the present proposal, when the new intervention will be ready for testing in the RCT described next.

D3. Methods

D3.1. Design Overview. *A randomized 2-arm design, with 700 smokers recruited into each of*

the conditions will be used to test the efficacy of our Spanish-language smoking cessation intervention. The 2 conditions are: (1) Usual care (UC), which will comprise a single, Spanish-language, smoking cessation booklet developed by NCI; and (2) the Stop Smoking for Good Intervention in Spanish (SS-SP), comprising a series of 11 booklets distributed over 18 months, plus additional monthly contacts via 9 supportive pamphlets. Assessments for both groups will occur at six-month intervals, through 24 months. An overview of the design and the timing of intervention components and assessments are depicted in Table 2. All conversations with participants, informed consent, intervention materials, and assessment instruments will be in Spanish.

Table 2. Overview of Study Design: Interventions and Assessments

Month	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	24
Assessment (Both Groups)	A						A						A						A	A
Usual Care Condition	N																			
SS-SP Condition	C,X	X	X	X	O	X	O	X	O	X	O	O	X	O	O	X	O	O	X	

Legend: *SS-SP = Stop Smoking for Good Intervention in Spanish; A = Time of assessment; N = NCI booklet; C = Initial Phone Contact; X = Stop Smoking for Good booklet; O = Supportive letter and tri-fold pamphlet. L = Monthly supportive letter in Contact Control condition. Shaded areas indicate the duration of the intervention.*

D3.2. Participants and Recruitment Feasibility. *Participants will be 1400 Spanish-speaking smokers recruited throughout the mainland United States and Puerto Rico. To ensure recruitment goals are met, we have developed a broad and thoughtful recruitment strategy that will include local, state, and national efforts. Our local and state efforts will be informed by input from our community advisory panel comprised of members of the Hispanic community, as well as our existing community and research partnerships in Central and South Florida. At a national level, our recruitment efforts will be guided by our cultural advisory board members, all of whom have experience in recruiting Hispanic individuals for research studies and reside in regions of high Hispanic/Latino density (South Florida, Texas, California, New Mexico, and Puerto Rico). Our recruitment strategies will include, but are not limited to, national ads (e.g., on the Telemundo network) as well as local multimedia advertisements (Spanish newspapers, radio, and cable TV; social media, public transportation signage). These recruitment strategies mirror potential avenues for future federal or state dissemination efforts if the intervention is deemed efficacious.* To maximize generalizability, we have minimal inclusion criteria: (1) smoking ≥ 5 tobacco cigarettes/week over the past year; (2) age ≥ 18 years; (4) not currently enrolled in a face-to-face smoking cessation program; and (5) monolingual Spanish-speaking, or bilingual Spanish-English and prefer receiving educational health materials in Spanish. Initial screening will be conducted via telephone. Participants that are unable to provide a mailing address within the mainland United States or Puerto Rico, or are unable to provide a mailing address (i.e., do not have one), will be excluded from participating in the study. We will assess whether participants use any other smoking cessation services (e.g., state quitline, websites) or pharmacotherapy for analysis, but will not exclude smokers who utilize these widely available smoking cessation tools.

Inclusion criteria will be confirmed with data provided in the baseline assessment. Participants who do not meet criteria based on baseline assessment will be withdrawn. Given that participants provided responses during the initial telephone contact that met the inclusion criteria, we created rules for 4 of the 5 inclusion criteria that required strong evidence from the baseline survey for exclusion. The rules acknowledge that participants may mark unintended responses.

Exclusion criterion #1: Insufficient smoking (<5 cigs per week) or have recently quit.

Rule #1: Page 4, Item 1 response is 'I have not smoked any in the past week'

Rule #2: Page 4, Drop if 2 of the following 3 items have the marked response.

a) item 2 = 'No use in past month'

b) item 3 = 'No use in past month'

c) item 4 = 'Do not smoke'

Rule #3: Page 4, responses to items 2 & 3 show less than 5 cigs per week.

Exclusion criterion #2: Less than 18 years old.

Rules #1: Page 1, Date of birth is less than 18 from date of survey completion.

Exclusion criterion #3: Currently enrolled in an 'in-person' cessation program.

Rule #1: From Quit Aids section on page 10, marked 'Currently Use' for In-person counseling or support program.

Participants will be randomized into the two arms (700 each) using balanced-permuted block, stratified by: sex, smoking rate (daily vs. non-daily smoking), and income (household income < $10,000). We are stratifying on income based on previously observed treatment effects for our self-help interventions that were moderated by income. Specifically, low-income participants derived greater benefit from the intervention (Brandon et al., 2012). Our smoking inclusion and stratification criterion are based on research demonstrating higher rates of non- daily and light smoking (e.g., less than 10 cigarettes per day) among Hispanic/Latinos (e.g., Kaplan et al., 2014, Okuyemi et al., 2002) and that different reasons for smoking exist among Hispanic/Latinos based on smoking level (Pulvers et al., 2014). To minimize treatment contamination, participation will be limited to one participant per household address.

We believe that it is feasible to accrue the target N of *1400* in the *20 months* allocated for accrual. In the previous self-help cessation study (D1.2.3), we successfully recruited 1874 smokers over the course of 16 months. Although the current study will be limited to Spanish- speaking smokers, which is a smaller population base, it is substantial and growing. Because all contact with participants will be by telephone, internet, and mail, we are not geographically limited and are thus able to recruit participants throughout the country. The rate of accrual is limited only by the amount of advertising, staffing levels, and logistic requirements of screening callers and processing baseline data. We have a history of meeting our accrual goals with high rates of participant retention in trials, even with particularly hard-to-reach low-income populations that required adjustments to accrual strategies. Most notably, we have recruited participants from a much smaller segment of the population: 700 women in months 4-8 of their pregnancy who had already quit smoking and were interested in relapse-prevention assistance (Brandon et al., 2012; Lopez et al., 2008). We also have a history of recruiting Hispanic/Latino smokers (Simmons et al., 2011a, 2011b). Moreover, as noted above, recruitment feasibility will be boosted by the assistance of our CAB members strategically located throughout the country.

D3.3. Study Arms

In this section, we describe the rationale and form of the two intervention conditions.

Note that in addition to hard copies of the intervention materials, participants in both conditions will have the option to also receive electronic versions via a link to a website managed by Moffitt Cancer Center's Survey Methods Core.

D3.3.1. Stop Smoking for Good Intervention in Spanish (SS-SP). This condition will comprise the 11 *Stop Smoking for Good* booklets and 9 supportive *My Story* pamphlets transcreated for Spanish speaking smokers to be delivered over 18 months (see Table 2).

Consistent with the recommendations of the USPHS Clinical Practice Guidelines (Fiore et al., 2008), our prior formative work with Hispanic/Latino smokers and Hispanic/Latino health care providers (Simmons et al., 2011a; 2011b; Bejarano et al., 2013) identified high degrees of interest and enthusiasm for self-help smoking intervention materials to be available in Spanish. Additionally, a reoccurring emergent theme among Hispanic/Latino participants was a desire for some form of personal contact to be provided along with the booklets. To satisfy this identified need, while maintaining dissemination and reach potential, we have added a single, brief telephone contact to this condition. This telephone contact will be timed to occur when the participant is due to receive the first *Stop Smoking for Good* booklet. The aim of this 10-minute call will be to build rapport and to provide a personal connection to garner trust and credibility in the intervention. During the call, we will briefly present the rationale for the intervention and offer suggestions for intended use of the intervention materials. If effective, this intervention could blend seamlessly into existing telephone Quitline services.

D3.3.2 Usual Care (UC). This condition will comprise a single, high-quality booklet that is currently in wide-dissemination and was developed by the National Cancer Institute: *Viva de forma más*

saludable para usted y su familia, deje de fumar hoy mismo (Live Healthier for You and Your Family, Quit Smoking Today; NCI, 2011). This is a comprehensive 40 page Spanish- language booklet with high quality content and visual presentation. We chose to use credible usual care as a comparison condition rather than a no-treatment control for two reasons. First, when using a reactive recruitment strategy that publicizes an offer of cessation assistance, we believe that there is an ethical obligation to provide at least high quality usual care to all participants. Second, it is simply more meaningful to evaluate a novel self-help intervention (our *Stop Smoking for Good* booklets) against an existing credible intervention. To have any public health significance, the new intervention must demonstrate greater efficacy than an existing, less intensive intervention. **In summary, the UC control condition enhances the <u>external</u> validity of the study by providing a comparison to an existing, credible intervention that a smoker could receive in a medical setting or elsewhere.**

D3.4. Assessments

As Table 2 indicates, assessments will occur at baseline and at 6-month intervals thereafter, through 24 months. Assessments will be conducted as we have before (Brandon et al., 2000, 2004), via the mail, with an internet option. A tension inherent in clinical trials, particularly trials of minimal interventions for behavior change, involves balancing the value of assessment against the risk of reactance effects. This is a concern in the current study because we posit that contact contributes to treatment effects. Moreover, assessment of specific domains may influence those very domains. For example, assessment of coping skill usage is itself a reminder to use coping skills. Finally, participants who enroll in studies of minimal interventions often will reject the burden of a heavy assessment load, increasing attrition and reducing generalizability. Therefore, in our self-help studies, we aim to keep both the frequency and magnitude of assessments to the minimum required to meet the specific aims. Compared to our traditional treatment studies, we must be more selective in choosing instruments to administer in our self-help studies, and we limit assessments to 6-month intervals.

All assessments will be conducted in Spanish. When existing Spanish-language versions are unavailable, they will be created by a certified translator, with verification via back- translation, and then provided to a small sample (N = 6) of representative men and women from Hispanic/Latino subgroups for key informant cognitive interviews to ensure that the instruments are "grounded" in accord with the capabilities of our population of interest (Jones et al., 2001). When Spanish-language versions of proposed measures exist, but they had not been developed and validated with diverse Hispanic/Latino populations, we will engage in a similar process to verify that the Spanish is understandable to individuals from different countries of origin.

D3.4.1. Assessment Instruments.

<u>Initial Telephone Contact</u>. When smokers call the toll-free phone number in response to recruitment efforts, the Spanish-speaking telephone operator will collect basic demographic information, a brief smoking history, and screen for the inclusion criteria.

<u>Baseline Assessment</u>. Smokers who meet inclusion criteria and provide initial verbal consent over the telephone will be sent a bound set of baseline Spanish-language questionnaires. The following questionnaires will be included: (1) a demographic (age, sex, socioeconomic status [measured by education, household income, number of members in household and debt level (Chiang & Borrelli, 2014)] country of origin, generational status, years living in the US, etc.) and smoking history questionnaire, including electronic cigarette use and quitting aids use. The Spanish-validated Fagerström Test for Nicotine Dependence (Becoña & Vazquez, 1998) will be administered. The FTND is the standard, validated, instrument to assess nicotine dependence. (2) an 11-point measure of readiness to quit, the Contemplation Ladder (Biener & Abrams, 1991). (3) the Stages of Change Algorithm (SOC) translated in Spanish (Becoña & Lorenzo, 2004). Although this algorithm lacks some of the psychometric advantages of the Contemplation Ladder and it produces a different distribution of quitting motivation (Nath et al., 2002), it is widely used, and its inclusion allows for comparisons with other published studies. We will also administer the brief measure of abstinence-related motivational engagement (Simmons et al., 2010) and two other motivation- related constructs: a situation-specific abstinence self-efficacy scale (Velicer et al., 1990); and a measure of smoking expectancies that has been validated among Spanish-speaking Latino smokers, the Smoking Consequences Questionnaire-Spanish (SCQ-Spanish; Irvin Vidrine et al., 2009; Reig-Ferrer & Cepeda-

Benito, 2007). Four subscales will be administered (negative affect reduction, craving/addiction, health risks, negative physical feelings). The Short Acculturation Scale for Hispanics (SASH; Marin et al., 1987) will be administered to assess level of acculturation. The SASH has demonstrated high reliability across Hispanic/Latino subgroups (Kaplan et al., 2014). In addition, we will assess level of familism using the Attitudinal Familism Scale (Steidel & Contreras, 2013). Finally we will administer the trait version of the Spanish Positive and Negative Affect Schedule (SPANAS; Joiner et al., 1997; from Watson et al., 1988), which has been validated in younger and older populations (Buz et al., 2015; Ortuño-Sierra et al., 2015). These measures of demographics, motivation, mood, acculturation, and familism will be tested as potential moderator variables (Secondary Aim).

Follow-Up Assessments. Participants will be sent follow-up assessment packets (by mail or e-mail link, as per their preference) at six-month intervals through 24 months, as indicated in Table 2. This follow-up duration provides for an assessment of smoking outcomes 6 months beyond the final mailing of the SS-SP intervention materials. These brief assessments are intended to minimize participant burden and consequent attrition and will include a questionnaire assessing tobacco use since the previous contact, as well as any pharmacotherapy or other smoking cessation assistance. We also will assess participants' use and evaluation of the self-help materials, using the eight-item Client Satisfaction Questionnaire developed in Spanish (Roberts et al.,1984) plus additional items to distinguish the benefits of the content and the repeated contact. To assess the impact of the smoking cessation intervention on health outcomes, we will use the Spanish version of the SF-12 health survey (Vilagut et al., 2008; Ware et al., 1995), which will be included in the 18 month and 24 month follow-up assessments. We will also administer the trait version of the SPANAS at 18 month and 24 month follow-up. Research staff will attempt to contact participants to complete any missing data on the completed baseline and follow-up assessments. To biochemically confirm self-reported abstinence, we will travel to participants residing within 75 miles of our laboratory to collect breath and saliva samples. At the 12 and 24 month assessments, an alveolar carbon monoxide (CO) sample will be collected, using a cut-off of 4 ppm (Cropsey et al., 2014). (see D3.6.) Due to higher than expected disconfirmation rates at the 12 month follow-up, we have elected to add an additional marker of smoking abstinence. Cotinine measurements, collected via saliva, provides an approximation of nicotine over a more extended period of time and is less influenced by environmental exposures and other forms of smoking (i.e., marijuana smoking). At the 24 month assessment, in addition to the breath sample, a saliva sample will be collected, using a cut-off of 10ng/ml (Benowitz et al.,2002). To collect biosamples, a researcher will make an appointment to visit the participant at home, work, or other location for a face-to-face interview. Participants will be compensated $20 for completing the interview and providing a breath and saliva samples. Participants will also be provided with the option of coming to the lab to complete the face-to-face interview, and if they elect to do so, they will receive an additional $20. During the interview, the researcher will obtain consent to collect the breath sample. The breath sample will be collected with a portable CO monitor (Micro CO™ by Micro Direct, Inc.), and the saliva sample will be collected in a 2ml tube for immediate cotinine analysis using the NicAlert™ dipstick by Nymox.

Participant Payment and Retention Procedures. We have developed a series of steps to minimize attrition in our prior longitudinal self-help studies (Brandon et al., 2000, 2004). As an incentive, we will pay participants a $20 gift card for completing each assessment packet, and also send participants a pre-selected gift (e.g., stylus pen, nail file, etc.) valued at approximately $1 if they return the forms within one week. In addition, participants will be told that they will receive a bonus payment of a $50 gift card if they complete all 5 assessments. Questionnaires will also be constructed in a manner to maximize participation (Dillman, 1991). Other procedures to reduce attrition include reminder phone calls, emails, text messages, and letters. We will also ask participants at baseline to supply the name and telephone number of a relative or significant other we can call if we lose contact with the participant. This will aid in reaching participants who move or change phone numbers.

If participants are unable to be reached using the retention procedures described above, additional methods of contact will be attempted:

1. Internet databases: If mail has been returned to us, indicating that we have a wrong address or the participant has moved, several free and paid services will be used to locate participants. Websites will include whitepages.com, smartpages.com, and Yahoo! People (people.yahoo.com). These services will allow us to search for individuals by name, address, and phone number. We will be able to verify whether or

not participants are in the armed forces, incarcerated, or have passed away by using Military.com and state websites like Florida.gov.

2. Facebook: If all avenues of contact have been exhausted, we will utilize the social media platform 'Facebook' in an attempt to contact participants.

Facebook Protocol

A Facebook account will be opened under the study name '*Libre del Cigarrillo*.' The profile will contain the study and Moffitt Cancer Center logo, along with a paragraph briefly describing the study. Facebook searches will be initiated using the participant's first and last names. If the first and last names result in a match, we will attempt to further verify we have identified the correct individual by confirming 'current city', 'age', or 'email address'. When we are confident that we have identified the right individual, we will use the internal messaging system of the Facebook platform. An initial message will be sent to the individual asking if they are participating in *Libre del Cigarrillo*. The message will emphasize that we have exhausted all other means of contact, provide our telephone number and email address, and request that the individual contact us or reply via the internal messaging system regarding their willingness to update their contact information and continue their participation in the study. The message will apologize in advance for possibly contacting the wrong individual. If this was the case, we will additionally request that they simply reply with this respect to ensure they are not to be contacted in the future. If the user does not reply, another message will be sent 14 days later.

D3.4.2. Outcome Variables. At each assessment point we will calculate 7-day point- prevalence abstinence rates. Point-prevalence measures are best for capturing the dynamic nature of cessation, maintenance, and relapse. Continuous abstinence is not feasible because quit dates will be highly variable across participants, and also because one goal of the intervention is to encourage lapsers to quit again (recycle). We need our outcome measures to reflect these changes in smoking status over time. We will also compare groups on continuous measures such as current smoking rate (cigarettes/day), months of smoking during the follow- up period, length of current abstinence period, and latency from quit date to relapse. Data will be analyzed following multiple imputation (see below). *Finally, we will calculate the cost per participant of each intervention, and then incremental cost-effectiveness ratios, using Usual Care as the reference, to determine the cost per quitter. These statistics will facilitate economic comparisons with other cessation interventions.*

D3.5. *Study Timeline*

Month	Activity
1 – 3	Hire and train staff; build database program; work with CAB and CAP to develop targeted recruitment plan and create advertising copy; translate assessment instruments; print intervention materials.
4 – 23	Accrue sample and begin distribution of interventions and follow-up assessments.
24 – 53	Continue Follow-up Assessments and prepare mid-term reports.
54 – 60	Complete final data analysis and prepare reports.

D3.6. Design Considerations

In this section we briefly address our rationale for a few important study-design decisions.

Should biochemical verification be employed? The decision regarding inclusion of biochemical verification (e.g., saliva, serum, or urine cotinine; breath carbon monoxide) of self- reported smoking status is complex (Benowitz et al., 2002). Considering the low-intensity nature of the intervention, that assessments will be done by mail/internet, and there should be little differential in social-desirability demand across conditions, we concluded, consistent with Benowitz et al. (2002) and Velicer et al. (1992) that bio-verification of the full sample is not warranted. Moreover, the cost of bioverification for a study of this size and geographic distribution would be prohibitive. In two prior studies, we conducted unannounced CO tests of 64 participants who self-reported abstinence at follow-up and who resided within 50-75 miles of our laboratory. Findings were consistent with self-reports for all but one participant. *We will use this same*

strategy to collect CO and saliva from a sample of participants residing within 75 miles at the 12 and 24 month follow-up points. In the unlikely possibility that we find nontrivial disconfirmation rates, we will use the data to adjust our outcome estimates.

Should pharmacotherapy use be an exclusion criterion? Excluding smokers who report using any pharmacotherapy would allow for a "cleaner" test of the self-help interventions per se. However, we ultimately decided against this exclusion criterion for the following reasons:
(1) It would reduce the ecological validity of the study, because pharmacotherapy is readily available to smokers and is likely to be used by many smokers in the population to which we wish to generalize; in fact, the *Stop Smoking for Good* booklets and supportive pamphlets themselves discuss pharmacotherapy options. (2) It would cause us to reject or drop a significant proportion of participants, necessitating a much larger initial sample size and a study of longer duration. Instead, we will assess pharmacotherapy use (as well as electronic nicotine delivery systems [i.e., e-cigarettes]) at each assessment and we will examine their contribution statistically.

C.7.1. ***Should materials be distributed only via the Internet or mobile modality?*** We propose to give participants an option to receive intervention materials electronically (via emailed link) in addition to printed "hard copies" delivered by the US Postal Service. Internet- only distribution would have the advantage of reduced cost and easier eventual dissemination (c.f.,Marcus et al., 2007). However, there are also advantages of tangible, printed intervention materials (Curry et al., 2003), and this was the modality that showed substantial efficacy in our prior studies, including the English-language version of the proposed intervention. A written intervention is also particularly useful for low-income individuals who may experience barriers to access of technological modalities. Rather than introducing additional variation, we feel that priority should be given to testing the booklets in their present form. Nevertheless, we will track use of the Internet option and include it as an exploratory moderator variable in analyses. We will collect metadata regarding use of the internet-based documents, namely how many times the link was accessed, and whether the electronic booklet(s) were downloaded, which will allow us to document their use and acceptability. We will also collect evaluations and preferences regarding internet distribution at follow-up to test as potential moderators or mediators of treatment effects. This information should assist us in deciding whether to transition fully to internet-based or mobile content (i.e., smart-phone/tablet apps) distribution in the future.

D3.7. Data Management and Analysis

D3.7.1. Data Management. Participant recruitment and contact information will be input through screens created by the Data Systems Team within Moffitt's Research Computing Support Group (Research IT) and will be subject to computerized range and consistency checks. The data will then populate an Access database, which will also be created and maintained by Research IT. This process will be supervised jointly by the PI and Study Data Manager/Biostatistician. Paper-and-pencils surveys will be entered into database files with computerized range and consistency checks. Online surveys will have range checks built into the survey items, as appropriate. The survey databases will be converted on a monthly basis to an analysis database. This analysis database and SAS version 9.4 (SAS Institute, Cary, NC) will be used by the statistician who will provide the PIs with reports and summaries on a regular basis and perform the final analyses.

D3.7.2. Sample Size and Study Power Analysis. The primary statistical analyses will assess the efficacy of the full intervention (SS-SP) in producing smoking cessation compared to Usual Care (UC) in two ways: (1) across all 4 follow-ups using generalized estimating equations (GEE), and (2) at the 24-month follow-up using logistic regression. The estimated 7-day point prevalence abstinence rates for this study were based on the cessation study (C1.2.3, Table 1) with an adjustment of 0.625 standard error units to decrease group differences. For the four follow-ups, the estimated abstinent rates are 12.3%, 15.2%, 19.1%, & 19.8% in the UC condition and 15.2%, 23.0%, 26.9%, & 28.8% in the SS-SP condition. Power was targeted to be > .80 with alpha=.05 and a 2-sided test. Using GEESIZE version 3.1 (Rochon, 1998; Dahmen 2004) with an AR(1) working correlation structure and coefficient of 0.7, sample size was estimated at 322/group for the GEE analyses. For the logistic regression at 24 months, sample size was estimated at 365/group. All analyses will be completed following multiple imputation to manage missing data (below). Therefore, no adjustments of

enrollment size will be needed to account for attrition. The final sample size for analyses was rounded up to 370 per group. An additional 500 participants will be recruited from the state of Florida.

We initially planned to enroll 1240 individuals, 740 nationally and 500 in Florida. However, due to higher-than-expected attrition, we are increasing our overall sample size to 1400 individuals, 850 nationally and 550 in Florida.

D3.7.3. Data Analysis Overview. Analyses will be conducted with SAS version 9.4 and Mplus Version 7 (Muthén & Muthén, 2008). Frequency distributions and contingency table analyses will be used as a point of departure for more advanced analyses. Group differences in baseline measures will be assessed and any variable that exhibits a significant group difference will be incorporated into the primary analyses.

To manage missing data, multiple imputation under the Missing at Random assumption will be applied using a Markov Chain Monte Carlo method (Schafer, 1997) via PROC MI in SAS, given the expected large number of non-monotonic missing data patterns and the expected large number of auxiliary variables (e.g., baseline measures that predict smoking status at follow-up) to be determined by preliminary analyses. A post hoc approach (Rubin, 1987) will address the influence of Missing Not at Random (MNAR) on smoking status (i.e., missing is due to smoking). Sensitivity analyses will be performed by comparing results from different multiple imputation data sets that were generated using different levels of MNAR influence.

D3.7.4. Analytic Plan for Addressing Specific Aims. All analyses will be performed on complete data sets following multiple imputation using all *1400* participants.

Specific Aims 1 . All analyses will be performed on complete data sets following multiple imputation. Generalized estimating equations (GEE) will be used to fit population-averaged models of the longitudinally measured 7-day point prevalence, with the main covariates of intervention condition (UC vs. SS-SP), time (months from baseline), and the interaction of condition and time. The GEE analysis will allow for assessment of changes in abstinent rates over time and group differences in changes. Logistic regression will be used to assess condition differences at the 24-month (final) follow-up, which is 6 months after the SS-SP intervention. In both the GEE models and logistic regression, potential confounding variables (e.g., group differences on demographic variable) that appear despite randomization will be included.

Secondary Aim. The secondary aim is to assess prospective moderators of the expected intervention effect (e.g., gender, SES, quitting motivation, nicotine dependence, *country of origin*, acculturation, *trait affect*, self-efficacy). Each moderator will be assessed individually within a logistic regression for the 24-month assessment and within a GEE model by adding the moderator and the interaction term for the moderator and condition. The GEE models will also include interaction terms for the moderator with time and with the time x condition interaction.

Significant interaction terms in a GEE model will be further explored using time-specific analyses. Significant interaction terms for the logistic regression at 24 months will be explored by assessing condition differences for each level of categorical moderators.

D8. Public Health Impact

The proposed research will test the efficacy a culturally-appropriate, Spanish-language version of a previously validated self-help intervention for tobacco dependence—the leading preventable cause of death and disability. If demonstrated efficacious, this research will improve the availability and delivery of smoking cessation assistance to a large underserved population of Spanish-speaking individuals throughout the country. This study responds to Healthy People 2020 goal TU-5.2 (*Increase recent smoking cessation success by adult smokers using evidence-based strategies*; USDHHS, 2014) and corresponds to the HHS Action Plan to Reduce Racial and Ethnic Health Disparities (USDHHS, 2011) Strategy IV.B (*Conduct and support research to inform disparities reduction initiatives*) and Action III.A.4 (*Reduce tobacco- related disparities through targeted evidence-based interventions in locations serving racial and ethnic minority populations*). Moreover, the intervention corresponds to the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (USDHHS, 2013). The intervention is expected to be efficacious, cost-effective, and easily disseminated.

As such, it would be attractive to both public and private stakeholders and health care services. By expanding the reach of evidence-based treatments for tobacco dependence, this line of research contributes to reducing the health and economic burden of tobacco at the individual and societal levels.

Protection of Human Subjects

1.RISKS TO HUMAN SUBJECTS

a. Human Subjects Involvement, Characteristics, Design

Participants *(N = 1400)* will be randomized to one of two smoking cessation interventions, *with 700 participants randomized to each condition.* The Stop Smoking for Good intervention in Spanish condition is comprised of a series of 10 booklets distributed over 18 months, plus additional monthly contacts via supportive pamphlets. The Usual Care condition will comprise a single, Spanish-language, smoking cessation booklet developed by the National Cancer Institute (NCI). All participants will complete five assessments comprised of self-report questionnaires: a baseline assessment and four follow-up assessments occurring at six-month intervals, through 24 months. Participants will be paid a $20 gift card for completing each assessment and a bonus payment of a $50 gift card if they complete all 5 assessments.

The subject population for the study will be comprised of male and female adult smokers recruited from the community and throughout the country via a variety of advertising methods.

Inclusion criteria will include: 1)18+ years of age; 2) monolingual Spanish-speaking, or bilingual Spanish-English and prefer educational health materials in Spanish; 3) have been smoking at least 5 cigarettes per week over the past year; and 4) not currently enrolled in a face-to-face smoking cessation program. Initial screening will be conducted via telephone. Inclusion criteria will be confirmed with data provided in the baseline assessment. Participants who do not meet criteria based on baseline assessment will be withdrawn. We will assess whether participants use any other smoking cessation services (e.g., state quitline, websites) or pharmacotherapy so that we can examine their impacts statistically, but we will not exclude smokers who utilize these widely available smoking cessation tools. To minimize treatment contamination, study participation will be limited to only one participant from each household address.

b. Sources of Research Material (to be used for research purposes only)

Questionnaires measuring sociodemographic characteristics, smoking history, current smoking status, motivation to quit smoking, acculturation, and evaluation of the program. Confidentiality will be maintained by using participant ID numbers on questionnaires, rather than names. *All assessment instruments will be in*

Spanish. Breath and saliva samples to be analyzed for carbon monoxide and nicotine from a subsample (i.e., participants residing within 75 miles of the laboratory) of participants at follow-up.

c. Potential Risks

Risks are judged to be extremely minimal. The interventions are minimal, self-help approaches, and the assessment is all self-report. The only potential risk involves confidentiality and loss of privacy related to the information provided during telephone screening and written assessments.

2.ADEQUECY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

These studies do not involve any deception. Participants will be recruited from the community and throughout the country through multimedia advertisements (Spanish newspapers, radio, cable TV, social media, public transportation signage) and community partnerships.

Eligibility Screening:

When smokers call the toll-free phone number in response to the advertisements or other recruitment efforts, the telephone operator will collect basic demographic information, a brief smoking history, and screen for the inclusion criteria. *All conversations will occur in Spanish*. Eligible participants will be sent a baseline questionnaire. The baseline questionnaire will include an introductory cover letter that contains a written explanation of the study and includes all the required elements of the informed consent. *All written materials will be in Spanish*.

Description of Informed Consent Process:

All participants will have the study explained to them in full by a member of the research team including an explanation of risks and benefits and confidentiality of the collected information, including that data will be shared with investigators and the Moffitt Cancer Center. They will be informed about all of the procedures involved in the study as well as participation duration and compensation. Participants will be informed that they can freely withdraw from the study at any time without penalty. All potential participants will be given an opportunity to ask questions prior to providing consent. *All conversations will occur in Spanish.*

Data collection will be conducted entirely via telephone, mail, and/or internet, and recruitment will occur throughout the country, thus we will request a waiver of written informed consent documentation (based on practicality and minimal risk), which has been granted by the IRB for the previous self-help intervention studies. Initial verbal consent will be obtained over the telephone after the telephone operator describes the study, explains that participation is voluntary, and that there is no penalty for non-completion of the study (i.e., for not returning questionnaires). In addition, operators will describe compensation, risks and benefits to participation, and confidentiality of the collected information. Callers will be given the opportunity to ask any questions prior to giving their verbal informed decision. In addition, the baseline questionnaire will include an introductory cover letter that contains a written explanation of the study and includes all the required elements of informed consent. The letter will explain that returning the completed baseline questionnaire will be considered their provision of informed consent. Return of the baseline questionnaire by participants will signify agreement to participate and formal enrollment into the clinical trial. *All conversations and documents will be in Spanish.*

b. Protections Against Risk

Potential risks involve confidentiality and loss of privacy because participants may provide personal information about themselves on questionnaires. To minimize potential risks all research assistants will receive training in research ethics. Confidentiality will be maintained by using participant ID numbers on data, rather than participants' names. Participant data will be kept separate from the identifying information. Demographic information with identifying information will be kept in a locked file cabinet separate from study data with ID numbers.
Participant data will be available only to research staff. Data will be kept in locked filing cabinets in locked laboratory rooms. Electronic data will be stored in a password-protected database. All results from the study will be published in aggregate form, and individual identifying information will not be reported. All participants will be fully informed that participation is voluntary and they may withdraw from the study at any time without penalty.

3.POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN SUBJECTS AND OTHERS

The potential risks are judged to be very minor. The main benefit to participants is that it may increase the odds of them quitting smoking and remaining abstinent. In addition, they are participating in research that may lead to the future dissemination of interventions to help Spanish-speaking smokers to stop smoking.

4.IMPORTANCE OF KNOWLEDGE TO BE GAINED

The goal of the proposed research is to increase the reach of smoking cessation treatment to Hispanics, the largest and fastest growing minority population in the US. Currently, few cessation interventions exist specifically for Spanish-speaking smokers. The proposed research study has the potential to yield a cost-effective smoking cessation intervention designed specifically for Spanish speaking smokers. If the Spanish-language intervention is efficacious, it has potential to have significant public health impact with respect to reducing smoking rates and smoking related illness and mortality among a large underserved minority population in the US.

5.DATA SAFETY AND MONITORING PLAN

Overview

This is an extremely minimal risk study. Nevertheless, the principal investigators, Drs. Brandon and Simmons, will implement a DSMP to ensure that the expected risk/benefit ratio is maintained throughout the study and that the confidentiality and accuracy of the data are preserved. All members of the study team will receive formal training in research ethics and HIPAA procedures through the University of South Florida IRB, as well as study-specific training provided during research team meetings. The study team will meet weekly to discuss study progress, including participant recruitment and retention, data management, any participant complaints, and confidentiality issues. In addition, study progress will be tracked by Moffitt Cancer Center's Protocol Review and Monitoring Committee (PRMC). The probability of an adverse event occurring in this study is extremely low, given the nature of the study. However, as per IRB policy, any serious or unexpected adverse events will be reported promptly (within 2- 5 business days, depending on the nature of the event) to the IRB and the PRMC. A summary of the adverse events that occurred during the previous year will be included in the annual progress report to NIH.

Description of the Protocol

We propose a two-arm randomized design. Participants (N =1400) will be randomized to one of two smoking cessation interventions. The Stop Smoking for Good intervention in Spanish (SS- SP) condition is comprised of a series of 10 booklets distributed over 18 months, plus additional monthly contacts via supportive pamphlets. The Usual Care (UC) condition will comprise a single, Spanish-language, smoking cessation booklet developed by the National Cancer Institute (NCI). Specific Aim 1 will test the efficacy of a Spanish-language extended self-help intervention compared to usual care. As a secondary aim, we will evaluate moderator variables that may aid in refining and targeting of the intervention to maximize impact.

Primary and Secondary Outcome Measures

At each assessment point we will calculate 7-day point-prevalence abstinence rates. Point- prevalence measures are best for capturing the dynamic nature of cessation, maintenance, and relapse. Continuous abstinence is not feasible because quit dates will be highly variable across participants, and also because one goal of the intervention is to encourage lapsers to quit again (recycle). We need our outcome measures

to reflect these changes in smoking status over time. We will also compare groups on continuous measures such as current smoking rate (cigarettes/day), months of smoking during the follow-up period, length of current abstinence period, and latency from quit date to relapse. *Finally, we will calculate the cost per participant of each intervention, and then incremental cost-effectiveness ratios, using Usual Care as the reference, to determine the cost per quitter. These statistics will facilitate economic comparisons with other cessation interventions.*

Inclusion/exclusion Criteria

1)18+ years of age; 2) monolingual Spanish-speaking, or bilingual Spanish-English and prefer educational health materials in Spanish; 3) have been smoking at least 5 cigarettes per week over the past year; and 4) not currently enrolled in a face-to-face smoking cessation program. We will assess whether participants use any other smoking cessation services (e.g., state quitline, websites) or pharmacotherapy so that we can examine their impacts statistically, but we will not exclude smokers who utilize these widely available smoking cessation tools. To minimize treatment contamination, study participation will be limited to only one participant from each household address.

List of Participating Data Collection Centers

Tobacco Research and Intervention Program at the H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida.

Data Acquisition and Data Entry

Participants will be randomized into the two arms (700 each) using balanced-permuted block, stratified by: sex, smoking rate (daily vs. non-daily smoking), and income (household income < $10,000) and data will be collected via (1) paper and pencil measures or (2) secure internet websites managed by Moffitt's Survey Core. Data from paper and pencil measures will be input through screens created by the Data Systems Team within Moffitt's Research Computing Support Group (Research IT) and will be subject to computerized range and consistency checks. The data will then populate an Access database, which will also be created and maintained by Research IT. This process will be supervised jointly by the PI and Study Data Manager/Statistician. The database will be converted on a monthly basis to a SAS database (SAS Institute, Cary, NC). This database and SAS will be used by the statistician who will provide the PI with reports and summaries on a regular basis and perform the final analyses.

To ensure participant confidentiality, baseline and follow-up assessment data will not include any unique identifiers.

Quality Assurance Plan

Validity checks of data values and ranges will be conducted upon data entry and again prior to analysis. Data entered by staff will be double-entered and compared for inconsistencies.
Online surveys will have range checks built into the survey items, as appropriate.

Reporting of AEs/SAEs

This is an extremely minimal risk study and Adverse Events as a direct result of study participation are not anticipated. Nevertheless, the study PIs and Project Director will review Adverse Events. Adverse Events will be reported in accordance with the IRB and Sponsor requirements. Any serious, related adverse events (and unanticipated) will be reported within two days (48 hours) to the IRB and to the designated Project Officer at NCI using the required reporting formats. Given the low-risk nature of the proposed research, this is considered an extremely remote possibility. Any IRB actions in relation to this protocol will also be reported to NIH/NCI. We do not anticipate any circumstances that would necessitate early stopping of this minimal-risk study.

Report of Changes or Amendments to the Protocol

All changes to the protocols will be submitted and reviewed by the Moffitt Cancer Center Scientific Review Committee and the Institutional Review Board prior to implementation. Major changes that affect the specific aims will reported to NCI for pre-approval. Other significant changes will be reported to NCI via the annual reports.

Trial Stopping Rules

Given the nature of the intervention under study (i.e., informational booklets and pamphlets), we do not anticipate any circumstances that would call for premature stoppage of the trial.

Conflict of Interest

All key personnel comply with federal and institutional conflict of interest reporting requirements.

Potential Risks and Benefits for Participants

The potential risks are judged to be extremely minor. The main benefit is that participants may receive information to help them quit smoking and maintain abstinence. In addition, they are participating in research that may lead to the future dissemination of interventions to help Spanish-speaking smokers to stop smoking.

Collection and Reporting of AEs and SAEs Management of

SAEs or other study risks See “Reporting of AEs/SAEs,”

above.

Plans for Interim Efficacy Analysis

We do not plan interim efficacy analysis.

Responsibility for Data and Safety Monitoring

The study data manger/statistician will have primary responsibility for data monitoring, and the project director will have primary responsibility for safety monitoring. Both will report to the MPIs, who will have ultimate responsibility over both areas.

Frequency of DSM Reviews

DSM reviews will take place on an ongoing basis during the weekly project meetings.

Content of DSM Report

Any DSM-related issues will be included in the minutes of the weekly project meetings.

DSM Board

Not applicable

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