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Culturally relevant acceptance-based telehealth wellness program for Latine adults who smoke and experience psychological distress: Findings from a feasibility study

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ABSTRACT

Latine adults who smoke have a low probability of receiving evidence-based smoking cessation interventions. Acceptance and Commitment Therapy (ACT) has shown to be efficacious for treating tobacco dependence, but its usefulness for Latine populations is just emerging and has not been studied in the context of a culturally tailored treatment. This single-arm study evaluated the feasibility of recruitment and retention, and treatment acceptability of the PRESENT Wellness Program: a culturally relevant ACT-based smoking cessation treatment for Latine adults who also experience psychological distress. Secondary objectives were the examination of smoking rates and levels of depression, anxiety, and psychological inflexibility (ACT core target) among Latine adults. Taking place during the COVID-19 pandemic, the treatment entailed 8 sessions delivered via telehealth (1 in-person/video and 7 by phone), and nicotine patches. Participants (N = 23) completed baseline assessments and follow-ups 1-week post-end of treatment (EOT) and 2-months post EOT. Most participants were women (70%), ranging from young adult to middle-aged, born in the US (57%), working full time (52.2%), and reporting financial strain (70%). Average number of sessions completed was 5.5. Follow-up rates were 61% at both follow-ups. The program was acceptable as indicated by quantitative and qualitative measures. Point-prevalence smoking abstinence was 35% at both follow-ups. Participants reported an average decline across time [% or M(SD)] in all secondary measures, as follows: everyday smoking [Baseline = 87%; 1-wk post EOT = 13%; 2 mo post EOT = 8.7%]; depression [Baseline = 13.7(6.3); 1-wk post EOT = 9.9 (6.6); 2 mo post EOT = 7.4 (5.8)]; anxiety [Baseline = 12.7 (5.4); 1-wk post EOT = 9.7 (6.4); 2 mo post EOT = 8.1 (5.2)]; and psychological inflexibility [Baseline = 50.6 (7.2); 1-wk post EOT = 33.0 (10.7); 2 mo post EOT = 32.6 (12.4)].
Conclusion: The current study observed that implementation of an acceptance-based smoking cessation treatment delivered in a hybrid mode is feasible and acceptable for English-speaking Latine persons. The PRESENT Wellness Program shows promise to address smoking and behavioral health challenges in the Latine community. Replication and expansion of the study is warranted, including the linguistic adaptation and evaluation of the program among Spanish-preferring Latine persons who smoke.

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1. Introduction

Individuals with behavioral health disorders are more than twice as likely to smoke cigarettes compared to their counterparts without a behavioral health condition; and they are more likely to die from smoking-related illness than they are from their behavioral health challenges (Centers for Disease Control and Prevention, 2013; Prochaska, Das, & Young-Wolff, 2017). Beyond specific diagnoses, serious psychological distress has been linked to smoking status. The prevalence of serious psychological distress is higher among people who currently smoke (including non-daily) compared to those who formerly smoked and never smoked; and there has been an increase in psychological distress overtime among individuals who smoke, including those smoking occasionally (Zvolensky, Jardin, Wall, et al., 2018). Anxiety and depressive disorders, two common causes of psychological distress, are more common among people who smoke compare to those who do not smoke (Ziedonis, Hitsman, Beckham, 2008; Lasser, Boyd, Woolhandler et al., 2000) and have been shown to be a risk factor for cessation failure [Burgess, Brown, Kahler, et al., 2002; Kahler, Brown, Ramsey, et al., 2002; Piper, Smith, Schlam, et al., 2010; Piper, Cook, Schlam, et al., 2011; Blalock, Robinson, Wetter, et al., 2006; Zvolensky, Gibson, Vujanovic, et al., 2008).

Similar to other racial/ethnic groups, associations between daily smoking and behavioral health challenges, such as depression and anxiety, have been demonstrated in the Hispanic/Latine community (hereafter Latine, a gender-neutral term) (Wassertheil-Smoller, Arredondo, Cai, et al., 2014; Lorenzo-Blanco & Cortina, 2013). For example, Latine adults who formerly or currently smoke are at an increased risk for anxiety compared to Latine adults who have never smoked (Wilkinson, Vatcheva, Perez, A, et al., 2014); and serious psychological distress has been found to be associated with cigarette use among this population (Correa-Fernández, Tavakoli, Motsenbocker, & Kim, 2021).

Latine individuals experience tobacco-related disparities due to the health consequences of tobacco use, inequities in healthcare support, and cultural barriers, among others. For instance, the three principal causes of mortality among Latine adults are smoking-related (American Cancer Society, 2018; Babb et al., 2020; Dominguez et al., 2015), and they experience disparities in cessation care because, despite similar levels of motivation to quit, they are less likely than non-Latine Whites to utilize pharmacotherapy and to receive advice from their health care provider during a quit attempt (Centers for Disease Control and Prevention, 2012; Trinidad, Perez-Stable, White, Emery, & Messer, 2011; Zinser, Pampel, & Flores, 2011; Levinson, Arnold, et al., 2004). In addition, insufficient culturally relevant cessation services as well as contextual and structural factors negatively impact Latine groups' health care (Brenes, 2019; Cabral & Cuevas, 2020; Kaplan et al., 2014; Morales, Lara, Kington, Valdez, & Escarce, 2002).

Given the relationship between smoking behavior and various manifestations of psychological distress among Latine adults, culturally appropriate interventions that address these concomitant behavioral health issues are warranted. Acceptance and Commitment Therapy (ACT) is a third generation Cognitive Behavior Therapy (CBT) and is positioned as a form of "contextual CBT" (Twohig, 2012). According to the ACT approach, humans learn to avoid thoughts, emotions, images, and physical sensations that they judge to be aversive, and this experiential avoidance is posited to underlie emotional dysregulation (Blackledge & Hayes, 2001; Clark, Ball, & Pape, 1991), serve as a barrier for the person's pursuit of valued outcomes, and generate drug use or mood disturbances. For example, substance-use behaviors, like smoking, are frequently motivated by attempts to regulate and control uncomfortable internal experiences, such as negative affect or craving, and become negatively reinforced, thereby making it difficult to quit (Marlatt & Gordon, 1985). An ACT-aligned therapeutic goal is the reduction of experiential avoidance and the development of what is known as "psychological flexibility", which refers to a person's willingness to identify and remain in the presence of unpleasant internal events and still commit to behaviors that are aligned with their life values. In ACT-based models for the treatment of tobacco dependence (Gifford, Kolenberg, Hayes, et al., 2004a,b), individuals are guided to notice the link between indicators of negative affect and their tobacco use as a way to control the uncomfortable internal experiences, and to practice more adaptive responses in the presence of triggers to smoking.

ACT has been shown to be applicable to diverse populations (Masuda, 2014) and to be efficacious for treating tobacco dependence, depression, and anxiety (Twohig, 2012; Gifford, Kolenberg, et al., 2004a,b; Archa Wolitzky-Taylor, Eifert; et al., 2012; O'Connor, Whelan, Bricker, & McHugh, 2020; Bricker, Watson, Mull, Sullivan, & Heffner, 2020). However, research on the usefulness of acceptance-based approaches for Latine populations, the largest ethnic minority group in the US (Colby & Ortman, 2017; U.S. Census Bureau, 2014), is just emerging. Although there are a handful of ACT-related studies that include a modest proportion of Latine persons in their samples (Archa, Wolitzky-Taylor, Eifert, et al., 2012; McClure, Bricker, Mull, & Heffner, 2020), only two recent published studies related to ACT and smoking specifically focused on Latine groups in the US (Kwon et al., 2022; Santiago-Torres, Mull, Sullivan, Zvolensky, & Bricker, 2022). Both studies mentioned are derived from a single project examining treatment engagement and efficacy among the general population, and thus, not necessarily culturally relevant to Latine individuals (Kwon et al., 2022; Santiago-Torres et al., 2022). Furthermore, to the best of our knowledge, there is no published research documenting the simultaneous treatment of smoking and psychological distress specifically among Latine individuals.

ACT represents a coherent theoretical framework to address many of the factors that can function as barriers to smoking cessation among Latine individuals experiencing psychological distress. Hence, our program of research aimed to develop and pilot test a culturally relevant ACT-based wellness program addressing smoking, depression, and anxiety among Latine adults (i.e., PRESENT Wellness Program). Details about the development and implementation of the program have been published (Correa-Fernández, Blalock, Piper, et al., 2023). This paper focuses on the outcomes of the pilot study. Specifically, it provides information on the feasibility and acceptability of the PRESENT Wellness Program, as well as pilot data on the effect of the intervention on decreasing smoking, psychological distress (i.e., anxiety and depression), and psychological inflexibility, an ACT-related construct. As primary outcomes, it was expected that recruitment and retention would be feasible, and that the intervention would be acceptable to participants (Correa- Fernández, Blalock, Piper, et al., 2023). For secondary outcomes, we expected an increase in participants' smoking abstinence and a decrease in depression and anxiety symptoms after the end of treatment (EOT) (Correa- Fernández, Blalock, Piper, et al., 2023). Findings from this research will inform large-scale ACT-based smoking cessation studies for Latine individuals with co-occurring psychological distress and will add to a growing body of research documenting the importance of culturally appropriate interventions to increase health equity.

2. Methods

2.1. Study design and participants

This study was a longitudinal, single-arm pre-post feasibility and pilot study conducted among 23 Latine adults who smoked combustible cigarettes and experienced psychological distress. *Inclusion criteria* were: currently smoking (average of $\geq$5 cigarettes/day for the past year and CO $\geq$ 6 ppm); 18+ years of age; self-identification as Latine (of any national heritage); interested in quitting in the next 30 days; screened positive for probable anxiety or probable depression (based on $\geq$10 in the General Anxiety Disorder scale and the Patient Health Questionnaire-8, respectively (Dhingra, Kroenke, Zack, Strine, & Balluz, 2011; Kroenke et al., 2009; Spitzer, Kroenke, Williams, et al., 2006); ability to speak English; at least marginal health literacy; functioning

telephone number; and physicians' release to participate if taking psychotropic medications. Although we recognize the importance of cessation studies in Spanish, we chose to recruit only English-speaking Latine individuals to maximize resources and the feasibility of completing the study within the allocated timeframe (i.e., supervision of sessions and preparation of materials in only one language). *Exclusion criteria* were: current use of tobacco cessation medications; current participation in counseling for smoking cessation, depression or anxiety; contraindication of nicotine patch usage; currently pregnant or nursing; current psychiatric disorder that would limit ability to participate; and having a household member enrolled in the project. The main reasons for ineligibility were: not meeting criteria for depression and/or anxiety (60%) and not self-identify as Latine (6%). Also, 23% were excluded due to multiple criteria.

2.2. Procedures

This project was approved by the University of Houston Institutional Review Board. Potential participants were recruited through print media (e.g., local newspaper), social media (e.g., Facebook), community outreach, flyers, and the ResearchMatch.org platform. Although this project was intended to take place partially in-person in the Houston metropolitan area, in Texas, US, due to the COVID-19 pandemic and resulting quarantine conditions, approval was obtained (i.e., IRB and grant sponsor) to transition procedures to remote recruitment and delivery. Thus, initial recruitment efforts focused solely in Houston while latter recruitment was open to individuals from other states and Puerto Rico. Interested individuals were screened for eligibility either by phone (with project staff) or by completing a self-screening accessed via a link or QR code located on the study promotional materials. Eligible individuals were scheduled for a baseline visit. Individuals who were not eligible were given referrals to other behavioral health or cessation programs.

During the baseline visit, project staff obtained informed consent. Enrolled participants completed the self-reported baseline assessments via the Qualtrics online platform and completed their first health counseling session. Again, due to the quarantine conditions imposed by the pandemic, we transitioned procedures to remote delivery, including substituting the proposed in-person baseline visit for a videocall. Out of the 23 participants, four attended the Baseline visit in-person and, thus, provided both informed consent via a paper copy and biochemical verification of their smoking status via a carbon monoxide test. The other 19 participants provided their consent to participate via Docusign, completed their session via an encrypted institutional Zoom account, and did not have their smoking status biochemically confirmed. After the Baseline visit, participants were scheduled and participated in the PRESENT Wellness Program as described in the "Intervention" section below.

After completing treatment, participants were scheduled for two follow-up visits; specifically one-week and two-months after the EOT. During these visits, participants completed assessments pertaining to tobacco use, anxiety, depression, and ACT-related constructs. Additionally, at the last follow-up visit, participants rated the acceptability and satisfaction with the PRESENT Wellness Program. Similar to the baseline visit, the original protocol proposed the follow-up assessments to take place in-person; however, they were successfully transitioned to remote visits during the pandemic. All follow-ups took place virtually.

Participants were compensated with a $30 electronic gift card for the baseline and the first follow-up visit and $40 for completion of the second follow-up visit. Also, to maintain engagement during the health counseling sessions throughout the difficult times of the pandemic, there was an additional distribution of $10 gift cards for attendance to sessions 2–8 each. Payments were added based on the positive effects of financial incentives on treatment adherence and smoking abstinence that have been documented (Mundt et al., 2019; Fraser et al., 2017). In sum, participants could obtain a maximum of $170/person for the completion of assessments and health counseling sessions.

2.3. Intervention

The PRESENT Wellness Program included the provision of nicotine replacement therapy (NRT) in the form of nicotine patches and eight 1-h individual counseling sessions, which occurred flexibly within a 3-month period. The first session, which occurred during the baseline visit, took place in-person or via Zoom, while all other sessions were conducted by phone. All participants received self-help materials in the form of a booklet. The content of the booklet was also ACT-based and followed the same session-by-session structure as the therapists' manual (Correa-Fernández, Blalock, Piper, Canino, & Wetter, 2023).

The counseling intervention was based on the ACT treatment approach (Hayes, 2019; Gifford, Kohlenberg, et al., 2004a,b) and was guided by the clinicians' treatment manual, which included modules about Latine groups' smoking patterns, ACT principles, depression, anxiety, culturally relevant service provision, and the session by session treatment protocol. Examples of aspects of the intervention that increased its cultural relevance include: (a) naming the intervention a "wellness program" and the interventionists "health counselors" to minimize stigma related to mental health seeking; (b) acknowledging occasional smoking and light smoking as common patterns among Latine groups; (c) incorporating Latine values in the counselor's communication style throughout the program (e.g., respect, personalism); and (d) focusing on Latine values and contextual factors within the content of the sessions (e.g., familism as a value during session 2 and immigration and discrimination as potential sources of stress). The first session focused on the ACT contextual interview and orientation about NRT; sessions 2-7 addressed, respectively, each of the ACT main components (i.e., values, committed action, acceptance, present moment, defusion, self-as context). The selection of a quit date was encouraged during session 3 as part of the goal setting and "committed action" discussion. The last session focused on consolidating participants' experience during treatment by highlighting their learning and successes as well as revisiting any ACT-component they wanted to review. During the last session, participants' plans and preparation for the next steps in their quitting journey (e.g., abstinence or relapse prevention) were also addressed. Details about the intervention content have been previously published (Correa- Fernández, Blalock, Piper, et al., 2023).

Three counselors provided the intervention. All of them had a masters or doctoral degree in psychology or counseling, had previous clinical experience delivering psychotherapeutic interventions, and were generally trained in tobacco dependence treatment and ACT, as well as specifically trained to deliver this study protocol. Prior to beginning their role as study interventionists, they demonstrated satisfactory adherence to the intervention protocol. To ensure treatment fidelity and monitor any deviation from the protocol, all counseling sessions were recorded and reviewed. All sessions from each counselor's first participant were evaluated using the ACT Core Competency Rating Form (Luoma, Hayes, & Walser, 2017) and an investigator-developed checklist to track fidelity to treatment content per session (Correa- Fernández, Blalock, Piper, et al., 2023); thereafter, a random sample of at least 15% of sessions per counselor were evaluated. The supervisor provided written feedback based on the ratings of the coded sessions, all of which met or surpassed the expected adherence ratings. Additional details of the counselors' training and the criteria to determine treatment fidelity are provided elsewhere (Correa- Fernández, Blalock, Piper, et al., 2023).

Nicotine patch dosage followed established guidelines and package inserts such that participants smoking 5–10 cigarettes per day started treatment with 14 mg patches while participants smoking more than 10 cigarettes per day were recommended 21 mg patches. Participants interested in using NRT were given a maximum of 6 weeks' worth of patches. The initial 2-week supply of nicotine patches was dispensed following completion of the baseline visit and then sent bi-weekly by regular mail. Participants were encouraged to start using the patches

one week before the quit date, consistent with data demonstrating the ability of pre-quit NRT use to reduce cravings and withdrawal symptoms and increase cessation self-efficacy pre-quit (Piper, Cook, Schlam, et al., 2017; Theodoulou, Chepkin, Ye, et al., 2023. During the informed consent process, participants received orientation about common side effects and potential adverse outcomes from patch usage. They were instructed to stop using the patch should adverse symptoms arise and to consult a medical doctor or pharmacist. Participants' experience with the NRT usage was monitored in each counseling session. Adverse events were never reported.

2.4. Measures

Study measures included a demographic questionnaire, assessments of the primary outcomes (feasibility of recruitment, feasibility of retention, and treatment acceptability) and secondary outcomes (smoking abstinence, depression, anxiety, and psychological inflexibility scores).

A demographic questionnaire was administered at baseline and included questions related to age, partner status, education, income, financial strain, and years in the US.

Feasibility of recruitment was measured by the proportion of participants who were enrolled out of the number of individuals who were eligible.

Feasibility of retention was measured by: (a) the number of health counseling sessions completed (i.e., treatment adherence) and (b) the rate of follow-up visits completed (i.e., study retention).

Treatment acceptability was measured using both quantitative and qualitative measures. First, it was measured using the Program Acceptability Questionnaire, an investigator-developed measure rating the degree of acceptability and helpfulness of the PRESENT Wellness Program (Correa- Fernández, Blalock, Piper, et al., 2023). This measure contains seven items, scored via a 5-point Likert scale ranging from *Completely Disagree* (1) to *Completely Agree (5)*. A sample item is: *"This program was applicable to someone such as myself who identifies with a Hispanic/Latino background"*. The total score is calculated by obtaining the mean of item scores. Higher scores indicate greater acceptability. Second, to also have a qualitative assessment of acceptability, we asked the open-ended question: *What was your overall experience in this wellness program?*

Smoking abstinence was assessed via 7-day and 30-day self-reported point-prevalence (Piper et al., 2020), defined as a self-report of no smoking during the previous 7 or 30 days (including a single puff), respectively. Seven-day point prevalence was measured at 1-week post EOT and 2-months post EOT, and 30-day point prevalence was measured only at the 2-month post EOT follow-up.

Depression was assessed by the Patient Health Questionnaire-8 (PHQ-8; Dhingra et al., 2011; Kroenke et al., 2009), which evaluated symptoms for the last two weeks. Items range from *not at all* (0) to *nearly every day* (3), and item scores are summated to produce a total score between 0 and 24 points. Higher scores indicate greater depressive symptoms. Probable depression is determined by a total score of 10 or above, which indicates at least moderate symptoms (Kroenke et al., 2009).

Anxiety was assessed by the Generalized Anxiety Disorder Scale (GAD-7; Spitzer et al., 2006), which evaluate symptoms for the last two weeks. Items range from *not at all* (0) to *nearly every day* (3), and item scores are summated to produce a total score ranging from 0 to 21. Higher scores indicate greater anxiety symptoms. Probable anxiety is determined by a total score of 10 or above, which indicates at least moderate symptoms (Spitzer, Kroenke, Williams, et al., 2006).

Psychological Inflexibility was assessed via the Avoidance and Inflexibility Scale (AIS), a smoking specific measure of experiential avoidance. It assesses cognitive processes and behaviors of avoidance and inflexibility towards smoking cessation (Gifford, Kohlenberg, et al., 2004a,b). The response scale ranges from *not at all* (1) to *very much* (5). The total score is derived by summing all items and it ranges from 13 to 65 points. Higher scores indicate greater psychological inflexibility (i.e., an avoidant strategy toward internal experiences as well as an inflexible link between these experiences and smoking behavior).

2.5. Data analyses

We conducted descriptive analyses of participants' characteristics, primary outcomes (recruitment, retention, and treatment acceptability), as well as participants' scores on secondary outcome measures at four different timepoints (Screening, Baseline, 1-week post EOT, and 2-months post EOT). Analyses in the context of pilot studies provide information regarding feasibility and acceptability of the intervention and are not hypothesis-driven (Leon, Davis, & Kraemer, 2011); however, we conducted one inferential analysis in an exploratory manner to identify trends in the smoking outcome. For instance, we conducted a Cochran-Mantel-Haenszel test to examine whether there was an association between time (measurement occasions) and smoking behavior while controlling for the data dependency that occurs for each participant. Finally, for the qualitative assessment of treatment acceptability, we reported verbatim various responses from participants to the open-ended question.

Ethics approval

The first author and principal investigator of the study received Institutional Review Board approval from the University of Houston. Informed Consent was obtained from study participants.

3. Results

The sample demographic characteristics as well as baseline scores are depicted in Table 1. In brief, most participants were women (70%), ranging from young adult to middle-aged, born in the US (57%),

Table 1
Demographic characteristics of the sample

Variable	M/SD No. (%)
Age	40 ± 11.4
Sex	
Female	16 (69.6)
Male	7 (30.4)
Race	
White	8 (34.8)
Asian	1 (4.3)
Other/multiracial	5 (21.7)
"Mixed"	9 (39.1)
Partner status	
Not partnered	10 (43.4)
Partnered	13 (56.5)
Education level	
High school or less	4 (17.4)
Some college/technical degree	10 (43.5)
College graduate	3 (13.0)
Post-bachelor	6 (26.0)
Nativity	
Born in the US	13 (56.5)
Foreign Born (including Puerto Rico)	10 (43.5)
Employment	
Employed	17 (73.9)
Unemployed	6 (26.1)
Financial Strain	
Living comfortably	7 (30.4)
Living "check to check"	14 (60.9)
Being almost poor/poor	2 (8.6)
Primary language (self-reported)	
English	12 (52.2)
Spanish	5 (21.7)
Both English and Spanish	5 (21.7)
Other (Portuguese)	1 (4.3)

working full time (52.2%), and experiencing financial strain (70%). Although 78% of participants received one or more boxes of the NRT patches, only 52% of the sample reported using them.

3.1. Primary outcomes

Feasibility of recruitment. Our feasibility of recruitment indicator was the proportion of participants who were enrolled out of the number of individuals who were eligible. We recruited 23 participants out of the 52 individuals who were eligible during the recruitment period, indicating a 44% recruitment rate.

Feasibility of retention. The average number of sessions completed was 5.5 (out of 8), with a SD = 2.74, and a range from 1 to 8. Over 42% of the sample completed all eight counseling sessions, and 70% completed at least 4 of the 8 sessions. The frequencies of attendance per session are depicted in Fig. 1. Follow-up rates related to assessments completion were 61% (n = 14) at both 1-week post EOT and 2-months post EOT.

Treatment acceptability. Among the participants who completed the 2-month post EOT follow-up (n = 14), the intervention was evaluated as highly acceptable as evidenced by a mean score of 4.62 (out of 5) on the Program Acceptability Questionnaire, with a SD = 0.49, and a range from 3.29 to 5.0. When asked about their experiences with the wellness program, participants share the following:

> "I believe the counselor was very helpful in my journey and toward my goal. I feel it is all a 'mind thing'. I overcame my cravings".
>
> "It was great; I have quit smoking and I do not struggle with it at all. The lessons and exercises that were taught I still use even in other parts of my life. Thank you."
>
> "When I smoked, I became more conscious of my smoking".
>
> "I enjoyed very much and it helped me in ways that are so different from other therapies. I wish I could have continued because it gave me so much insight …"

3.2. Secondary outcomes

Smoking abstinence. Utilizing an intent-to-treat approach in which participants lost to follow-up were considered "smoking", the 7-day point-prevalence abstinence rate was 35% at both follow-ups; and the 30-day point prevalence abstinence was 26% at 2-months post EOT. In addition, when exploring the frequency of smoking among participants, we observed a reduction in the number of participants who smoked daily (see Fig. 2). The Cochran-Mantel-Hasenszel test indicated that there was a significant association between measurement occasions and the 7-day point-prevalence abstinence: χ^2 (3) = 22.60, $p < 0.001$, indicating that participants were more likely to be abstinent at 1-week post EOT than 2-months post EOT. Given the limited follow-up completion (61%), we conducted sensitivity analyses to examine smoking rates only among follow-up completers at 1-week and 2-months post EOT. Among those assessed at either follow-up, 57% reported 7-day point-prevalence smoking abstinence.

Depression. Estimated marginal means of PHQ-8 scores indicate a reduction of depression scores across time. The average depression score is consistent with meeting criteria for probable depression at 1-week post EOT but not at 2-months post EOT (see Fig. 3). Among completers, specific proportions of participants who met criteria for probable depression at each time point were as follows: screening: 87.0%; baseline: 72.7%; 1-week post EOT: 42.9%; and 2-months post EOT: 42.9%.

Anxiety. Estimated marginal means of GAD-7 scores indicate a reduction of anxiety scores across time, suggesting that the average anxiety score doesn't meet the probable anxiety criterion at any follow up (see Fig. 4). Among completers, specific proportions of participants who met criteria for probable anxiety at each time point were as follows: screening: 82.6%; baseline: 65.2%; 1-week post EOT: 42.9%; and 2-months post EOT: 42.9%.

Psychological Inflexibility. Estimated marginal means of AIS scores indicate a reduction of smoking-related psychological inflexibility after the intervention which was maintained at 2-months post EOT (see Fig. 5).

4. Discussion

The current formative research reports on feasibility of recruitment and retention, and the treatment acceptability of the PRESENT Wellness Program, an acceptance-based intervention specifically developed to simultaneously address smoking cessation and psychological distress among English-speaking Latine adults. Findings suggest moderate recruitment feasibility and high retention feasibility and treatment acceptability. Of note, this intervention showed promise in increasing smoking abstinence, and in reducing depression, anxiety and psychological inflexibility by 1 week and 2-months post EOT.

4.1. Primary outcomes

Based on the ratio of eligible to enrolled participants, this study's

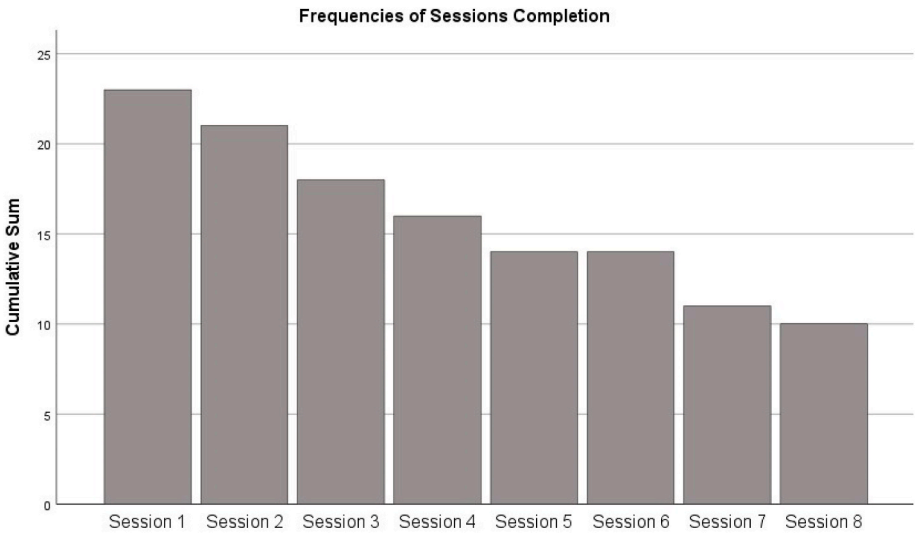

Fig. 1. Session by session attendance.

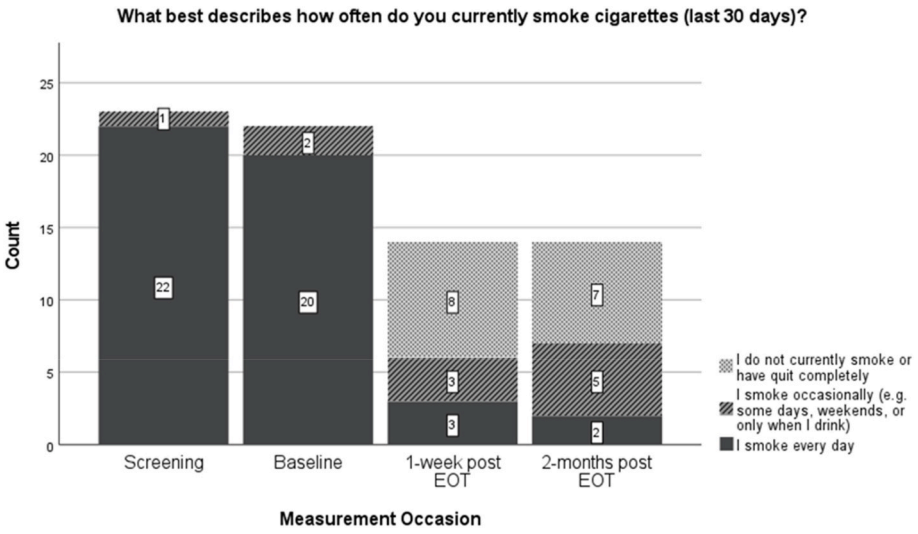

Fig. 2. Smoking frequency.

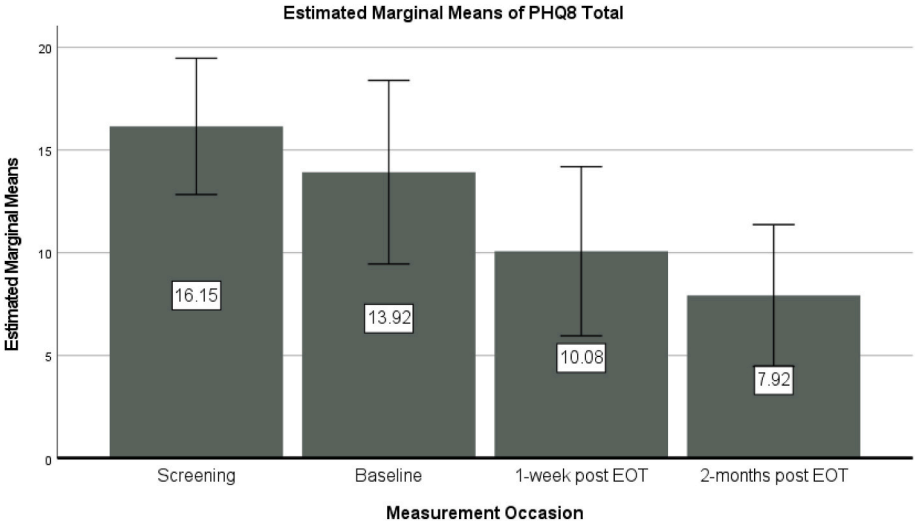

Fig. 3. Estimated marginal means of depression scores across time.

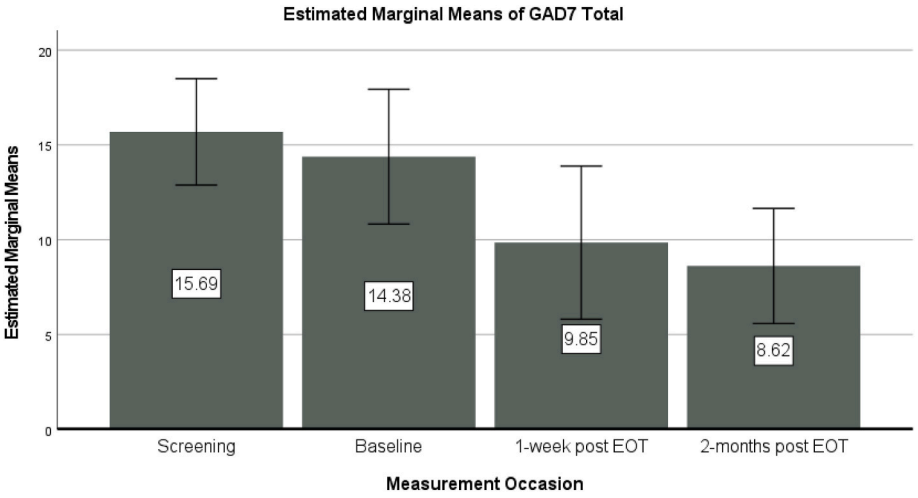

Fig. 4. Estimated marginal means of anxiety scores across time.

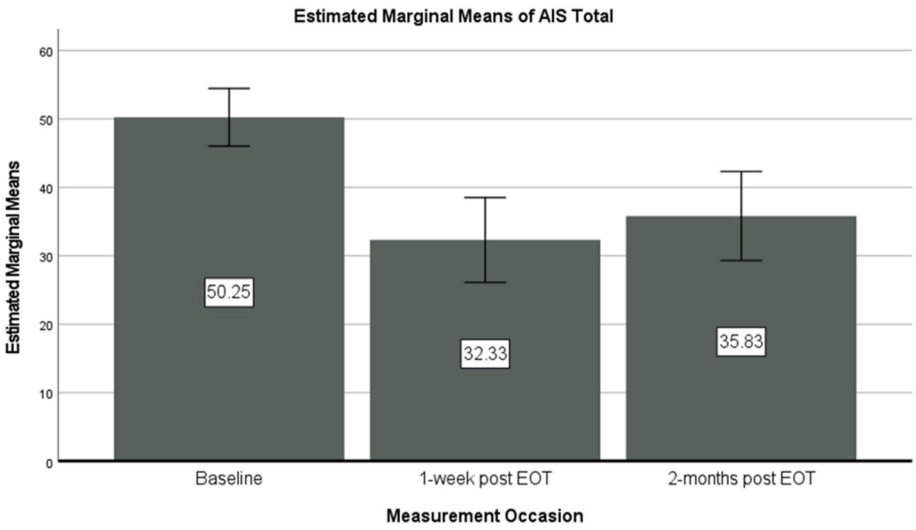

Fig. 5. Estimated marginal means of psychological inflexibility scores across time.

recruitment rate was 44%. This proportion is lower than recruitment rates documented in previous studies of treatment-seeking individuals who smoke (Gariti et al., 2008), including other acceptance-based studies delivered by telephone (Bricker, Mann, Marek, Liu, & Peterson, 2010) or via apps (Bricker et al., 2017; Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014a,b). These studies, all conducted pre-pandemic, obtained recruitment rates from 49% to 58% (Bricker et al., 2017; Bricker et al., 2010; Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014a,b; Gariti et al., 2008). Given most of our study took place during the pandemic, we could argue that this contextual factor may have influenced our recruitment rates, as the majority of eligible people who didn't enroll were unreachable for baseline scheduling. It is uncertain how the pandemic would have impacted treatment engagement relative to times where people were not locked down or experiencing a world health crisis. However, a previous telephone-based smoking cessation intervention among men documented a lower recruitment rate post-COVID (compared to pre-COVID; Leventakou et al., 2022). Also, it has been previously reported that calls to the states Quitlines dropped significantly during 2020, suggesting a decrease in people's motivation or attempts to quit smoking (Chiu, 2021). Taking into account the increased levels of psychological distress experienced during the pandemic, it is reasonable to argue that quitting smoking may have been a lower priority for individuals, including Latine persons, a group for whom social and structural factors put them at higher risk for COVID-19 acquisition (e.g. living in multigenerational households, having jobs considered essential with limited protections and/or work-from-home policies that did not apply to them; Rodriguez-Diaz, Guilamo-Ramos, Mena, et al., 2020). Regardless, the experience and results from this research will help refine recruitment methods for a larger scale study and motivate understanding of and adherence to recent guidelines for conducting and evaluating recruitment of diverse populations (Stewart, Nápoles, Piawah, Santoyo-Olsson, & Teresi, 2020).

Findings suggest feasibility of retention into treatment as indicated by the average of 5.5 completed counseling sessions out of eight. The majority of participants completed at least half of the sessions, which is consistent with a previous cessation study conducted by telephone among Latine adults (Correa-Fernández, Díaz-Toro, Reitzel, et al., 2017). Of note, the strong sustained engagement rate may have been influenced by the provision of a small financial incentive for session attendance (i.e., $10), thereby influencing the feasibility outcome. Previous research among low-income persons who smoke has documented that a financial incentive resulted in higher participation in quitline calls compared with non-incentivized calls (Mundt et al., 2019; Fraser et al., 2017). Importantly, our incentives were smaller than these previous studies suggesting a promising area for both implementation and research.

Given that this intervention was conducted in English, it was important to understand the impact of language. Among participants who identified either "English" or "English and Spanish" as their primary language (n = 17), 80% completed the mean number of sessions or more. This stands in contrast to the fact that only 20% of participants who identified Spanish as their primary language (n = 5), completed the mean number of sessions or more. In fact, only 1 out of the 5 participants who self-reported Spanish as their primary language completed all counseling sessions. Thus, it is possible that although they spoke enough English to attend the treatment, they would still prefer their native language (i.e., Spanish) for service provision and would have been more engaged if it had been provided in Spanish. Of course, this is speculative at this point and only further research examining reasons for treatment engagement (or lack thereof) would shed light on these adherence aspects, including the importance of having the intervention conducted in Spanish. This area of inquiry is promising as recent research indicate that Latine adults using the Spanish version of National Cancer Institute's text-based cessation program showed higher engagement than those using the traditional English version (El-Toukhy & Kamke, 2023).

Besides treatment adherence, we assessed study retention and obtained 61% follow-up retention rates. These rates rank lower than other ACT-based smoking cessation studies delivered by telephone among the general population (Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014a,b; Bricker et al., 2010) or a telephone-based smoking cessation treatment among Spanish-speaking Latine people utilizing a different therapeutic modality (Correa-Fernández, Díaz-Toro, Reitzel, et al., 2017). The reasons for dropout are likely multifactorial and may include factors at the individual or contextual levels. For instance, as discussed above, language preference could have influenced participants' diminished engagement with the overall study procedures. In addition, the comorbid psychological distress of participants and/or the challenges imposed by the ongoing pandemic could have impacted individuals' motivation or ability for continued participation. Future work will benefit from revisiting strategies aimed at improving retention rates and reducing attrition among this population, such as increasing flexible scheduling and consistency of study staff, gathering information of multiple contacts, utilizing various methods for reminders (calls, text, email), offering participants a choice of follow-up mode, and re-training staff when needed. Importantly, future and larger studies among Latine individuals who want to quit smoking should examine factors influencing study retention both negatively and positively (Pfledderer et al., 2024).

This PRESENT Wellness Program was acceptable among participants who completed the 2-month post EOT follow-up (i.e., 61%), including treatment usefulness in managing cravings and mood, and its relevance for Latine people. This treatment acceptability is consistent with previous studies highlighting the importance of culturally appropriate interventions for Latine persons who smoke (Cartujano-Barrera et al., 2020). In addition, ACT-based approaches have been shown to be applicable to diverse populations (Masuda, 2014) and its focus on value-based living facilitates its adaptation to Latine community values, smoking patterns, and contextual factors influencing psychological distress and tobacco use. We recognize, however, the possibility that people who stopped participating in treatment and didn't complete the follow-ups found the intervention less helpful than those who continued. Nonetheless, it is worth noting that at least 28% participants who completed the Program Acceptability Questions (4 out of 14) completed a maximum of five sessions, indicating that some participants who didn't complete treatment as indicated still found the program acceptable.

4.2. Secondary outcomes

Findings related to all secondary outcomes were in the expected direction. That is, after treatment, smoking abstinence rates increased, and depression and anxiety symptomatology decreased as did psychological inflexibility levels. Seven-day point-prevalence abstinence rates at EOT were 35%, which compares favorably to other acceptance-based smoking treatments (Bricker et al., 2017; Bricker et al., 2010; Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014a,b; Kwon et al., 2022) as well as other types of cessation interventions among Latine adults (Cartujano-Barrera, Sanderson Cox, Arana-Chicas et al., 2020; Simmons et al., 2022). Similarly, reductions in depression and anxiety symptomatology suggests that this is a promising approach to address smoking and behavioral health challenges in the Latine community. Notably, the decrease in both depression and anxiety scores initiated after screening but were most pronounced from Baseline to EOT and were maintained through 2 months post EOT.

4.3. Strengths and limitations

The study has various notable strengths. First, it addresses the adaptation and testing of an ACT-based smoking cessation intervention for Latine people who smoke and experience probable depression and anxiety symptomatology. This represents the first documented ACT-based smoking cessation treatment developed specifically for English-speaking Latine adults in the US (Correa- Fernández, Blalock, Piper, et al., 2023). Previous reports of ACT-based smoking cessation treatment among Latine adults were based on secondary analyses of trials targeting the general population (Kwon et al., 2022; Santiago-Torres et al., 2022). Importantly, this study is a novel application of an evidence-based treatment to address comorbid behavioral health challenges among an underserved ethnic group. Second, the intervention delivery via a telehealth hybrid format (video and phone) represents an innovation as well as an advantage as it addressed common treatment barriers for Latine individuals (e.g., childcare, transportation). Various studies testing acceptance-based smoking cessation treatment have been delivered by phone (Bricker, Mann, Marek, 2010; Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014a,b) but not via video. Three, the unexpected but successful transition of the project from an in-person trial to a remote one during the pandemic speaks to the feasibility of remote implementation of smoking cessation studies and opens the door to a variety of methods, as documented recently (Vinci et al., 2022). Lastly, the program was specifically developed for individuals of Latine ancestry, which speaks about its cultural relevance and contribution to the body of evidence regarding acceptance-based treatment for diverse groups. Importantly, this culturally appropriate treatment set the foundation for the conduct of future comparative effectiveness research evaluating general acceptance-based treatment vs. culturally targeted ones.

There are several study limitations. First, the main limitation of this study is its small sample size, which precludes the possibility of hypotheses testing or formal examination of treatment effects or mechanisms. Second, given the pilot nature of the study, there was no control group as a point of comparison for primary and secondary outcomes. Third, due to the need to transition the project to a remote format during the pandemic, smoking outcomes were defined via self-report and were not biochemically verified, which could have introduced bias in terms of the smoking abstinence rates reported. Fortunately, since this project's implementation, new methodology for remote verification of smoking abstinence has emerged (Thrul et al., 2023). Fourth, providing financial incentives for treatment completion may bias individuals' adherence to treatment outside of a research environment and reduces the generalizability of findings. This strategy was chosen to increase the probability of retention during the challenging times of the pandemic. Despite the ongoing debate about the use of financial incentives in clinical trials (Parkinson et al., 2019), the ethical importance of recruitment and retention in early stages intervention trials suggest that offering these incentives is not only appropriate but also necessary. Lastly, mainly for pragmatic reasons (Correa- Fernández, Blalock, Piper, et al., 2023), participants of this formative research were English-speaking Latine individuals; providing and testing the intervention only in English reduces the generalizability of findings to the broader Latine community. Along this line, participants' English proficiency was not formally evaluated; it is possible that participants' English proficiency could have influenced their participation in the program as well the outcomes. Future work should address the adaptation of this intervention for Spanish-speaking individuals, assess English and/or Spanish language proficiency of the participants, increase the sample size, add a control group, add longer follow-up periods, and identify the methodology for remote biochemical verification of smoking abstinence that best fits the study design.

5. Conclusion

The PRESENT Wellness Program resulted in satisfactory levels of treatment adherence and acceptability, which were comparable to or higher than previous published studies, even during a global pandemic. Feasibility of recruitment and study retention was lower compared to previous studies. Participant outcomes regarding smoking abstinence, reduction of depression and anxiety levels, and the reduction in psychological inflexibility were in the expected direction and sustained at 2 months after the EOT. Findings suggest this program's potential to positively impact the behavioral health of Latine adults interested in quitting smoking, even beyond the EOT. Reductions in psychological inflexibility, an ACT core component, indicates that the wellness program impacted a theory-based construct hypothesized to influence both smoking and psychological distress. Future studies should follow recent guidelines aimed at improving recruitment and retention among diverse populations (Stewart et al., 2020), implement longer follow-up periods, and examine treatment effects and mechanisms of change.

CRediT authorship contribution statement

Virmarie Correa-Fernández: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Niloofar Tavakoli:** Writing – review & editing, Project administration, Investigation. **Marshall Motsenbocker:** Writing – review & editing, Project administration, Investigation, Data curation. **Hanjoe Kim:** Writing – review & editing, Visualization, Validation, Formal analysis, Data curation. **David W. Wetter:** Writing – review & editing, Resources, Methodology, Funding acquisition, Conceptualization. **Janice A. Blalock:** Writing – review & editing, Resources, Conceptualization. **Glorisa Canino:** Writing – review & editing,

Resources, Conceptualization. **Megan E. Piper:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

Authors declare no conflicts of interest related to this work.

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