



# Process evaluation of counseling delivered by a patient navigator in an efficacious smoking cessation intervention among low-income primary care patients

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## ABSTRACT

**Introduction:** This exploratory study examined the relationship between receipt of counseling by a patient navigator and socio-demographic characteristics of primary care patients enrolled in a smoking cessation trial.

**Methods:** We grouped intervention participants ( $n = 177$ ) into two categories: 1) no or some contact with the navigator or 2) minimum counseling intervention dose or higher delivered.

**Results:** In logistic regression analyses, controlling for patient race/ethnicity, education, age, gender, household annual income, stress/chaos/hassles composite score, heavy smoking, and substance use, non-Hispanic white participants had lower odds (aOR 0.30; 95% CI 0.13–0.70,  $p < 0.01$ ) of receiving the minimum intervention dose or higher compared to all other race/ethnicity categories. There was also effect modification such that patients aged 50 or younger who were non-Hispanic white were less likely (aOR 0.09, 95% CI: 0.02–0.54,  $p < 0.01$ ) to receive the minimum intervention dose compared to older patients from all other race/ethnicity groups.

**Conclusions:** Future research should explore issues such as acceptability of the intervention to white and younger age participants, and the potential impact of co-occurring substance use disorders on intervention uptake.

## 1. Introduction

While smoking prevalence has declined over the past decade in the U.S., disparities by education, poverty status, race/ethnicity, and psychological status remain (Centers for Disease Control and Prevention, 2018). Smoking cessation interventions targeting disparity-facing populations are needed. We conducted a randomized controlled trial designed for primary care patients at a large urban safety-net hospital who were current smokers and primarily from racial/ethnic minority and low socio-economic status groups. The trial protocol and 7-day biochemically validated point prevalence for smoking cessation at 12-months have been previously reported (Lasser et al., 2017; Quintiliani et al., 2015). We randomized 352 participants to one of two groups. In the enhanced traditional care control group ( $n = 175$ ), participants received a low literacy smoking cessation brochure and a list of hospital and community resources for smoking cessation. Intervention

participants ( $n = 177$ ) received the same brochure and list of resources; in addition, they received up to \$750 in financial incentives for biochemically confirmed smoking cessation and access to a patient navigator to assist with cessation. Two navigators (one Haitian-American and the other Hispanic) delivered the navigation intervention for up to 4 h over 6 months. The navigators' goal was to link participants to cessation resources such as quit lines or hospital-based cessation groups. Navigators led participants through a structured counseling session using a motivational interviewing-based guide to increase motivation to quit smoking and use medications such as nicotine replacement therapy. The motivational interviewing-based guide was targeted to different stages of readiness to quit smoking. For all participants regardless of their stage of change with respect to smoking cessation, the navigators assessed how smoking fits into their daily life, the pros and cons of changing their smoking behavior, and helped participants to set goals. At the 12-month assessment, 11.9% of

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participants in the navigation and incentives group, as compared with 2.3% in the control group, had quit smoking based on biochemical verification ( $p < 0.001$ ) (Lasser et al., 2017).

Subgroup analyses revealed that the intervention was more effective among older participants, women, those with the lowest incomes, smokers who did not smoke heavily, those thinking about quitting (contemplation stage of change), and non-white participants (Lasser et al., 2017). For example, among non-white smokers, 3% quit in the control group vs. 15% in the intervention group; no white smokers quit in either study group. Because of well-documented racial disparities in smoking cessation outcomes, in which African Americans generally have lower rates of receipt of smoking cessation assistance (Bailey et al., 2018; Cokkinides et al., 2008), race is an important variable to examine in conjunction with receipt of patient navigation in the context of our trial. For example, Hooks-Anderson and colleagues found that white primary care patients were less likely to receive smoking cessation counseling but more likely to receive a medication prescription to assist with smoking cessation during a clinical encounter (as documented in the medical record) compared to African-American patients (Hooks-Anderson et al., 2018).

Because all intervention participants in our trial were exposed to the financial incentives component of the intervention, but there were varying levels of receipt of the patient navigation intervention component, we were interested in whether receipt of the minimum intervention dose of counseling delivered by a patient navigator could help explain why certain patient subgroups responded more positively to the intervention. Therefore, the objective of this exploratory study is to evaluate whether socio-demographic and smoking-related characteristics are associated with different levels of receipt of smoking cessation counseling as delivered by a patient navigator.

## 2. Materials and methods

This evaluation is based on data from the intervention group collected during the parent study, a randomized controlled trial (NCT02351609), which was approved by the Institutional Review Board of Boston University/Boston Medical Center.

For this process evaluation, we used socio-demographic and smoking-related variables that were collected through interviewer-administered surveys using questions taken from standardized questionnaires (age, race/ethnicity, education, smoking amount, etc.) and existing instruments with previously demonstrated validity and reliability. We measured perceived stress using the 4-item Perceived Stress Scale (Cohen et al., 1983), life chaos the 6-item Chaos Scale (Wong et al., 2007), and daily life hassles using the 9-item Abbreviated Hassles Index (Kanner et al., 1981; Romano et al., 1991) to assess life circumstances that may be barriers to cessation. We also measured stage of readiness to quit smoking (Prochaska et al., 2008) and level of nicotine dependence with the Fagerstrom Test for Nicotine Dependence (Heatherton et al., 1991). We performed a manual electronic health record chart review of the 177 trial participants from the intervention arm, recording substance use diagnoses from the electronic health record problem list. Such diagnoses included unhealthy alcohol use, alcohol use disorders, opioid use disorders, cocaine use disorders, amphetamine use disorders, benzodiazepine use disorder, cannabis use, and other prescription drug use disorders. Navigators recorded their interactions and contact attempts with participants in a computer log and documented the outcome of each contact attempt and whether or not the motivational interviewing guide was completed.

To examine relationships between socio-demographic characteristics and receipt of patient navigation, intervention group participants ( $n = 177$ ) were divided into 2 groups. Group 1 included both those who received no or nearly no contact (e.g., navigator never made contact, or was asked to call back another time,  $n = 48$  (27.1%)) or some navigation (e.g., brief contact established, but navigator was not able to conduct a complete session based on the motivational interviewing

guide,  $n = 36$  (20.3%)). Group 2 included those who received the minimum dose or higher (e.g., navigator completed at least one complete session based on the motivational interviewing guide,  $n = 93$  (52.5%)). Because the stress, chaos, and hassles variables were highly correlated, we used factor analysis to create a composite stress/chaos/hassles factor score to mitigate potential collinearity in the regression model. The eigenvalue of the extracted factor was 1.83 suggesting a one factor solution was adequate to represent these three variables (Velicer and Jackson, 1990). We examined associations between receipt of navigation and sociodemographic and smoking-related variables, using bivariable analyses (one-way ANOVA for continuous variables and Chi-square tests for categorical variables) and multivariable logistic regression analyses. Based on knowledge from prior literature and clinical experience, we included the following covariates in the model: race/ethnicity, education, age, gender, household annual income, stress/chaos/hassles factor score, smoking amount, and substance use. We calculated the variance inflation factor (VIF) for all terms in the regression model to detect potential multicollinearity. We used a criterion of  $VIF > 10$  to indicate collinearity. The largest observed VIF was 1.41, suggesting multicollinearity was likely not an issue in the regression model. We explored effect modification for variables that were statistically significant at the  $p = 0.05$  level in the logistic regression model.

## 3. Results

Most participants were non-Hispanic black (57%), had a high school education or less (66%), and were low-income (54.8%). In bivariable analyses, age and race were significantly associated with receipt of patient navigation counseling (Table 1). Participants who received the minimum dose or higher were older than participants who received less than the minimum dose (51.9 vs. 47.6 years,  $p < 0.05$ ). Among non-Hispanic white participants, 30.8% received the minimum dose or higher vs. 58.7% of those in all other racial/ethnic categories. In multivariable analyses, which controlled for race/ethnicity, education, age, gender, household annual income, stress/chaos/hassles factor score, smoking amount, and substance use variables, non-Hispanic whites were less likely (aOR 0.30, 95% CI: 0.13–0.70,  $p = 0.005$ ) to receive the minimum counseling dose or higher compared to all other race/ethnic groups (Table 2). Patients age 50 and under who were non-Hispanic white were less likely (aOR 0.09, 95% CI: 0.02–0.54,  $p < 0.01$ ) to receive the minimum intervention dose compared to older patients from all other race/ethnicity groups. With marginal significance, we also found that patients who had a substance use diagnosis on the EHR problem list and were non-Hispanic white were less likely to receive the minimum intervention dose compared to patients without a substance use diagnosis from all other race/ethnicity groups (aOR 0.22, 95% CI: 0.04–1.24,  $p = 0.08$ ). All other interaction term  $p$  values were  $> 0.1$  (range of 0.15–0.32).

## 4. Discussion

Failure to receive the minimum dose of patient navigation counseling may, at least in part, help explain our previously reported finding that the intervention was particularly ineffective for white participants. We believe there are a few potential reasons why non-Hispanic white individuals received less patient navigation counseling than other racial/ethnic patients groups. First, it is possible that a lack of racial/ethnic concordance between navigators and non-Hispanic white participants made participants less receptive to patient navigation. In the parent trial, most navigation interactions took place by phone (86%), therefore we are not able to examine racial/ethnic concordance. However, previous research has suggested that racial/ethnic concordance between navigators and patients may lead to more meaningful connections and facilitate timely cancer care (Charlot et al., 2015). Second, high rates of acceptance of patient navigator interventions among African-American populations (Halbert et al., 2014) and higher

**Table 1**

Bivariable relationships between motivational interviewing counseling receipt from a patient navigator and baseline socio-demographic and smoking variables.

Socio-demographic and smoking variables	Overall (n = 177)	No/minimal contact + Some navigation (n = 84)	Minimum dose or higher achieved <sup>a</sup> (n = 93)
Race/ethnicity, n (%)			
Non-Hispanic White	39 (22)	27 (69.2)	12 (30.8) <sup>h</sup>
Non-Hispanic Black	101 (57)	42 (41.6)	59 (58.4)
Hispanic (any race)	19 (11)	7 (36.8)	12 (63.2)
Other/unknown	18 (10)	8 (44.4)	10 (55.6)
Education, n (%)			
< High school	38 (22)	19 (50.0)	19 (50.0)
High school or GED	78 (44)	41 (52.6)	37 (47.4)
More than high school	61 (35)	24 (39.3)	37 (60.7)
Household annual income			
≤ \$20,000	97 (54.8)	42 (43.3)	55 (56.7)
> \$20,000	51 (28.8)	25 (49.0)	26 (51.0)
Don't know/refused	29 (16.4)	17 (58.6)	12 (41.4)
Mean age, mean years (SD)	49.9 (11)	47.6 (12.3)	51.9 (8.9) <sup>h</sup>
Gender, n (%)			
Women	101 (57)	42 (41.6)	59 (58.4)
Men	76 (42.9)	42 (55.3)	34 (44.7)
Stress, <sup>b</sup> mean score (SD)	7.1 (4.0)	6.7 (4.2)	7.5 (3.8)
Hassles, <sup>c</sup> mean score (SD)	3.8 (2.2)	3.6 (2.1)	4.0 (2.3)
Chaos, <sup>d</sup> mean score (SD)	16.1 (6.3)	16.0 (6.4)	16.1 (6.3)
Number of cigarettes, mean (SD)	15.1 (6.5)	15.6 (6.5)	14.7 (6.6)
Fagerstrom scale, <sup>e</sup> mean score (sd)	4.9 (1.9)	4.8 (1.8)	5.0 (2.0)
Stages of change <sup>f</sup>			
Contemplation	52 (29.4)	23 (44.2)	29 (55.8)
Preparation	125 (70.6)	61 (48.8)	64 (51.2)
Substance use, <sup>g</sup> n (%)	97 (54.8)	48 (49.5)	49 (50.5)

<sup>a</sup> At least one complete counseling session using the motivational interviewing guide with the patient navigator was achieved or more, up to 4 h of contact over 6 months.

<sup>b</sup> Stress: a global level of perceived stress; Score range, 0–16.

<sup>c</sup> Hassles: daily life hassles or demands that come with usual interactions such as having arguments or concerns about safety; Score range, 0–9.

<sup>d</sup> Chaos: life chaos pertaining to general life events including being on time, employment, and housing; Score range, 6–30.

<sup>e</sup> Scores range from 1 to 10, with higher scores indicating a more intense physical dependence on nicotine.

<sup>f</sup> Participants in pre-contemplation were excluded from participation in the main trial.

<sup>g</sup> Substance use was defined as presence of documented substance use on the patient's problem list in their electronic health record.

<sup>h</sup> P value < 0.05.

levels of trust in informal networks (such as patient navigation) among black compared to white individuals (Musa et al., 2009), may also help to explain our findings. There is also some evidence of effectiveness of patient navigation interventions among older adult versus younger adult populations, potentially due to older adults' lower health literacy (Roundtable on Health Literacy et al., 2018) and more perceived system-level barriers that could lead to more interactions with the patient navigators (DeSalvo et al., 2018). We found marginally significant ( $p = 0.08$ ) effect modification by substance use diagnosis status in this exploratory process evaluation. Other research has shown that unhealthy substance use is a risk factor for not receiving preventive health services, such as vaccinations and cancer screenings (Lasser et al., 2011). It is possible that the presence of a substance use disorder may also have served as a barrier to receipt of navigation among non-Hispanic whites.

**Table 2**

Associated factors of receiving minimum dose or higher of motivational interviewing counseling from a navigator among underserved primary care smokers.

Variable	Adjusted odds ratio (95% CI)	P value
Race/ethnicity		
Non-Hispanic white	0.30 (0.13–0.70)	0.005
All other racial/ethnic groups	1.00 [reference]	
Education		
High school or lower	0.75 (0.37–1.40)	0.41
More than high school	1.00 [reference]	
Age		
50 years old or younger	0.72 (0.71–2.68)	0.34
> 50 years	1.00 [reference]	
Gender		
Female	1.36 (0.70–2.62)	0.36
Male	1.00 [reference]	
Household annual income		
≤ \$20,000	1.12 (0.54–2.34)	0.75
Refused/do not know	0.50 (0.17–1.41)	0.19
> \$20,000	1.00 [reference]	
Stress/chaos/hassles composite score <sup>a</sup>		
Lower score	1.22 (0.89–1.70)	0.24
Higher score	1.00 [reference]	
Smoking amount		
Heavy smoker <sup>b</sup>	1.05 (0.52–2.13)	0.89
Not a heavy smoker	1.00 [reference]	
Substance use		
Substance use <sup>c</sup>	1.25 (0.64–2.43)	0.52
No substance use	1.00 [reference]	

<sup>a</sup> Higher score indicates higher levels of stress, chaos, and number of hassles.

<sup>b</sup> Heavy smoking is defined as smoking ≥20 cigarettes per day.

<sup>c</sup> Substance use was defined as presence of documented substance use on the patient's problem list in their electronic health record.

Limitations to our exploratory study include the collection of data from patients attending only one health system. In addition, substance use diagnoses were based on the electronic health record problem list, which may underestimate the true prevalence of such conditions due to under-diagnosis and under-documentation. While this study has some limitations, our evaluation demonstrates important avenues for future research and practice. Patient navigation interventions, which are being widely applied in primary care settings, may not improve health outcomes in all subgroups of patients. Future work could explore barriers to receipt of patient navigation among young white smokers, both with and without substance use. In conclusion, non-Hispanic white participants were less likely than participants from other racial/ethnic groups to receive a sufficient dose of patient navigation in this smoking cessation trial in a low-income primary care setting.

## Declarations of interest

None.

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