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Patient navigation and financial incentives to promote smoking cessation in an underserved primary care population: A randomized controlled trial protocol

Lisa M. Quintiliani [a,b,*], Zlatka L. Russinova [c], Philippe P. Bloch [c], Ve Truong [a], Ziming Xuan [b], Lori Pbert [d], Karen E. Lasser [a,b]

[a] Boston University, School of Medicine, Section of General Internal Medicine, 801 Massachusetts Ave., Crosstown Center, 2nd Floor, Boston, MA 02118, USA
[b] Boston University, School of Public Health, Department of Community Health Sciences, 801 Massachusetts Ave. Crosstown Center, 4th Floor, Boston, MA 02118, USA
[c] Boston University, Center for Psychiatric Rehabilitation, 940 Commonwealth Ave., West, Boston, MA 02215, USA
[d] University of Massachusetts Medical School, Department of Medicine, Division of Preventive and Behavioral Medicine, 55 Lake Ave. North, Worcester, MA 01655, USA

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ABSTRACT

Despite the high risk of tobacco-related morbidity and mortality among low-income persons, few studies have connected low-income smokers to evidence-based treatments. We will examine a smoking cessation intervention integrated into primary care. To begin, we completed qualitative formative research to refine an intervention utilizing the services of a patient navigator trained to promote smoking cessation. Next, we will conduct a randomized controlled trial combining two interventions: patient navigation and financial incentives. The goal of the intervention is to promote smoking cessation among patients who receive primary care in a large urban safety-net hospital. Our intervention will encourage patients to utilize existing smoking cessation resources (e.g., quit lines, smoking cessation groups, discussing smoking cessation with their primary care providers). To test our intervention, we will conduct a randomized controlled trial, randomizing 352 patients to the intervention condition (patient navigation and financial incentives) or an enhanced traditional care control condition. We will perform follow-up at 6, 12, and 18 months following the start of the intervention. Evaluation of the intervention will target several implementation variables: reach (participation rate and representativeness), effectiveness (smoking cessation at 12 months [primary outcome]), unintended consequences (e.g., purchase of illicit substances with incentive money), adoption (use of intervention across primary care suites), implementation (delivery of intervention), and maintenance (smoking cessation after conclusion of intervention). Improving the implementation of smoking cessation interventions in primary care settings serving large underserved populations could have substantial public health impact, reducing cancer-related morbidity/mortality and associated health disparities.

1. Background/introduction

Smoking and tobacco smoke exposure are a highly significant health threat [1], responsible for more than 480,000 deaths annually [2]. Smoking rates are higher among those with low socioeconomic status (SES), indicated by lower income and education level, compared to persons with higher SES [3]. For example, in 2013 the percentage of U.S. adults 18 or older who were current cigarette smokers was 16.2% for those at or above poverty level and 29.2% for those below the poverty level [3]. Primary care settings provide an opportunity to reach large proportions of low-income smokers, as 61% of such smokers are engaged in medical care [4]. Yet, such smokers are less likely than other smokers to receive advice to stop smoking or to use cessation services [5], indicating the need for innovative approaches to address this under-utilization of available smoking cessation services [6–9].

Financial incentives have been found to be effective in promoting smoking cessation across a broad array of populations and conditions [10–14]. Among low SES populations, incentives for completing smoking cessation programs and achieving abstinence may be effective as they may alleviate some of financial strain, provide a substitute source of reinforcement for smoking (e.g., in lieu of hobbies, physical activity, and work satisfaction often absent in environments of low SES smokers) [15–17], and may provide extrinsic motivation for patients to quit smoking, which may be particularly effective among low SES smokers, many of whom have low levels of intrinsic motivation [18]. Volpp et al. [19] found that use of incentives may be most effective among smokers at <200% of the poverty level, but the small number of

* Corresponding author at: 801 Massachusetts Ave., Crosstown Center, 2nd Floor, Boston, MA 02118, USA.
E-mail addresses: Lmquinti@bu.edu (L.M. Quintiliani), zlatka@bu.edu (Z.L. Russinova), bloch@bu.edu (P.P. Bloch), ve.truong@bmc.org (V. Truong), zxuan@bu.edu (Z. Xuan), lori.pbert@umassmed.edu (L. Pbert), karen.lasser@bmc.org (K.E. Lasser).

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such smokers in that study makes the finding inconclusive. Kendzor and colleagues also found promising short-term results from providing financial incentives to low SES smokers [20].

Patient navigators are lay persons from the community who guide patients through the health care system so that they receive appropriate services [21]. While patient navigation has been shown to be effective in reducing health care disparities [22–25], prior studies have mostly been limited to cancer screening and diagnosis. Our intervention combines financial incentives with patient navigation because the two interventions may work in complementary ways. Incentives may augment people's willingness to connect with a navigator, and the navigator will put people in touch with smoking cessation resources, which may be more effective because the participant may receive incentives for cessation.

Our approach will foster connections between patients most at risk from the harms of tobacco and existing interventions that may improve cessation rates. The primary aim of this study is to determine whether patient navigation and financial incentives increase the rates at which patients receiving primary care in a large urban safety-net hospital quit smoking, defined as biochemically confirmed cessation at 12 months. A secondary aim is to determine whether the intervention promotes engagement in smoking cessation treatment. In addition, we seek to understand the individual and setting-level variables that influence the implementation of our program in safety-net hospital primary care settings. In this paper, we present the rationale, study design, and methods of the upcoming randomized controlled trial.

2. Methods/design

2.1. Design overview

The setting for this research is the primary care clinical practice at Boston Medical Center, a large urban safety net hospital that serves the most racially and ethnically diverse patient population in New England. We began by conducting a qualitative research study using photovoice methodology to identify factors related to smoking behavior in our population of primary care patients. We used these findings to modify the patient navigation component of the intervention. This intervention will be tested in a two-group randomized controlled trial in which participants will be randomized to either the smoking cessation intervention group (patient navigation and financial incentives) or an enhanced traditional care control group, with evaluation focusing on multiple implementation variables including the achievement of biochemically confirmed smoking cessation (primary outcome) and engagement in smoking cessation treatment (secondary outcome). All aspects of this research have been approved by the Boston University Medical Campus Institutional Review Board. The clinicaltrials.gov registration number is NCT02351609.

2.2. Conceptual basis of intervention model

We base our intervention on the Social Contextual Model [26], a multi-level approach to health promotion which stresses the influence of life experiences (e.g. stress/financial problems) and social relationships (e.g. social networks and family roles) on the practice of health behaviors. By incorporating constructs from health behavior theories such as Social Cognitive Theory [27], the Theory of Reasoned Action [28], and the Transtheoretical Model of Behavior Change [29], this model not only presents factors that intervention planners can target in their programming (mediating mechanisms such as self-efficacy), but also presents aspects of the participants' social context (modifying conditions such as: stress, financial problems, social networks and multiple family roles) that influence how population characteristics (race/ethnicity and SES) might affect behavior patterns. Incorporating social contextual factors into intervention design has been shown to be an effective way to promote beneficial behavior changes among groups experiencing health disparities, including racial/ethnic minority groups [30]. The factors presented in Fig. 1 are informed by our review of the literature and augmented by our findings from the qualitative formative research we conducted (see Section 2.3). Patient navigators will discuss these salient social contextual factors, and identify any new factors, during the delivery of the intervention using motivational interviewing techniques [31]. The financial incentives intervention component are intended to promote self-efficacy and readiness to quit [10] and while the efficacy of financial incentives-based interventions are not limited to only populations with low-income, the financial incentives could at least temporarily address social contextual factors such as stress and hassles related to financial limitations in our study. Our evaluation will be guided by the RE-AIM framework, which includes multiple aspects related to external validity, study implementation, and context intended to provide insight into the dissemination of effective interventions to both policy makers and other researchers over the long-term [32,33]. The components of RE-AIM correspond to both the individual level (Reach, Effectiveness) and the setting level (Adoption, Implementation), and both the individual and setting levels (Maintenance).

2.3. Formative research.

While much is known about patient-reported barriers to and facilitators of smoking cessation, the use of innovative qualitative methods, such as photovoice, may reveal new or additional perspectives about these factors that may then be useful in intervention design. Photovoice is a promising participatory research methodology that allows individuals to document specific life experiences using photography, and then to explain these experiences through a guided discussion and creation of brief narratives [34]. Photovoice methodology has been widely used to address broader community and health concerns [35] and recently it has been employed successfully as a clinical tool embedded in a psychosocial intervention for individuals with serious mental illnesses [36]. Photovoice uses visual images to allow access to settings and perspectives not typically available to researchers (homes, neighborhoods, and interior lives). Haines and colleagues [37] have shown that images produced by smokers illustrate the role of social context in shaping smoking status, as well as the private struggles experienced by smokers in their day-to-day lives and relationships. In addition, photovoice facilitates deeper thinking about smoking and self-reflection among participants. Finally, tobacco users may have unique "insider" knowledge, as well as the empathy and language to support the smoking cessation efforts of their peers who smoke [37]. The presence of "insider" knowledge suggests that photovoice methodology can be used to further inform concepts about the meaning of smoking among a target population and the social and environmental contexts in which people smoke. This information can then be used to personalize intervention content, such as the content and delivery of a patient navigation program.

We conducted a series of photovoice-based group discussions with primary care patients recruited from waiting rooms in a large urban safety-net hospital. To be eligible, patients needed to report smoking at least 10 cigarettes per day in the past week, have a primary care provider at the hospital, be at least 18 years old, and have a working telephone. We implemented a photovoice design which included three separate 2-hour group sessions. The first was a training session, in which a moderator provided instructions on how to use the camera, protect the privacy of potential photography subjects, and to write a narrative about a photograph following standardized prompts. The privacy of photography subjects was protected by notifying participants that if they chose to take a picture of another person, they had to obtain written consent from this person to do so. This consent was obtained through a signed photography consent form which was provided to participants in the photovoice sessions. Any signed photography consent forms were returned to researchers; or in the case of photographing a minor, the minor's parent or guardian needed to sign the consent document. The moderator then gave the topic of the first photography assignment: "What is it like to be a smoker?" Participants