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Developing a nicotine patch adherence intervention for HIV-positive Latino smokers

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HIGHLIGHTS

- The results of these studies suggest that improved adherence with the nicotine patch include information around:
  - Safety and side effects of the nicotine patch
  - Realistic expectations for nicotine patch efficacy
  - Problem solving to weave patch use into daily routines
- These adherence strategies may have implications beyond HIV-positive and Latino smokers.
- Research is needed to evaluate whether including such an adherence intervention to smoking cessation treatment improves clinical outcomes.

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ABSTRACT

This paper describes two phases of formative research that had the goal of developing a treatment designed to improve adherence with the nicotine patch in HIV-positive Latino smokers. Each research phase (Phase I and II) was conducted independent of the other and used different qualitative methods to inform the development of the intervention. Phase I interviewed $n = 14$ smokers who had previous experience using the nicotine patch to gain detailed understanding of how, when, and why they used it; their perceived barriers to using it; and their perspective on ways to improve adherence to it. Phase II provided $n = 35$ smokers with brief smoking cessation treatment and nicotine patches, then interviewed them in "near real time" over a two month period about their use of the patch during a quit attempt (e.g., perceived barriers and facilitators). Authors of the paper extracted relevant themes emerging from the interview transcripts across the two phases. Results indicated that consistent use of the nicotine patch was associated with maintaining high motivation for use (i.e., not necessarily motivation to quit, but motivation to continue patch use); linking its use with established daily routines (e.g., with taking other medications, with brushing teeth); and maintaining realistic expectations for patch efficacy (e.g., that users may still experience some level of craving and/or withdrawal). This information will used to develop and pilot test a brief treatment module that focuses on improving nicotine patch adherence.

1. Introduction

Cigarette smoking is more prevalent among HIV-positive persons than in the general population (Gritz, Vidrine, Lazev, Amick, & Arduino, 2004; Pacek, Harrell, & Martins, 2014). As such, HIV-positive smokers are at risk of developing the diseases associated with cigarette smoking and are at greater risk for developing diseases unique to HIV-positive persons. Moreover, fewer HIV-positive persons are dying from AIDS-related illnesses and more are dying from diseases that result from behavioral risk factors, especially cigarette smoking (Novoa et al., 2008).

Unfortunately, efficacious smoking cessation programs for this population are lacking. Prior research in this area offered some form of behavioral counseling (e.g., tailored behavioral treatment; motivational interviewing; varying lengths of follow-up) with nicotine replacement (Gritz et al., 2013; Humfleet, Hall, Delucchi, & Dilley, 2013; Ingersoll, Cropsey, & Heckman, 2009; Lloyd-Richardson et al., 2009; Moadel et al., 2012; Stanton et al., 2015; Vidrine, Arduino, Lazev, & Gritz, 2006; Vidrine, Marks, Arduino, & Gritz, 2012; Wewers, Neidig, &

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Kihm, 2000). HIV-positive smokers were able to quit with these treatments, but no treatment was found to work especially well over the long term compared to any number of standard control treatments (Moscou-Jackson, Commodore-Mensah, Farley, & DiGiacomo, 2014). One consistent finding that emerged from this literature was that close adherence to nicotine patch treatment predicted better treatment outcomes (Gritz et al., 2013; Ingersoll et al., 2009; Lloyd-Richardson et al., 2009; Vidrine et al., 2006, 2012). A potentially fruitful direction for future clinical research with HIV-positive smokers, then, is to improve adherence with the nicotine patch.

Adherence to the nicotine patch generally tends to be very low (Hollands et al., 2015). Cost, side effects, and beliefs that nicotine replacement is not effective have been cited as reasons for non-adherence (Balmford, Borland, Hammond, & Cummings, 2011). However, simply providing accurate information to smokers about costs, side effects, and efficacy does not improve adherence (Hollands et al., 2015). This finding argues strongly for a more formative approach to research designed to develop an adherence-based intervention for nicotine replacement. Indeed, qualitative research is especially important when adding new components to existing behavioral treatments (Ritchie & Lewis, 2003).

This paper describes the results of two phases of qualitative research that were undertaken to develop a smoking cessation treatment module that specifically improves nicotine patch adherence with HIV-positive smokers.[1] Each research phase was conducted independent of the other and each phase used different methods (retrospective interview in Phase I; prospective treatment study in Phase II) to inform the development of the intervention (i.e., the results of Phase II did not depend on the results of Phase I). We focused specifically on Latino smokers due to their higher risk of AIDS-related (Hariri & McKenna, 2007) and non-AIDS-related diseases (Sackoff, Hanna, Pfeiffer, & Torian, 2006) compared to non-Latino smokers. Although studies have found that Latino smokers want to quit smoking (Collins et al., 2001; see also Tesoriero, Gieryic, Carrascal, & Lavigne, 2010), this population has been historically neglected by health care providers for smoking cessation services (Levinson, Pérez-Stable, Espinoza, Flores, & Byers, 2004; cf., Lloyd-Richardson et al., 2009).

2. Materials and methods

2.1. Phase I

The goal of Phase I was to uncover barriers and facilitators of adherence to the patch during a prior quit attempt. We conducted semi-structured individual interviews with HIV-positive smokers who previously tried to quit smoking with the nicotine patch. The procedures, questionnaires, and interview were conducted in participants' preferred language (Spanish or English). The study was approved by the Institutional Review Boards of RAND and Bienestar Human Services, and participants were further protected by a Certificate of Confidentiality granted by the National Institute on Drug Abuse.

2.1.1. Participants

Media advertising at health clinics and social service agencies serving HIV-positive individuals was used to recruit participants. Individuals were also referred by the staff of Bienestar Human Services, Inc. Bienestar is a non-profit organization serving the HIV-positive Latino community in Southern California. Interested individuals called the study center for more information about the study and to determine eligibility. Participants were eligible if they were at least 18 years of age, Latino, HIV-positive, smoked at least 5 cigarettes per day for at least the last 20 days, and had used the nicotine patch during any past quit attempt.

2.1.2. Interview regarding past use of the nicotine patch

Eligible participants attended an in-person session with one of two bilingual female research assistants (Master's educated) who explained the study, conducted informed consent procedures, and led the interview. The research assistants were trained by a member of the authorship team in conducting interviews with study participants (JST). Neither research assistant had a previous established relationship with any of the participants.

Participants completed a brief questionnaire that assessed demographic, smoking and quitting history variables, including number of cigarettes smoked per day, number of minutes to smoking their first cigarette of the day upon waking (i.e., as an index of nicotine dependence; see Baker et al., 2007) and previous quit attempts (Niaura & Shadel, 2003). They then completed a semi-structured interview that focused on their past experiences with using the nicotine patch. Three broad domains were covered in the interview: Challenges they encountered when using the nicotine patch; whether they had trouble remembering to use the patch; and if they had no trouble remembering, what strategies they employed to help them to use the patch. Interviews were audio-recorded and transcribed. Transcripts were not returned to participants for corrections or supplemental data collection. Individuals were compensated with a $30 gift card for participating.

2.2. Phase II

The goal of Phase II was to uncover barriers and facilitators of adherence to the patch in "near real time" during a quit attempt. We provided brief behavioral treatment and an 8 week course of nicotine patch treatment for Phase II participants. We followed them for 8 weeks, calling them up to seven times during that period to assess their use of the nicotine patch. The procedures, questionnaires, and interview were conducted in participants preferred language (Spanish or English). The procedures of Phase II were approved by the Institutional Review Boards of RAND and Bienestar, and participants were further protected by a Certificate of Confidentiality from the National Institute on Drug Abuse.

2.2.1. Participants

Participants were recruited using the same procedures as in Phase I. The inclusion/exclusion criteria for Phase II encompassed the criteria for Phase I but additionally included: being motivated to quit smoking, as indicated by a score in excess of 150 on their responses to two questions (each scaled from 0 to 100, from 0 (not at all) to 100 (extremely): "How motivated are you right now to quit smoking?" and "How confident are you right now to quit smoking?". This motivation inclusion cut point has been utilized in prior clinical studies with smokers (see Shadel et al., 2011). Individuals were excluded from participating if they reported being or having been treated for a number of medical and/or psychological conditions within the last 12 months (e.g., heart disease, diabetes, chronic obstructive pulmonary disease, skin allergies or allergies to adhesives; being actively treated for depression) or were receiving treatment for smoking cessation. Women who were pregnant or who were planning to become pregnant in the next 30 days were also excluded. These exclusion criteria were employed because they are contraindicated for the nicotine patch.

2.2.2. Brief treatment and nicotine patch protocol

After completing baseline questions as in Phase I (see above), participants were provided with a 20 min smoking cessation treatment (see Shadel & Niaura, 2003). The treatment was delivered by one of two bilingual research assistants who was trained and supervised by PhD level psychologists (JST, WGS). The treatment provided information on the benefits of quitting, engaging in coping skill building to manage

[1] The research methods, results, and discussion are presented with attention to the COREQ (Tong, Sainsbury, & Craig, 2007) checklist for conducting and analyzing qualitative interviews.