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Treatment Satisfaction in a Randomized Clinical Trial of mHealth Smoking Abstinence Reinforcement[☆]

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ABSTRACT

The importance of patient satisfaction in modern healthcare is widely recognized, but research on satisfaction in the context of smoking cessation has not kept pace. The purpose of this study was to explore treatment satisfaction in a sample of smokers ($N = 84$) randomized to one of two smoking cessation treatment interventions (mHealth reinforcement and mHealth monitoring) that used cell phone-based procedures to monitor smoking status in individuals' natural environments for 4 weeks. Starting on the target quit date, participants received usual care smoking cessation treatment consisting of 8 weeks of transdermal nicotine and 4 weeks of twice-weekly telephone counseling were also prompted 1 to 3 times daily (with exact number and timing not disclosed beforehand) to use a study cell phone and CO monitor to complete a CO self-test, video-record the process, and submit videos using multimedia messaging within 2 hours. mHealth reinforcement participants could earn prizes for smoking-negative on-time CO tests. A treatment satisfaction survey was completed at the end of the 4-week monitoring/reinforcement phase. Results indicate that participants overwhelmingly endorsed high levels of overall satisfaction in both conditions. Treatment adherence did not differ between conditions, but was positively associated with endorsing the highest satisfaction with help quitting with the intervention ($p < .01$ to $.03$). mHealth reinforcement was associated with increased longest duration of abstinence ($p < .01$). Controlling for relevant participant characteristics and treatment adherence, longest duration of abstinence robustly predicted highest satisfaction with help quitting and mediated the effect of treatment condition on that satisfaction. Further research on treatment satisfaction may aid the development of effective abstinence reinforcement and other smoking cessation interventions.

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1. Introduction

Satisfaction can be defined as an individual's experience compared with his or her expectations (Pascoe, 1983). The assessment of patient (or, consumer) satisfaction is now ubiquitous in health services sectors, and is consistent with patient-centered care, coordination of care, and other shared decision-making models of modern healthcare (The Institute of Medicine, 2001). Slower to occur has been the evaluation of patient satisfaction in randomized controlled trials (Kelley, Kraft-Todd, Schapira, Kossowsky, & Riess, 2014), especially in the field of smoking cessation or substance abuse treatment in general (Carroll & Rounsaville, 2003). Observational studies generally support a positive relation between patient satisfaction and substance use outcomes (Boden & Moos, 2009; Carlson & Gabriel, 2001; Crosier, Scott, & Steinfeld, 2012; Hawkins, Baer, & Kivlahan, 2008; Hser, Evans, Huang, & Anglin, 2004; Sanford, Donahue, & Cosden, 2014, c.f., McLellan & Hunkeler, 1998). For example, in a large

national panel survey involving patients at 62 methadone, outpatient, and residential programs in the U.S., positive treatment satisfaction near discharge predicted improved drug use outcomes at 1-year, controlling for baseline patient characteristics, treatment duration, counseling intensity, and treatment adherence (Zhang, Gerstein, & Friedmann, 2008). A positive association between treatment satisfaction and long-term outcomes is also evident in other domains, such as treatment for comorbid psychiatric and substance use disorder treatment (Boden & Moos, 2009).

Feedback from patients has also been used to inform modifications to services that then lead to improved patient satisfaction (Crosier et al., 2012), with implications for improved treatment engagement and outcomes going forward. In the smoking cessation research literature, this is particularly evident in efforts to develop and evaluate technology-based interventions, including telemedicine (Richter et al., 2015), web-based (Shahab & McEwen, 2009) and text messaging-based (Kong, Ells, Camenga, & Krishnan-Sarin, 2014) programs. This is a fast growing area of research that often involves assessing the acceptability of interventions that differ in the frequency or intensity of technology-related aspects of treatment. For example, abstinence reinforcement (contingency management) is an efficacious behavioral treatment for reducing substance use (Lussier, Heil, Mongeon, Badger, & Higgins, 2006; Prendergast, Podus, Finney, Greenwell, & Roll, 2006), and recent work has examined

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technology-based methods to deliver this intervention remotely (i.e., in individuals' natural environment, without intensive in-person demands). Reinforcement interventions use tangible incentives like vouchers for goods or services, or "prizes" like gift cards, to systematically reinforce objective evidence of abstinence. Dallery and colleagues have examined the acceptability of delivering reinforcement and other smoking treatment components via web-based procedures (Meredith & Dallery, 2013; Meredith, Grabinski, & Dallery, 2011; Raiff, Jarvis, Turturici, & Dallery, 2013; Reynolds et al., 2015). For example, in the first of a two-trial study (Raiff et al., 2013), smokers were randomized to a 7-week reinforcement condition with incentives for smoking-negative breath tests or a control condition without abstinence reinforcement. In both groups, participants conducted CO self-tests and submitted results via web cam, and received web-based counseling and feedback on CO results. In a second trial, participants were randomized to view a video with a description of the same web-based reinforcement intervention or an intervention that required users to deposit their own money and earn it back by testing smoking-negative on breath tests (as a potential means to off-set the cost of incentives). Overall, participants rated the Internet-based treatment intervention acceptable.

We recently completed a randomized controlled trial of a novel mHealth abstinence reinforcement intervention for treatment-seeking smokers (Alessi, Rash, & Petry, *in press*). The World Health Organization defines mHealth as, for example, the provision of health services and information via mobile technologies such as mobile phones, tablet computers and personal digital assistants (World Health Organization, 2015). To our knowledge, no studies have examined patient satisfaction in the context of mHealth-based abstinence reinforcement for smoking cessation. Information about participant experience is particularly valuable in the context of technology-based applications because of the rapid pace of change, and the related ability to potentially pivot based on feedback if needed. In addition, although our mHealth procedures reduce patient burden related to attending in-person appointments and provide services ecologically and with minimized delay, it also comes with higher demands in terms of patient-directed breath testing. Thus, assessment of acceptability is important. The purpose of the current study was to use data from our recent mHealth reinforcement trial to examine patient satisfaction across a number of areas, and to examine predictors and mediators of global patient satisfaction. Specifically, we expected high levels of satisfaction with treatment overall, and higher satisfaction among those in the mHealth reinforcement condition. We also hypothesized that (1) treatment condition would predict treatment satisfaction, and that (2) adherence and (3) longest duration of abstinence (a primary outcome) may at least partially mediate the relation between treatment condition and satisfaction. We did not have specific hypotheses about relations between participant characteristics and treatment satisfaction.

2. Materials and methods

2.1. Participants and setting

Data were examined from participants in our mHealth abstinence reinforcement trial who completed a treatment satisfaction survey ($N = 84$, 93.3% of the total sample). Participants were adults at least 18 years of age who (1) smoked a minimum of 10 cigarettes daily, verified by a breath carbon monoxide (CO) test reading ≥ 8 parts per million (ppm), (2) had no past-year abstinence exceeding 3 months, (3) intended to quit within 3 weeks, and (4) had a valid photo I.D. and mailing address (for the purpose of loaning out study equipment). Individuals were excluded for (1) past month smoking cessation treatment, (2) serious and unstable psychiatric illness (e.g., schizophrenia, non-nicotine substance use disorder) or medical disease, (3) medication or other contraindications for transdermal nicotine, and (4) use of monoamine oxidase inhibitors, antipsychotics, mood stabilizers, bupropion, or naltrexone. Procedures were provided in English. A master's-level licensed research

therapist completed telephone counseling sessions and a baccalaureate-level research assistant completed remaining assessments. The in-person study visits (intake, follow-up) occurred at a university health center between January 2012 and December 2014. Participants provided written informed consent, and the institutional review board approved study procedures. See Fig. 1 for participant flow.

2.2. Assessments

At intake, a patient form captured demographic and eligibility-related information. The Fagerström Test of Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, & Fagerström, 1991) and the Readiness to Change Questionnaire (Rollnick, Heather, Gold, & Hall, 1992) were completed. At intake, baseline, counseling sessions and the week 4 (end of behavioral treatment) interview, the Timeline Follow-back procedure (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Sobell & Sobell, 1992) captured frequency and intensity of smoking in the past 30 days (intake) or since the last visit (remaining sessions). CO tests were conducted using a Micro Plus Smokerlyzer (Bedfont Scientific Ltd., Kent, England). Treatment satisfaction was assessed at the end of the mHealth phase (week 4) with a 5-item in-house form, to briefly evaluate satisfaction with the intervention overall, satisfaction with help quitting with the intervention, and satisfaction with specific aspects of the mHealth procedures.

2.3. Procedures

Procedures directly related to the current study are presented here and otherwise outlined; see the main study report for details (Alessi et al., *in press*). Briefly, starting on the target quit date, twice-weekly supportive telephone counseling was provided for 4 weeks, and a standard regimen of transdermal nicotine was provided for 8 weeks. Also on the quit date, participants were randomized to one of two treatment conditions: mHealth reinforcement or mHealth monitoring. All participants were instructed that an interactive voice response (IVR) system would send prompts to conduct CO self-tests up to 3 times daily between 7 a.m. and 10 p.m. for the next 4 weeks, with the exact number and timing not disclosed. When prompted, participants used the video-record function on their study cell phone (with a front-facing lens) to record the CO self-test process, and sent the date and time-stamped video to research staff using multimedia messaging. Participants also reported the CO results and number of cigarettes smoked using the IVR. Video test results were compared against IVR reports to confirm accuracy (confirmed in all but 2 instances). mHealth reinforcement participants also earned chances for prizes contingent on on-time and smoking-negative breath tests (CO ≤ 6 parts per million (ppm)). Earnings were determined immediately via computer algorithm during IVR calls, and were available for redemption after IVR reports were confirmed against video clips. The mean (SD) amount earned for smoking-negative tests was \$349.66 (184.12) out of an expected \$502 maximum. Participants were compensated \$25 for the intake interview, \$35 for that at week 4 and \$50 for returning study equipment in good condition (100%). To promote adherence, all participants also received \$1 per CO test and a \$10 bonus each week for submitting all tests.

2.4. Data analysis

Demographic and baseline data were examined for differences between treatment conditions, as well as for differences between those who did and did not endorse the highest satisfaction with help quitting with the intervention, using chi-square, Mann–Whitney U , and analysis of variance (ANOVA) depending on the underlying distribution. Response patterns on all treatment satisfaction survey items were examined visually, and differences between treatment conditions tested using Mann–Whitney U and chi-square as needed. Demographic

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