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The effect of motivational lung age feedback on short-term quit rates in smokers seeking intensive group treatment: A randomized controlled pilot study☆

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ABSTRACT

Background: A brief "Lung Age" feedback intervention has shown promise for personalizing the health impact of smoking and promoting cessation in unselected smokers. Now that many healthcare organizations provide face-to-face cessation services, it is reasonable to ask whether such motivational feedback of lung function tests might improve treatment compliance and cessation rates in smokers wanting to quit. This study assessed effects of baseline motivational spirometry-based "Lung Age" feedback on treatment compliance and tobacco abstinence at 28-day follow-up.

Methods: This randomized controlled pilot study took place in Penn State University-affiliated outpatient medical practices. Participants were 225 adult smokers (≥5 cigarettes/day) willing to attend tobacco dependence treatment. At assessment lung function (FEV-1) and exhaled carbon-monoxide (CO) were assessed. The Intervention group ($n = 120$) were randomly allocated to receive motivational "Lung Age" feedback estimated by FEV-1 and on exhaled CO; Control group ($n = 105$) received minimal feedback. Participants were offered 6 weekly group smoking cessation sessions and nicotine patches and followed-up 28 days after target quit date. The primary outcome measure was self-reported 7-day tobacco abstinence, confirmed by CO < 10 ppm at 28-day follow-up.

Results: Quit rates were similar at follow-up (Intervention 50.8%; Control 52.4%; $p = 0.65$) after controlling for abstinence predictors. Group attendance and patch use were similar. Among those attending follow-up ($n = 164$, 73%), a greater proportion of the Intervention group had improved lung function (67% vs. 46%; $p = 0.0083$).

Conclusions: Baseline Lung Age feedback did not improve quit rates or compliance at 28-day follow-up in smokers seeking intensive treatment.

1. Introduction

Cigarette dependence is caused by the psychoactive effects of nicotine in the smoke (USDHHS, 1988; RCP, 2000) and is characterized by difficulty quitting smoking despite serious attempts, often despite awareness of serious health impacts. Cigarette smokers are more than 10 times more likely to develop lung diseases such as lung cancer and chronic obstructive pulmonary disease (COPD) as compared to non-smokers (USDHHS, 2004). Smoking also causes serious diseases affecting virtually every organ system in the body, and smokers are more than three times as likely as non-smokers to die of ischemic heart disease before the age of 65 (USDHHS, 2004).

Smoking cessation reverses these risks, such that a smoker who quits by age 50 has one-half the risk of dying in the next 15 years as compared to a continuing smoker (USDHHS, 1990). Some physiological measures such as exhaled carbon monoxide (CO) return to non-smoker levels within a few days of quitting smoking, and lung function improves within months of quitting (Bize et al., 2012;

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Scanlon et al., 2000; Jang et al., 2010). It has been suggested that providing smokers with feedback on biomedical tests and the possible future effects of smoking and quitting on such test results may be a strategy for increasing smoking cessation rates (Bize et al., 2012).

A meta-analysis of biomedical risk assessment as an aid for smoking cessation (Bize et al., 2012) concluded that, "There is little evidence about the effects of most types of biomedical tests for risk assessment on *smoking cessation*. Of the fifteen included studies, only two detected a significant effect of the intervention. Spirometry combined with an interpretation of the results in terms of '*lung age*' had a significant effect in a single good quality trial but the evidence is not optimal." That trial (Parkes et al., 2008) found that smokers receiving lung age feedback – that is, lung function test results demonstrating lung function in relation to expected performance by age – were more likely to be quit a year later (13.6%) as compared with those who had the measurement carried out and score provided, but not explained (6.4%). Measurement of exhaled CO has also shown effects on smoking cessation in some studies (Jamrozik et al., 1984; Sanders et al., 1989). For example, Sanders et al. (1989) randomized 751 smokers attending a nurse health screening to either brief smoking cessation advice or brief advice plus CO measurement. One month later 11.7% of the CO measurement group had quit, compared with 7.5% in the Control group. Risser and Belcher (1990) compared education alone or education plus an additional motivational intervention that contained immediate feedback about the smoker's exhaled CO, spirometry results, and pulmonary symptoms. They found that 20% versus 7% remained quit 12 months later. This relatively brief intervention (providing feedback on spirometry-based "Lung Age" plus exhaled CO) therefore shows promise as a way to personalize the health impact of smoking and cessation to patients.

Most of the trials finding positive effects of motivational lung feedback at baseline were conducted in unselected smokers attending for screenings on other medical assessments. This includes the National Lung Screening Trial (Grannis, 2014), the results of which could be interpreted to indicate that smokers who receive negative (high risk) lung screening results are more likely to quit, or, on the other hand, that smokers receiving neutral or positive (low risk) lung screening results are less likely to quit (Kaminsky et al., 2011). This highlights the need for randomized studies. In addition, now that many healthcare organizations provide face-to-face cessation services, it is reasonable to ask whether addition of such measures and motivational feedback might improve treatment compliance and cessation rates in smokers already wanting to quit. A trial with sufficient statistical power (>80%) to detect a meaningful effect on long-term cessation rates (e.g., 25% vs. 35% at 6 months) would require over 800 participants. We, therefore, conducted a smaller pilot study that was designed to identify whether there is any evidence that Lung Age and CO feedback at assessment can improve treatment compliance and short-term (28-day) cessation rates.

2. Materials and methods

2.1. Power calculation

This study had 87% power to detect a 40% increase in 28-day abstinence rates (i.e., from 50% to 70%) based on a two-tailed chi-squared test and alpha = 0.05. We selected this effect size as being at the lower end of the effect size continuum that would be clinically meaningful at 28 days and have the potential to still be meaningful in the longer term even with similar relapse rates in both groups over subsequent months.

2.2. Recruitment and inclusion criteria

This study was registered at ClinicalTrials.gov. Community smokers were recruited via posters and clinician referrals to attend a smoking cessation group treatment and were offered free group support and a two-week supply of nicotine patches. Participants were eligible if they smoked ≥5 cigarettes per day, were ready to make a quit attempt within the next month, ≥21 years old, willing to attend study visits and able to provide informed consent. Exclusion criteria included contraindications for nicotine patch (allergy, pregnancy, recent cardiac problems) or lung function testing (i.e., recent or planned surgery). Other exclusions included current use of smoking cessation medicines, uncontrolled mental illness or substance use in past 6 months, life expectancy <1 year or unwillingness to quit all tobacco products.

Potential volunteers were screened for eligibility by phone and then an assessment appointment with a Nurse Practitioner (SH) was scheduled. Both the assessments and group support sessions took place at outpatient facilities (primarily Penn State Family Practices based in the community) affiliated with Penn State College of Medicine. Recruitment and follow-up occurred between February, 2012 and November, 2013. Eligible participants provided informed consent and completed a comprehensive baseline assessment (as part of a separate study of predictors of cessation), including a full medical and tobacco use history that included the following measures: Penn State Cigarette Dependence Index (PSCDI; Foulds et al., 2015), Fagerstrom Test for Nicotine Dependence (FTND; Heatherton et al., 1991), Hooked on Nicotine Checklist (HONC; DiFranza et al., 2002), Wisconsin Predicting Patients' Relapse (WI-PREPARE) questionnaire (Bolt et al., 2009), education, sex, age, race, employment status, Body Mass Index (BMI), number of quit attempts in the last year, weight gain on longest previous quit attempt, weight concerns (Borrelli and Mermelstein, 1998), confidence to maintain weight after quitting (Borrelli and Mermelstein, 1998), current dieting status, daily alcoholic beverage servings, caffeine consumption (mg/day), cigarettes per day, dietary measurements, confidence in quitting (Boudreaux et al., 2012), importance of quitting (Boudreaux et al., 2012), Brief Perceived Stress score (Cohen et al., 1983), having previously received substance abuse treatment, history of depression treatment, anxiety or other mental health problem, total Kessler 6 (K6) score (Furukawa et al., 2003), total Patient Health Questionnaire (PHQ-9) score (Kroenke et al., 2001), Alcohol Use Disorders Identification Test (AUDIT) score (Frank et al., 2008), Clinical COPD Questionnaire (CCQ) scores (van der Molen et al., 2003), Pittsburgh Sleep Quality Index (PSQI) score (Buysse et al., 1989), total Minnesota Nicotine Withdrawal Scale (MNWS) score (Hughes and Hatsukami, 1986), history of eating disorders, and smoking mentholated cigarettes. 199 of 225 participants provided blood samples for analysis of nicotine and metabolites. For all participants, assessment included measurement of FEV-1 and Lung Age using the Care Fusion SpiroUSB spirometer and Spirometry PC software (SPCS), which selects the best measure from three valid attempts and compares the patient's results to NHANES III-based norms adjusting for age, sex, height, weight and race, yielding percent of predicted FEV-1 and "effective lung age". This spirometer is similar to that used in the original study (Parkes et al., 2008). Exhaled CO was measured using a breath "Smokerlyzer" manufactured by Bedfont Scientific. This type of CO monitor has been validated and used in numerous research studies (Bize et al., 2012).

2.3. Randomization

A CONSORT diagram is included in Fig. 1. 373 individuals were assessed for eligibility using a phone screen. Of these 373 individuals, 16 were not interested in participating in the study; 2 did not