A novel and remote biochemical verification method of smoking abstinence: Predictors of participant compliance

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ABSTRACT

INTRODUCTION Biochemical verification of smoking abstinence remains an important validity check of cessation trial outcomes. Digital health trials rarely establish in-person contacts between participants and intervention providers, requiring novel strategies to biochemically verify outcomes. We describe remote verification of smoking abstinence via saliva cotinine and individual predictors of compliance in a digital intervention.

METHODS Data came from a feasibility trial and randomized controlled trial of a Facebook smoking cessation intervention for young adults. In both trials, participants completed baseline and follow-up surveys at 3, 6 and 12 months. Participants indicating past 7-day point prevalence smoking abstinence were mailed a saliva cotinine kit. Participants were instructed to electronically send two photos — one of them giving a saliva sample and the other with the test results. We investigated predictors of compliance with these procedures, independent of verification results, among participants that were mailed a kit at any follow-up point (N=130; mean age = 21.3; 59.2% female) using logistic and multinomial regression.

RESULTS A total of 189 kits were sent out, of which 97 were completed (51.3% compliance). We did not identify significant predictors of completing any vs no kits using logistic regression. We also found no significant predictors of extent of kit completion (none vs some; none vs all) using multinomial regression and controlling for number of kits sent.

CONCLUSIONS Findings demonstrate the feasibility of this biochemical verification method and suggest low risk for bias of results. Future studies should replicate findings in larger samples and improve compliance with verification procedures.

INTRODUCTION

Biochemical verification of smoking abstinence remains an important validity check of smoking cessation trial outcomes[1-3]. Reliance on self-reported smoking status may lead to over-reporting of smoking abstinence due to inclinations to report socially desirable behavior, especially in the context of intervention trials[2]. Salivary cotinine is commonly used[4] while other methods include more expensive expiratory carbon monoxide (CO) testing and more invasive urinary or serum cotinine testing. Biochemical verification can be costly and time intensive, and a burden to participants who may be required to travel to a field site or clinic to provide the required bio-sample.

Biochemical verification of intervention outcomes is especially challenging in the context of digital smoking cessation interventions. Interventions delivered via text message, smartphone apps or social media have the potential to provide smoking cessation treatment and support to a large number of smokers from geographically diverse locations[3,5], yet they rarely establish in-person contact between participants and intervention providers. Therefore,

strategies are needed to implement biochemical verification of abstinence remotely[6].

Biochemical verification methods in digital smoking cessation trials have made use of both salivary cotinine and carbon monoxide breath samples, yet remote testing is rare. One text-message based intervention required in-person assessment of biochemically verified abstinence[7], while others used postal salivary cotinine testing in which participants were mailed kits and had to return a saliva sample by mail[8,9]. A few studies reported using videos to verify use of a CO monitor and online reporting of CO value[10,11]. However, the need to send costly equipment through the mail limits the study sample size.

Few digital smoking cessation trials have reported participant compliance with biochemical verification procedures. Studies of text message cessation trials in the general population report rates of biochemical verification compliance through mail that range from 64.7%[8] to 81.3%[9], and do not report participant level predictors of compliance. An even lower proportion of participants (39.2%) who self-reported abstinence attended an in-person salivary cotinine testing verification visit as part of a mobile phone text messaging intervention trial[7]. Only one study has reported participant level predictors of compliance. In a study of Veterans Administration patients receiving an in-patient smoking cessation intervention, the 90% of patients who returned a urinary cotinine strip by mail at the 6-month follow up were younger, more likely to be thinking about quitting, more likely to have arthritis, and less likely to have heart disease compared to patients who did not return a test strip[12]. In the absence of predictors of biochemical verification compliance for digital smoking cessation trials, it is unclear how representative obtained results are.

We describe here a novel method for verifying smoking abstinence through remote testing of salivary cotinine and verification via digital photos, among young adults participating in a Facebook smoking cessation intervention. We also investigated whether baseline demographics, smoking behavior and readiness to quit smoking might explain differences in compliance with biochemical verification procedures.

METHODS
Procedure
Data came from two trials investigating the feasibility and efficacy of the Tobacco Status Project (TSP) — a motivationally-tailored smoking cessation intervention delivered through Facebook. First, a feasibility trial (N=79)[13-15] assigned participants to a TSP intervention group. In the second study, a Randomized Controlled Trial (RCT, N=500)[16,17], participants were randomized to one of two conditions: 1) the TSP intervention, or 2) a control condition (referral to the Smokefree.gov website). TSP was delivered entirely on Facebook and consisted of motivationally-tailored automated daily posts to secret Facebook groups and weekly live smoking cessation counselor contact. In both studies, assessments were conducted online at baseline and at 3, 6 and 12 months follow-up. Participants received their choice of gift cards of $20 per survey assessment, and a $20 bonus for completing all three assessments, for a possible total incentive of $100. At every follow-up assessment (at 3, 6 and 12 months) participants who reported past 7-day point prevalence abstinence were mailed a NicAlert saliva cotinine test kit (Confirm Biosciences) with study-designed instructions for its use (see Appendix 1), with a maximum of 3 test kits per participant. Participants were instructed to take two photos: one of the participant giving the saliva sample and the other of the strip showing the resulting cotinine range (from Level 0, corresponding to the range 0–10 ng/mL, to Level 6, in the range 1000+ ng/mL). The two photos were then emailed or sent by Facebook messenger to study coordinators. If biochemical verification was requested, the $20 gift card was only sent if participants also completed verification procedures in addition to the survey. There was no incentive given for reporting abstinence. All study procedures were approved by the Institutional Review Board of the University of California San Francisco.

Participants
Participants were literate in English, aged 18–25 years, reported smoking ≥ 100 cigarettes in their lifetime and smoking at least 1 cigarette per day on 3 or more days of the week. Intention to quit smoking was not required for trial enrollment. Additional inclusion criteria were regular (≥4 days/week)

Facebook use and access to a digital camera to verify smoking abstinence. For the current analyses we included only participants that ever self-reported smoking abstinence during any of the follow-up assessments and were sent a biochemical verification kit (N=130; n=21 feasibility; n=109 RCT).

Measures

Baseline
Measures included age, gender, race/ethnicity, completed education, annual income, employment and Smoking History Questionnaire[18], including time of first cigarette on waking up (≤30 min or < 30 min) to assess nicotine dependence[19] and a measure of smoking cessation goals[20].

Biochemical verification
The primary outcome was compliance with biochemical verification procedures at 3, 6 and 12 months, defined as study receipt of two digital photos, clearly showing the participant giving the saliva sample (Appendix photo 1) and the resulting cotinine range (Appendix photo 2), regardless of the cotinine result.

Statistical analyses

First, predictors of compliance with biochemical verification procedures at any follow-up point (any vs none) were modelled using logistic regression. Second, extent of biochemical verification compliance (none, some, all) over 12 months was modelled using multinomial regressions with 'none' as the reference category. To account for the fact that participants who more frequently self-reported abstinence were mailed more kits, these analyses additionally controlled for number of kits that were mailed to a given participant. There was no difference in compliance by condition ($\chi^2[1]=0.05$, p=0.83); thus condition was not included in the regression analyses.

RESULTS

Participant characteristics are reported in Table 1. A total of 189 biochemical verification kits were sent out to participants throughout the follow-up period of each trial (Feasibility: 33; RCT: 156), of which 97 (51.3%) were completed (Feasibility: 17; 51.5%; RCT: 80; 51.2%) with 85 (87.7%) of these

Table 1: Sample description and logistic regression results predicting any compliance with biochemical verification procedures[1] (N=130)

	N or mean	% or SD	OR	95% CI
Age (M, SD)	21.3	2.2	1.0	0.9–1.2
Gender identity: female	77	59.2%	0.5	0.3–1.1
Race/Ethnicity Non-White	35	26.9%	1.0	0.5–2.3
Household Income				
$20 000 or less	38	29.2%	Ref.	
$21 000 – 40 000	41	31.5%	0.8	0.3–1.8
$41 000 – 60 000	18	13.8%	0.4	0.1–1.3
$61 000 or more	33	25.4%	0.8	0.3–2.0
Highest level of education				
Less than high school	12	9.2%	Ref.	
Complete high school/GED	30	23.1%	0.4	0.1–1.8
Some college	81	62.3%	0.6	0.2–2.2
Completed college	7	5.4%	0.4	0.1–2.6
Employment status (compared to employed full-time)				
Employed full-time	54	41.5%	Ref.	
Employed part-time	31	23.9%	0.7	0.2–4.2
Unemployed	45	34.6%	1.0	0.2–3.0
Daily smoker	93	71.5%	0.7	0.3–1.6
Number of smoking days per week (M, SD)	6.3	1.2	1.0	0.9–1.0
Number of cigarettes per smoking day (M, SD)	9.1	6.3	1.0	0.8–1.3
Smoke first cigarette ≤ 30 min of waking (TTFC)	57	43.9%	0.8	0.4–1.6
Any past year quit attempt	94	72.3%	1.1	0.5–2.3
Smoking cessation goal				
No goal	18	13.9%	Ref.	
Reduction	80	61.5%	1.3	0.5–3.6
Abstinence	32	24.6%	1.0	0.3–3.2
Readiness to quit				
Pre-contemplation	18	13.9%	Ref.	
Contemplation	68	52.3%	1.3	0.4–3.6
Preparation	44	33.8%	2.2	0.7–6.7

OR = odds ratio; 95% CI = 95% confidence interval; Ref. = reference category for logistic regression;
1 Biochemical verification of abstinence was considered completed when a participant returned to study staff photos of giving saliva sample and of test results. Biochemical verification was completed by 70/130 participants (53.7%).

confirmed abstinent (Feasibility: 16/17; 94.1%; RCT: 69/80; 86.3%). Over half of the participants (n=70; 53.9%) completed a biochemical verification kit at any follow-up. There were no significant participant baseline predictors of any vs no compliance with biochemical verification procedures (Table 1).

In total, 20 participants (15.4%) completed some of the kits and 50 participants (38.5%) completed all of the kits. In multinomial logistic regression analyses, there were no significant participant baseline predictors of extent of compliance with biochemical verification procedures (data not shown).

DISCUSSION

The current study investigated predictors of compliance with remote biochemical verification of smoking abstinence among young adults participating in two trials of a Facebook smoking cessation intervention. We did not find any significant predictors of biochemical verification compliance or extent of compliance compared to non-compliance among participants who self-reported 7-day point prevalence smoking abstinence.

We observed an overall compliance rate of 51.3% with our biochemical verification procedures. This rate is lower than some studies among general population samples of smokers, that required participants to return saliva samples or test strips in the mail. Previous studies with adults motivated to quit smoking and in-person contacts within a system of care (e.g. Veterans Affairs – VA) reported compliance rates of 90%[12], 81.3%[9] and 64.7%[8]. Our results compare favorably to a study that required participants to attend an in-person session for salivary cotinine testing, which resulted in a compliance rate of 39.2%[7]. We expected that our method of asking participants to return digital photos of saliva cotinine test results would yield higher compliance than requiring a return through the mail in a young adult population, yet, this was not directly evaluated through our trials. We also did not compare compliance with our saliva test to compliance with urine testing used in other studies[12] because we anticipated problems with implementing a urine testing procedure remotely in this entirely digital study.

It is unclear how our sample of young adult participants, only some of whom were ready to quit smoking at baseline, may have impacted on observed compliance rates. Previous studies have suggested that it may be more difficult to engage young adults in highly compliant behavior in studies on tobacco use, especially if there is no in-person contact between participants and study staff[21].

Limitations

Our sample consisted of young adult smokers participating in a Facebook smoking cessation intervention and findings may not be generalizable to other populations of different ages or levels of experience in using technology. Moreover, we did not use other methods of biochemical verification, including mailing of saliva samples or in-person verification, for direct comparison of compliance rates. Additionally, our analytical sample size of 130 may have limited power to detect significant differences, although 130 is well above the rule of thumb of 10 observations per independent variable in logistic regression analyses[22], and there was a relatively even distribution between returned (i.e. compliant) and not-returned biochemical verification test kits.

CONCLUSIONS

Findings are promising and suggest that this method of conducting biochemical verification of smoking cessation intervention outcomes is feasible. There may be low risk of systematic biases regarding how young adult participants comply with verification procedures in the context of a Facebook intervention. Biochemical verification results of a subset of participants can potentially be used to extrapolate to the entire sample of study participants self-reporting smoking abstinence. Future studies are needed to replicate findings in larger samples, directly compare multiple methods of biochemical verification and investigate strategies to improve compliance with verification procedures.

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