2023

Impact of COVID-19 on a Smoking Cessation Intervention: A Look at Recruitment and Retention

Elizabeth S. Hawes
University Of Alabama At Birmingham

IMPACT OF COVID-19 ON A SMOKING CESSATION INTERVENTION: A LOOK AT RECRUITMENT AND RETENTION

by

ELIZABETH S. HAWES

KAREN L. CROPSEY, COMMITTEE CHAIR
ANDRES AZUERO
CHRISTOPHER HENRICH

A THESIS

Submitted to the graduate faculty of The University of Alabama at Birmingham,
in partial fulfillment of the requirements for the degree of
Masters of Arts

BIRMINGHAM, ALABAMA

2023

IMPACT OF COVID-19 ON A SMOKING CESSATION INTERVENTION: A LOOK AT RECRUITMENT AND RETENTION

ELIZABETH S. HAWES

MEDICAL CLINICAL PSYCHOLOGY

ABSTRACT

While smoking prevalence rates have declined in the general population over the past 50 years, persons in the criminal legal population have disproportionally high rates of smoking. Previous research suggests that smoking cessation interventions and campaigns have missed targeting this population. Due to the COVD-19 pandemic, many ongoing clinical trials had to rapidly shift to using remote trials, including our smoking cessation trial with the criminal legal population. The purpose of this secondary analysis was to compare recruitment rate, study adherence, retention, NRT adherence, and quit attempts for participants who completed the study as planned (In Person), after implementation of a voucher system and additional check-in appointments (Incentivized), and after the pandemic began (Hybrid). There were no significant differences in any of the study outcomes between the methodology groups, suggesting that hybrid methods of research do not result in a slower recruitment pace, less visits attended, or a higher likelihood of drop-out. Completing the study remotely did not appear to impact study outcomes such as likelihood of making a quit attempt or using NRT. These results contribute to a better understanding of how remote research methods impact recruitment, retention, and other study outcomes.

Keywords: remote methods, hybrid methods, NRT

TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

Figure *Page*

INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC, 2023) smoking is the number one cause of preventable disease, disability, and death in the U.S. and in many other countries around the world. About 11.5% of the U.S. population smokes cigarettes (CDC, 2023) and in certain populations (e.g., people with low SES, mental illness, substance use disorders, or those with criminal legal involvement), the prevalence rate is much higher (Andrade & Kinner, 2017). Smoking prevalence rates among incarcerated individuals are substantially higher than non-incarcerated adults, with estimates ranging from 60% to 80%, constituting about 12% of people who smoke cigarettes in the United States (Ahalt et al., 2019; Winkelman et al., 2019). As a result, individuals involved with the criminal legal system are at an even higher risk for severe health conditions associated with smoking such as cardiovascular disease, cancer, circulatory and respiratory problems, kidney and liver problems, and diabetes (Armstrong et al., 2021). Despite most jails and prisons implementing smoking bans (Kauffman et al., 2008), there is almost universal relapse back to smoking post-release (Andrade & Kinner, 2017; Lincoln et al., 2009). In fact, most of the criminal legal population remains under supervision in the community (e.g., probation, parole, specialty courts) and do not have any limitations placed on their smoking behaviors. Previous smoking cessation intervention research in criminal legal populations (including in prison) has demonstrated

the efficacy of using nicotine replacement therapy (Andrade & Kinner, 2017; Cropsey et al., 2008; Cropsey, Hendricks, et al., 2017) and bupropion (Cropsey, Clark, et al., 2017).

Nicotine Replacement Therapy and Medication Adherence

Nicotine replacement therapy (NRT) is an FDA-approved smoking cessation aid which includes nicotine patches, gum, lozenges, nasal spray, and inhalers. The patch, lozenge, and gum are sold over the counter and are generally widely available and easy to access (Carpenter et al., 2013). Despite these benefits, most people who smoke discontinue use of NRT prematurely and use less of the product per day than is recommended (Balmford et al., 2011; Mersha et al., 2020; Raupach et al., 2014). A general lack of knowledge about NRT, misperceptions, and a low rate of medication adherence all contribute to premature stopping of NRT (Carpenter et al., 2011). Nonadherence to medications generally can be attributed to many reasons such as high cost of the medication, lack of coordination of care, and individual factors (Cutler & Everett, 2010). However, medication adherence is crucial as studies with NRT (Raupach et al., 2014; Shiffman et al., 2008) and other smoking cessation medications (bupropion and varenicline; Catz et al., 2011; Cropsey, Clark, et al., 2017), have demonstrated high adherence to be associated with better smoking cessation outcomes. This was also true among the criminal legal population where medication adherence was the strongest predictor of smoking cessation (Cropsey, Clark, et al., 2017).

Remote Research Methods

Slow recruitment pace, low enrollment, and high attrition rates are some of the main challenges in conducting clinical trials (Cooper et al., 2018; Mahoney et al., 2021; Nipp et al., 2019; Rodríguez-Torres et al., 2021). However, remote trials afford researchers the opportunity to reach participants who might not be able to participate otherwise due to time commitments, lack of transportation, or other reasons (Alemayehu et al., 2021; Mahoney et al., 2021; Nipp et al., 2019; Rodríguez-Torres et al., 2021). In the tobacco research field, many researchers have incorporated remote methods into their research design. For example, methods such as text-messaging, delivery of therapy or assessments pushed to smartphones as well as internet-based smoking cessation interventions have all recently been developed (Abroms et al., 2014; Hammett et al., 2018; Squiers et al., 2017; Taylor et al., 2017; Whittaker et al., 2019). With the invention of a smartphone-enabled carbon monoxide monitor, researchers can even receive bio-chemically verified smoking data without the need to perform in-person carbon monoxide (CO) testing, allowing for remote biochemical verification of smoking status (Tuck et al., 2021). Despite the use of remote methods, few studies have directly compared in-person to remote strategies within a single study. In one smoking cessation trial conducted during the pandemic, participants who pivoted to remote visits completed a similar number of visits and provided around the same number of saliva specimens as the participants who completed all study procedures in person (Mahoney et al., 2021), suggesting that remote methods are feasible. In another telehealth trial, similar cessation rates were found for an in-person vs. telehealth intervention in rural areas for smoking cessation (Carlson et al., 2012). Only one pilot trial examined remote methods in the

criminal legal population and demonstrated benefit to persons in rural prisons (Valera et al., 2021). Overall, while these previous studies show promise for remote methods, they were also generally conducted with small samples which limited opportunities to examine differences in important study outcomes of interest.

The Current Study

Given the preliminary success of giving free samples of NRT to people who smoke to help them quit in the general population (Jardin et al., 2014) and based on the study team's pilot interventions among people who smoke who are low-income (Cropsey et al., 2021) and in the criminal legal population (Cropsey, Hendricks, et al., 2017) this study provided an intervention that was intended to increase medication adherence as a way to increase successful cessation attempts. We compared study outcomes between participants who completed the study 1) as planned (In-Person), 2) after incentives and check-in appointments were implemented (Incentivized), and 3) were recruited after the pandemic began (Hybrid). The hybrid group consists of participants who were incentivized but completed all study procedures remotely except for the baseline visit. It was hypothesized that those participants in the Hybrid group who completed all study procedures remotely other than the baseline were recruited faster, were more likely to stay in the study until study end and attended more study appointments overall than those who completed study procedures in the first two groups.

METHOD

Participants

Participants (N_{total}=515) were recruited from the UAB Substance Abuse programs with flyers posted in locations that provide services to individuals under criminal legal supervision. Inclusion criteria were: (a) under community criminal legal supervision over the next 6 months, (b) smoking at least 5 cigarettes/day for the past year (c) 18 years of age or older, (d) able to read and speak English, (e) able to provide contact information for at least two people who would know how to reach the participant if unable to contact (f) living in an unrestricted environment that allows smoking, (g) able to access a smartphone or a personal email address. Participants could not (a) be pregnant or breastfeeding, (b) have a cognitive impairment or untreated mental illness that interferes with informed consent, (c) have experienced (within 6 months) post-myocardial infarction or untreated severe angina, (d) have a known sensitivity to NRT or adhesive products (e) exclusively use other tobacco products (e.g., cigars, e-cigarettes; although concurrent use of other tobacco products was not an exclusion criterion), or (f) be currently receiving treatment to quit smoking.

The current sample includes participants who completed the study entirely in person (In-Person; *n*= 236), participants who started the study in person after we started a voucher incentive program and additional check-in visits to improve retention and recruitment (Incentivized; n=126), and participants who completed every aspect of the study, except baseline assessment, remotely (Hybrid; n=153). It is important to note that

the second group includes some participants who may have completed some of their visits remotely, due to pandemic-related shutdowns. However, they began the study before the pandemic started and intended to complete all study procedures in person.

Procedures

Eligible participants were required to attend the baseline visit in person to determine final eligibility, with smoking status verified with both a breath and urine sample. After eligibility was confirmed, participants completed a battery of assessment measures by trained staff members and were randomized to one of two conditions (1:1). The intervention (in vivo) group sampled NRT at each weekly session (Session 1: Patch, Session 2: Lozenge, Session 3: Combined Patch & Lozenge) and was given the product sampled in session to use at home between appointments. Participants were asked about their expectations and real-time experience with the medication during the sessions. The control group received behavioral smoking cessation counseling during the first three sessions covering standard smoking session techniques, such as cognitive and behavioral strategies for coping with cravings and withdrawal, stimulus control, and relaxation techniques. After the third session, the control group also received combo NRT; however, NRT was not used *in vivo* during counseling sessions and was dispensed like what they would receive from a pharmacy. For the in vivo group, the last intervention session focused on the participants' experiences with NRT the prior week while the counseling group largely focused on gains made during the intervention and the threat of relapse. Both groups were provided with a total of 8 weeks' worth of patches and lozenges to use for cessation.

Participants completed five follow-up visits (week 8, week 12, months 1, 3, and 6). During these visits, participants completed questionnaires and exhaled into a carbon monoxide (CO) monitor as an indicator of smoking status. Initially CO was measured at each visit using the Vitalograph CO monitor; however, when recruitment resumed following the COVID lockdown, participants were taught how to use an iCO Smokerlyzer device at the baseline appointment to use remotely for each subsequent visit. Participants who completed the entire study received $440 compensation.

Participants were given multiple reminders when they had upcoming study appointments. A time point was considered missing if the participant's CO reading or weekly smoking behavior survey was incomplete. This was used to assess study retention and adherence for all groups. Missing information on individual items was minimal given the nature of REDCap questionnaires, which prevents participants from skipping items before moving forward in the questionnaire series.

Measures

Data was collected as part of the parent study for all outcomes. The measures below were used in this secondary analysis.

Demographic Form

Demographic information such as age, sex, number of children, employment, and education level were collected at their baseline appointment. The continuous variable for number of children in the house was recoded into the following categories: 0 children, 1 child, 2 children, or 3 or more children. The variable for usual employment status over

the past three years was recoded from the original eight categories: full time, part time (regular hours), part time (irregular hours), student, military service, retired/disability, unemployed, in controlled environment to the following categories: full-time, part-time, unemployed, or other by collapsing the prior categories into fewer groupings. The variable for paid for working within the past 30 days was created by creating two groups (yes/no) based on the question "How many days were you paid for working in the past 30 days?".

Perceived Stress Scale

This is a 10-item measure assessing one's perceived stress over the past month. There are five answer choices ranging from "never" to "very often". An example question is "In the last month, how often have you been upset because of something that happened unexpectedly?" Total scores can range from 0-40, with a score of 27-40 indicating high perceived stress.

Weekly Smoking Behavior Survey

This measure assesses smoking behavior over the past week and collects information such as average cigarettes smoked per day, other tobacco product use, and 24-hour quit attempts made.

NRT Use Calendar

These measures collect information about the number of nicotine patches used and nicotine lozenges used every day over the past week. These measures are used to examine NRT adherence at session 4.

Data Analytic Approach

Preliminary Data Analysis

Descriptive and graphical analyses for all variables of interest were conducted to identify possible outliers and out-of-range values, which were subsequently examined for validity. Preliminary analyses verified that the assumptions specific to the statistical techniques that were used were met, and adjustments were made for heteroscedasticity and overdispersion, in linear and Poisson regression models, respectively.

If a carbon monoxide (CO) sample was collected and reported for a visit or the weekly smoking behavior survey was completed, then a visit was marked as complete for the purpose of the study adherence and retention analyses.

Primary Analysis

The Statistical Package for the Social Sciences (SPSS; IBM Corp., 2022) version 29 and RStudio (version 4.2.2, R Core Team, 2022) were used to conduct all analyses. First, descriptive statistics were obtained for all sociodemographic and primary study variables. Recruitment rate was evaluated using Poisson regression with aggregated data, comparing the number of participants recruited for the duration in days of each methodology group (as offset variable). Methodology group, sex, employment (whether

paid over the last 30 days), and perceived stress score (split into quartiles) were used as adjusting covariates. The unadjusted Poisson model included data from 3 aggregated profiles (one for each methodology group), while the adjusted Poisson model included data from 48 aggregated profiles (resulting from the combinations of explanatory variable categories).

For the remainder of the analyses, the role of the methodology group was examined as an effect modifier with interaction terms between methodology group (e.g., In-Person, Incentivized, Hybrid) and treatment group (e.g., Intervention, Control), to determine if methodology group resulted in differential effect of the treatment. The study adherence variable was computed by taking the total number of visits a participant attended and dividing it by ten (the total number of visits possible) to create a fraction between 0 and 1. Study adherence was evaluated using fractional logistic regression models for a continuous proportion bounded to the interval 0-1 to examine the effects of treatment group, methodology group, and the treatment by methodology group interaction. The following variables were also included as covariates: age, sex, employment (status over the past three years, paid over the last 30 days), children in the home, education, and perceived stress score.

Patch adherence was calculated by computing the proportion of hours the patch was worn divided by 24 hours for each day of the week and then by taking the average for the week. Similarly for lozenge adherence, the number of lozenges used for each day was divided by 8 (the recommended dosage). If a participant took more than 8 lozenges on any given day, the data was capped so that they could not have a higher proportion than 1. An average of the seven days was then calculated to create the weekly lozenge

adherence variable. Fractional logistic regression models were used fitted to the NRT adherence variables with treatment group, methodology group, and the treatment by methodology group interaction as main explanatory variables. The following variables were also included as covariates: age, sex, employment (status over the past three years, paid over the last 30 days), children in the home, education, and perceived stress score.

Study retention (number of people who remained in the study until the last follow-up session) and quit attempts at session four were evaluated using logistic regression. If a participant made any quit attempt between session three and four, they were coded as “yes”, otherwise participants that did not make any quit attempts were coded as “no”. Main explanatory variables for the logistic models were treatment group, methodology group, and the treatment by methodology group interaction. Age, sex, employment (status over the past three years, paid over the last 30 days), number of children in the home, education, and perceived stress score were included as covariates. Similarly, those that attended the 6-month follow-up visit were coded as “yes” and those that did not were coded as “no” for examining study retention using logistic regression.

RESULTS

Demographic Information

Descriptive statistics for sociodemographic variables for the overall sample and by methodology group (In-Person, Incentivized, and Hybrid) are reported in Table 1. Descriptive statistics are also included for primary study outcomes in Table 1.

Recruitment Rate

The overall test of group differences in recruitment rate was significant ($\chi^2(2) = 12.07$, $p = .002$). The incentivized group (.41 participants/day) was recruited faster than the In-Person (.29 participants/day) and Hybrid (.28 participants/day) groups. Figure 1 depicts the cumulative recruitment for each group. After adding confounding variables that were significantly different between groups, (employment, sex, PSS score), the recruitment rate difference between the incentivized group and in-person group remained; however, the difference between the hybrid group and incentivized group was not significant (see Table 2). An incidental finding was that participants who reported that they were not employed over the past 30 days (i.e., reported being paid for 0/30 days) were recruited faster than participants who had reported being paid from employment over the past 30 days.

Study Adherence

Type II tests for treatment group ($\chi^2(1) = 0.19$, $p = 0.66$), methodology group ($\chi^2(2) = 0.5592$, $p = 0.76$), and the treatment and methodology group interaction ($\chi^2(2) = 1.71$, $p = 0.42$) indicated these variables were not significant predictors. As an incidental finding, having two children compared to zero children was associated with a 10.8% decrease in attendance. Females were additionally 6.6% more likely to attend visits than males. Lastly, as age increased, so did the likelihood of attending more visits. There was an average difference of approximately 16% in completion between 30-year-old and 60-year-old participants.

Study Retention

304 participants (59%) completed the six-month follow-up visit and one case was excluded from the analysis because of missing covariate data. The omnibus logistic regression model test was statistically significant, $\chi^2(17) = 40.73$, $p = .001$. However, the model correctly classified only 62.1% of cases (Nagelkerke $R^2=.10$). Treatment group, methodology group, and the treatment and methodology group interaction were not significant predictors. As an incidental finding, age was the only significant predictor (OR = 1.04, 95%CI [1.02; 1.06]); the odds of attending the 6-month follow-up visit increased by 4.4% for every one-year increase in age.

NRT Adherence

416 participants (80.8%) completed the session four visit and six of these cases were excluded from this analysis due to missing data. While the treatment group by methodology group interaction was not significant, there was a significant main effect of treatment group on lozenge adherence (Figure 2). Participants in the intervention group had on average 31.8% higher adherence to the recommended number of lozenges (at least eight) per day than the standard counseling group (73.4% vs. 41.6%, OR= 3.86, $p<.001$). For nicotine patch adherence, a similar effect of treatment group was evident, although the relationship was not as strong. Participants in the intervention group had on average 12.4% higher adherence to use one patch/day for 24 hours over the final week of the intervention period than participants in the standard counseling group (76.3% vs. 63.9%, OR= 1.82, $p<.001$). An incidental finding was that age was a significant predictor; there was an average difference of approximately 10.4% in patch adherence between 30-year-old and 60-year-old participants with older participants being more adherent.

Quit Attempts

416 participants (80.8%) completed the session four visit and two of these cases were excluded from this analysis due to missing data. The omnibus test for the logistic regression model was not statistically significant, $\chi^2(17) = 23.48$, $p = .13$. The treatment by methodology group interaction was not significant; however, after removing the interaction from the model, the results suggested a main effect of treatment group (OR=1.62, 95% CI [1.07, 2.45]). Compared to their control counterparts, participants in the in vivo group had 62% higher odds of reporting a quit attempt at session four.

DISCUSSION

This study was one of the first to compare remote/hybrid to in-person study methods. Overall, the hybrid group did not fare any better or any worse than other groups on recruitment rate, appointment adherence, retention, NRT adherence, or quit attempts. One possible reason that the recruitment rate for the hybrid group was not faster than the other groups as hypothesized is because of the impact of the COVID-19 pandemic, and not because of the difference in methodology groups. Dealing with the stress of the pandemic and changes that ensued in daily life could have made participants less likely to want to participate in a study, even one that included only one in-person visit. Some individuals, especially people who smoke, may not have wanted to risk contracting the COVID-19 virus knowing that smoking put them at a higher risk for complications (Haddad et al., 2021). Additionally, people involved in the criminal legal system under community supervision may have faced even more barriers to participating as a result of the pandemic, such as being at a higher risk for severe COVID-19 compared to people not under community supervision because of their interactions with jails and prisons, as well as high levels of mortality and worse access to healthcare compared to those who are incarcerated (Gutierrez & Patterson, 2021). Order effects provide another possible explanation as to why the recruitment rate was not faster for the hybrid group. It is typically harder to find participants for a large-scale study as time passes, and the hybrid group was composed of the last 153 participants out of 515.

The findings that the methodology by treatment group interaction was not significant for the number of study visits attended and the number of people who attended the six-month follow-up suggest that remote/hybrid methods do not have a large impact on study protocol adherence and study retention. This is good news for researchers since remote research typically allows for a more diverse sample of participants to be recruited and is associated with less study burden on participants. Participants do not need to factor in travel time, finding a ride, parking difficulties, childcare, etc. for remote visits. The use of mobile technology in particular is especially useful for people across socioeconomic groups, as 97% of Americans with a household income under $30,000 own a cellphone (Sharma et al., 2022). Of course, participants do need to be more familiar with technology in most cases (e.g., filling out online surveys, joining video calls, etc.), however technological literacy is improving with each passing year, especially since the COVID-19 pandemic (Martínez-Alcalá et al., 2021).

The methodology by treatment group interaction was not significant for making a quit attempt at the last intervention session nor was it significant for NRT adherence. Again, this is good news for tobacco researchers and other interventionists who may be concerned that remote methods are less effective than in-person methods. Regarding NRT adherence, trying the NRT products for the previous three weeks, during session with the study staff (in vivo group), greatly improved adherence between sessions three and four compared to the standard smoking cessation counseling group.

COVID-19 accelerated the adoption of remote methods given the risks of in-person contact with research participants (Dahne et al., 2020; Izmailova et al., 2020). For many research teams, this was the first time they started obtaining consent via online

methods (e.g., using Docusign, Qualtrics, etc.), using video conferencing platforms to substitute for in-person visits (e.g., Microsoft Teams, Zoom, etc.), and transitioning from pen and paper assessments to online assessments (e.g., REDCap, Qualtrics, etc.; McDermott & Newman, 2021; Saberi, 2020). While this comparison was unplanned due to the pandemic's effects on our in-person protocol, there are benefits to digitizing clinical trials that should be considered outside of the context of the pandemic (Inan et al., 2020), such as increased reach of participants for recruitment and reduced costs. While remote clinical trials have many advantages, they also have some limitations (Mahoney et al., 2021). For example, it is more difficult to monitor participants from their own home, therefore protocol standardization is decreased, and the intervention setting is not uniform (Chiamulera et al., 2021). Even more concerning is the possibility that participants can deceitfully fill out screening surveys and therefore enroll in a study they are not eligible for or, alternatively, participate in the same study more than once, compromising the integrity of the data (Teitcher et al., 2015). More research is needed to be able to accurately weigh these costs and benefits when designing a study.

Strengths and Limitations

A major limitation is that the quasi-experimental nature of the study design does not afford the opportunity to discern how much the results are affected by COVID-19 (people getting sick, using technology more and in some cases using for the first time, working from home or losing a job, smoking less because of fear of covid, different childcare responsibilities, etc.). This list is not exhaustive and is just a sample of the various ways the pandemic could have affected participation in this trial. Similarly,

participants were not randomized to the different approaches but were in these groups due to COVID-19; thus, a study design in which participants are randomized to in-person vs. remote groups would allow for a better understanding of recruitment rate and study protocol adherence as well as treatment outcomes due to these different approaches. Finally, another potential limitation is our conservative approach to include many variables in the model to control for potential confounds given that the methodology groups were not created via random assignment. It is possible that the overlapping variance between these variables (i.e., multicollinearity) could have reduced our statistical power to the point where identifying real treatment by methodology group effects was too low. In the absence of a randomized controlled trial, propensity score matching could be used to reduce the influence of confounds between groups in a more quasi-experimental design where random assignment to in-person vs. remote is not used. However, this study is one of the first to examine the impact of transitioning to hybrid methods and demonstrates that study outcomes of interest remained largely unaffected. Strengths of this study include a robust sample size in each of the three groups and incorporation of the same measures and procedures (e.g., same surveys, biochemical verification, same intervention) across all groups despite the onset of COVID-19.

REFERENCES

Abroms, L. C., Boal, A. L., Simmens, S. J., Mendel, J. A., & Windsor, R. A. (2014). A randomized trial of Text2Quit: A text messaging program for smoking cessation. *American Journal of Preventive Medicine*, *47*(3), 242–250. https://doi.org/10.1016/j.amepre.2014.04.010

Ahalt, C., Buisker, T., Myers, J., & Williams, B. (2019). Smoking and smoking cessation among criminal justice–involved older adults. *Tobacco Use Insights*, *12*, 1179173X19833357. https://doi.org/10.1177/1179173X19833357

Alemayehu, D., Hemmings, R., Natarajan, K., & Roychoudhury, S. (2021). Perspectives on virtual (remote) clinical trials as the "new normal" to accelerate drug development. *Clinical Pharmacology and Therapeutics*. https://doi.org/10.1002/cpt.2248

Andrade, D. de, & Kinner, S. A. (2017). Systematic review of health and behavioural outcomes of smoking cessation interventions in prisons. *Tobacco Control*, *26*(5), 495–501. https://doi.org/10.1136/tobaccocontrol-2016-053297

Armstrong, J. D., Bauman, A., Moroney, K. J., & Clark, C. B. (2021). *Assessment and Treatment of Addictions in Community Corrections*. IntechOpen. https://doi.org/10.5772/intechopen.96770

Balmford, J., Borland, R., Hammond, D., & Cummings, K. M. (2011). Adherence to and reasons for premature discontinuation from stop-smoking medications: Data from the ITC Four-Country Survey. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, *13*(2), 94–102. https://doi.org/10.1093/ntr/ntq215

Carlson, L. E., Lounsberry, J. J., Maciejewski, O., Wright, K., Collacutt, V., & Taenzer, P. (2012). Telehealth-delivered group smoking cessation for rural and urban participants: Feasibility and cessation rates. *Addictive Behaviors*, *37*(1), 108–114. https://doi.org/10.1016/j.addbeh.2011.09.011

Carpenter, M. J., Ford, M. E., Cartmell, K., & Alberg, A. J. (2011). Misperceptions of nicotine replacement therapy within racially and ethnically diverse smokers. *Journal of the National Medical Association*, *103*(9), 885–896. https://doi.org/10.1016/S0027-9684(15)30444-2

Carpenter, M. J., Jardin, B. F., Burris, J. L., Mathew, A. R., Schnoll, R. A., Rigotti, N. A., & Cummings, K. M. (2013). Clinical strategies to enhance the efficacy of nicotine replacement therapy for smoking cessation: A review of the literature. *Drugs*, *73*(5), 407–426. https://doi.org/10.1007/s40265-013-0038-y

Catz, S. L., Jack, L. M., McClure, J. B., Javitz, H. S., Deprey, M., Zbikowski, S. M., McAfee, T., Richards, J., & Swan, G. E. (2011). Adherence to varenicline in the COMPASS smoking cessation intervention trial. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, *13*(5), 361–368. https://doi.org/10.1093/ntr/ntr003

CDC. (2022, August 22). *Current Cigarette Smoking Among Adults in the United States*. Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm

Chiamulera, C., Mantovani, E., & Tamburin, S. (2021). Remote clinical trials: A timely opportunity for a virtual reality approach and its potential application in neurology. *British Journal of Clinical Pharmacology*, *87*(10), 3639–3642. https://doi.org/10.1111/bcp.14922

Cooper, C. L., Whitehead, A., Pottrill, E., Julious, S. A., & Walters, S. J. (2018). Are pilot trials useful for predicting randomisation and attrition rates in definitive studies: A review of publicly funded trials. *Clinical Trials*, *15*(2), 189–196. https://doi.org/10.1177/1740774517752113

Cropsey, K., Eldridge, G., Weaver, M., Villalobos, G., Stitzer, M., & Best, A. (2008). Smoking cessation intervention for female prisoners: Addressing an urgent public health need. *American Journal of Public Health*, *98*(10), 1894–1901. https://doi.org/10.2105/AJPH.2007.128207

Cropsey, K. L., Clark, C. B., Stevens, E. N., Schiavon, S., Lahti, A. C., & Hendricks, P. S. (2017). Predictors of medication adherence and smoking cessation among smokers under community corrections supervision. *Addictive Behaviors*, *65*, 111–117. https://doi.org/10.1016/j.addbeh.2016.10.010

Cropsey, K. L., Hendricks, P. S., Schiavon, S., Sellers, A., Froelich, M., Shelton, R. C., & Carpenter, M. J. (2017). A pilot trial of in vivo NRT sampling to increase medication adherence in community corrections smokers. *Addictive Behaviors*, *67*, 92–99. https://doi.org/10.1016/j.addbeh.2016.12.011

Cropsey, K. L., Wolford-Clevenger, C., Sisson, M. L., Chichester, K. R., Hugley, M., Azuero, A., Businelle, M. S., Hendricks, P. S., Shelton, R. C., & Carpenter, M. J. (2021). A pilot study of nicotine replacement therapy sampling and selection to increase medication adherence in low-income smokers. *Nicotine & Tobacco Research*, *23*(9), 1575–1583. https://doi.org/10.1093/ntr/ntab029

Cutler, D. M., & Everett, W. (2010). Thinking outside the pillbox—Medication adherence as a priority for health care reform. *New England Journal of Medicine*, *362*(17), 1553–1555. https://doi.org/10.1056/NEJMp1002305

Dahne, J., Tomko, R. L., McClure, E. A., Obeid, J. S., & Carpenter, M. J. (2020). Remote methods for conducting tobacco-focused clinical trials. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, *22*(12), 2134–2140. https://doi.org/10.1093/ntr/ntaa105

Gutierrez, C., & Patterson, E. J. (2021). Risk and implications of COVID-19 among the community supervised population. *Criminology & Public Policy*, *20*(3), 437–461. https://doi.org/10.1111/1745-9133.12563

Haddad, C., Bou Malhab, S., Sacre, H., & Salameh, P. (2021). Smoking and COVID-19: A scoping review. *Tobacco Use Insights*, *14*, 1179173X21994612. https://doi.org/10.1177/1179173X21994612

Hammett, E., Veldheer, S., Hrabovsky, S., Yingst, J., Berg, A., Poole, E., Stauffer, D., & Foulds, J. (2018). TXT2STAYQUIT: Pilot randomized trial of brief automated smoking cessation texting intervention for inpatient smokers discharged from the hospital. *Journal of Hospital Medicine*, *13*(7), 488–489. https://doi.org/10.12788/jhm.2907

Inan, O. T., Tenaerts, P., Prindiville, S. A., Reynolds, H. R., Dizon, D. S., Cooper-Arnold, K., Turakhia, M., Pletcher, M. J., Preston, K. L., Krumholz, H. M., Marlin, B. M., Mandl, K. D., Klasnja, P., Spring, B., Iturriaga, E., Campo, R., Desvigne-Nickens, P., Rosenberg, Y., Steinhubl, S. R., & Califf, R. M. (2020). Digitizing clinical trials. *NPJ Digital Medicine*, *3*, 101. https://doi.org/10.1038/s41746-020-0302-y

Izmailova, E. S., Ellis, R., & Benko, C. (2020). Remote monitoring in clinical trials during the covid-19 pandemic. *Clinical and Translational Science*, *13*(5), 838–841. https://doi.org/10.1111/cts.12834

Jardin, B. F., Cropsey, K. L., Wahlquist, A. E., Gray, K. M., Silvestri, G. A., Cummings, K. M., & Carpenter, M. J. (2014). Evaluating the effect of access to free medication to quit smoking: A clinical trial testing the role of motivation. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, *16*(7), 992–999. https://doi.org/10.1093/ntr/ntu025

Kauffman, R. M., Ferketich, A. K., & Wewers, M. E. (2008). Tobacco policy in American prisons, 2007. *Tobacco Control*, *17*(5), 357–360. https://doi.org/10.1136/tc.2007.024448

Lincoln, T., Tuthill, R. W., Roberts, C. A., Kennedy, S., Hammett, T. M., Langmore-Avila, E., & Conklin, T. J. (2009). Resumption of smoking after release from a tobacco-free correctional facility. *Journal of Correctional Health Care: The*

Official Journal of the National Commission on Correctional Health Care, *15*(3), 190–196. https://doi.org/10.1177/1078345809333388

Mahoney, M. C., Park, E., Schlienz, N. J., Duerr, C., & Hawk, L. W. (2021). Transitioning to remote clinic visits in a smoking cessation trial during the covid-19 pandemic: Mixed methods evaluation. *JMIR Formative Research*, *5*(4), e25541. https://doi.org/10.2196/25541

Martínez-Alcalá, C. I., Rosales-Lagarde, A., Pérez-Pérez, Y. M., Lopez-Noguerola, J. S., Bautista-Díaz, M. L., & Agis-Juarez, R. A. (2021). The effects of covid-19 on the digital literacy of the elderly: Norms for digital inclusion. *Frontiers in Education*, *6*. https://www.frontiersin.org/articles/10.3389/feduc.2021.716025

McDermott, M. M., & Newman, A. B. (2021). Remote research and clinical trial integrity during and after the coronavirus pandemic. *JAMA*, *325*(19), 1935–1936. https://doi.org/10.1001/jama.2021.4609

Mersha, A. G., Gould, G. S., Bovill, M., & Eftekhari, P. (2020). Barriers and facilitators of adherence to nicotine replacement therapy: a systematic review and analysis using the capability, opportunity, motivation, and behaviour (COM-B) model. *International Journal of Environmental Research and Public Health*, *17*(23), 8895. https://doi.org/10.3390/ijerph17238895

Nipp, R. D., Hong, K., & Paskett, E. D. (2019). Overcoming barriers to clinical trial enrollment. *American Society of Clinical Oncology Educational Book*. https://doi.org/10.1200/EDBK_243729

Raupach, T., Brown, J., Herbec, A., Brose, L., & West, R. (2014). A systematic review of studies assessing the association between adherence to smoking cessation medication and treatment success. *Addiction (Abingdon, England)*, *109*(1), 35–43. https://doi.org/10.1111/add.12319

Rodríguez-Torres, E., González-Pérez, M. M., & Díaz-Pérez, C. (2021). Barriers and facilitators to the participation of subjects in clinical trials: An overview of reviews. *Contemporary Clinical Trials Communications*, *23*, 100829. https://doi.org/10.1016/j.conctc.2021.100829

Saberi, P. (2020). Research in the time of coronavirus: Continuing ongoing studies in the midst of the COVID-19 pandemic. *AIDS and Behavior*, *24*(8), 2232–2235. https://doi.org/10.1007/s10461-020-02868-4

Sharma, S., Barnett, K. G., Maypole, J. (Jack), & Mishuris, R. G. (2022). Evaluation of mHealth apps for diverse, low-income patient populations: Framework development and application study. *JMIR Formative Research*, *6*(2), e29922. https://doi.org/10.2196/29922

Shiffman, S., Sweeney, C. T., Ferguson, S. G., Sembower, M. A., & Gitchell, J. G. (2008). Relationship between adherence to daily nicotine patch use and treatment

efficacy: Secondary analysis of a 10-week randomized, double-blind, placebo-controlled clinical trial simulating over-the-counter use in adult smokers. *Clinical Therapeutics*, *30*(10), 1852–1858. https://doi.org/10.1016/j.clinthera.2008.09.016

Squiers, L. B., Augustson, E., Brown, D., Kelly, B., Southwell, B., Dever, J., Dolina, S., Tzeng, J., Parvanta, S., Holt, S., Sanders, A., Zulkiewicz, B., & Hunt, Y. (2017). An experimental comparison of mobile texting programs to help young adults quit smoking. *Health Systems*, *6*(1), 1–14. https://doi.org/10.1057/s41306-016-0014-3

Taylor, G. M. J., Dalili, M. N., Semwal, M., Civljak, M., Sheikh, A., & Car, J. (2017). Internet-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, *9*. https://doi.org/10.1002/14651858.CD007078.pub5

Teitcher, J. E. F., Bockting, W. O., Bauermeister, J. A., Hoefer, C. J., Miner, M. H., & Klitzman, R. L. (2015). Detecting, preventing, and responding to "fraudsters" in internet research: ethics and tradeoffs. *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics*, *43*(1), 116–133. https://doi.org/10.1111/jlme.12200

Tuck, B. M., Karelitz, J. L., Tomko, R. L., Dahne, J., Cato, P., & McClure, E. A. (2021). Mobile, remote, and individual focused: Comparing breath carbon monoxide readings and abstinence between smartphone-enabled and stand-alone monitors. *Nicotine & Tobacco Research*, *23*(4), 741–747. https://doi.org/10.1093/ntr/ntaa203

Valera, P., Malarkey, S., Smith, N., & McLaughlin, C. (2021). Exploring the role of telehealth: A novel approach to group-based smoking cessation treatment for men incarcerated in a rural state prison. *Journal of Telemedicine and Telecare*, 1357633X211034734. https://doi.org/10.1177/1357633X211034734

Whittaker, R., McRobbie, H., Bullen, C., Rodgers, A., Gu, Y., & Dobson, R. (2019). Mobile phone text messaging and app-based interventions for smoking cessation. *The Cochrane Database of Systematic Reviews*, *10*, CD006611. https://doi.org/10.1002/14651858.CD006611.pub5

Winkelman, T. N. A., Vickery, K. D., & Busch, A. M. (2019). Tobacco use among non-elderly adults with and without criminal justice involvement in the past year: United States, 2008–2016. *Addiction Science & Clinical Practice*, *14*(1), 2. https://doi.org/10.1186/s13722-019-0131-y

Table 1. Sample Characteristics.

	Overall		**Group**	**In-Person**		**Incentivized**		**Hybrid**	
	(*n* = 515)		**Differences**	**(*n* = 236)**		**(*n* = 126)**		**(*n* = 153)**	
	M	***SD***	***p* value**	***M***	***SD***	***M***	***SD***	***M***	***SD***
Age $n_{missing} = 0$	39.9	10.6	.12	39.6	11.2	41.4	10.2	39.1	10.1
Perceived Stress	17.3	7.2	<.01	18.4	7.4	17.4	6.9	15.6	7.0
% Patch Adherence at S4	70.7	34.1	.70	69.4	34.4	70.8	35.7	72.8	32.3
% Lozenge Adherence at S4	59.3	37.5	.45	58.7	38.1	56.4	36.9	62.6	37.2
% of Visits Completed	78.3	30.5	.56	77.8	31.1	76.7	30.3	77.8	31.1
	n	***%***		***n***	***%***	***n***	***%***	***n***	***%***
Sex $n_{missing} = 0$			<.01						
Female	247	48	-	105	44.5	34	27.0	108	70.6
Male	268	52	-	131	55.5	92	73.0	45	29.4
Race $n_{missing} = 0$			<.01						

White/Caucasian	289	56.1	-	112	47.5	58	46.0	119	77.8
African-American/Black	213	41.4	-	121	51.3	66	52.4	26	17.0
Bi-racial	13	2.5	-	3	1.3	2	1.6	8	5.2
Ethnicity $n_{missing} = 0$			.25						
Hispanic	15	2.9	-	4	1.7	4	3.2	7	4.6
Non-Hispanic	500	97.1	-	232	98.3	122	96.8	146	95.4
Number of children in the home $n_{missing} = 0$			.31						
None	115	22.3	-	59	25.0	30	23.8	26	17.0
1 child	100	19.4	-	44	18.6	29	23.0	27	17.6
2 children	119	23.1	-	54	22.9	23	18.3	42	27.5
3 or more children	181	35.1	-	79	33.5	44	34.9	58	37.9
Education $n_{missing} = 0$			.09						
Less than high school	127	24.7	-	60	25.4	33	26.2	34	22.2
High school graduate/GED	200	38.8	-	92	39.0	57	45.2	51	33.3

More than high school	188	36.5	-	84	35.6	36	28.6	68	44.4
Employment-Last 3 Years $n_{missing} = 0$			.02						
Full-time	187	36.3	-	76	32.2	54	42.9	57	37.3
Part-time	94	18.3	-	38	16.1	28	22.2	28	18.3
Unemployed	120	23.3	-	56	23.7	23	18.3	41	26.8
Retired/disabled	58	11.3	-	37	15.7	13	10.3	8	5.2
Other	56	10.9	-	29	12.3	8	6.4	19	12.4
Employment-Paid in the past 30 days			.01						
$n_{missing} = 1$									
Yes	136	26.5	-	75	31.8	22	17.5	39	25.5
No	378	73.5	-	161	68.2	103	81.8	114	74.5
Quit Attempt Made at S4	160	38.6	.13	74	38.9	44	42.7	42	34.4

Notes: GED: Graduate Equivalency Degree; *CPD:* Cigarettes Per Day; Missing data values are due to participants' being allowed to decline answering certain questions.

*Significance determined by chi-square tests and one-way ANOVAs between groups.

Table 2. Recruitment Rate by Group				
Unadjusted Analyses				
Group	Recruitment Rate in	Standard Error	Lower CI	Upper CI
In Person	0.29	0.02	0.25	0.33
Incentivized	0.41	0.04	0.34	0.49
Hybrid	0.28	0.02	0.24	0.33
Rate Comparisons				
Groups	Rate Ratios	Lower CI	Upper CI	Significance
Incentivized vs. In Person	1.01	1.00	1.02	0.00
Incentivized vs. Hybrid	1.01	1.00	1.01	0.01
Hybrid vs. In Person	1.00	1.00	1.01	0.28
Adjusted Analyses				
Group	Recruitment Rate in	Standard Error	Lower CI	Upper CI
In-Person	0.02	.00	0.01	0.02
Incentivized	0.03	0.00	0.02	0.03
Hybrid	0.02	0.00	0.02	0.02
Rate Comparisons				
Groups	Rate Ratios	Lower CI	Upper CI	Significance

Incentivized vs. In-Person	1.48	1.10	1.99	0.01
Incentivized vs. Hybrid	1.34	0.97	1.85	0.08
Hybrid vs. In-Person	1.11	0.84	1.46	0.47

*Note pairwise comparisons are made using the model adjusted for covariates (PSS, sex, & employment)

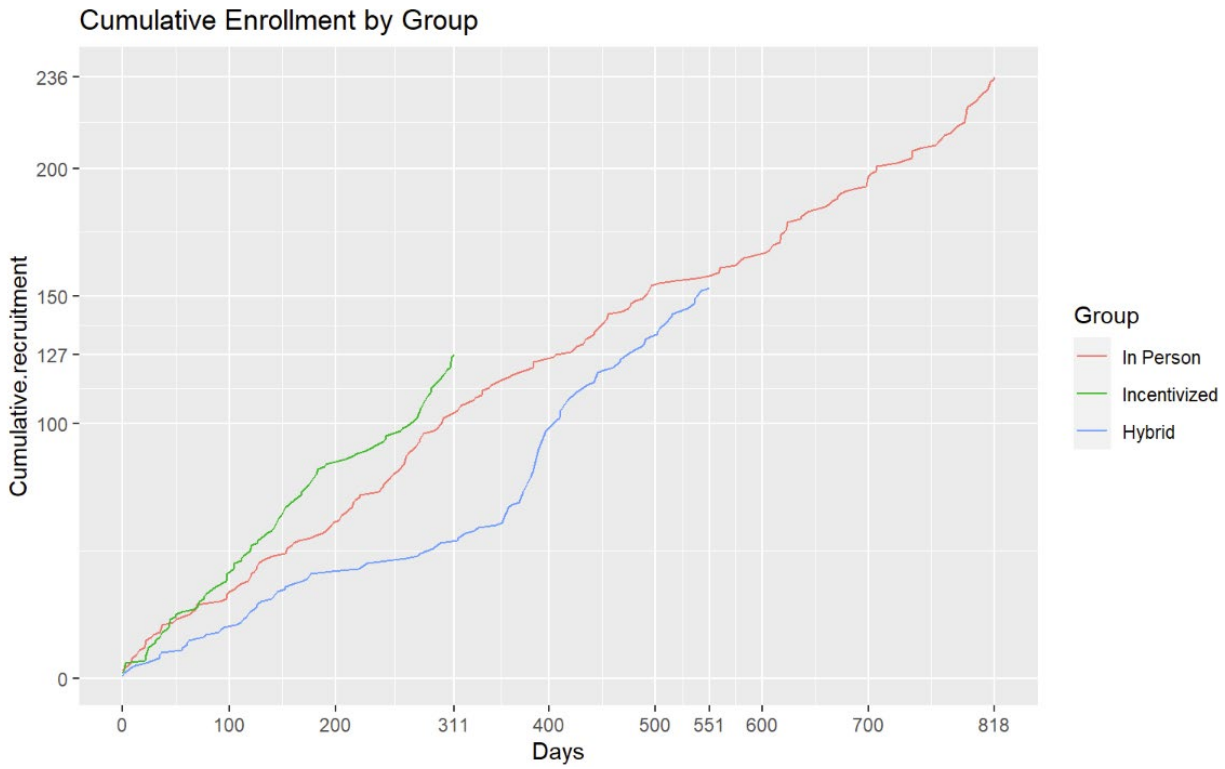

Figure 1. Cumulative Enrollment by Group

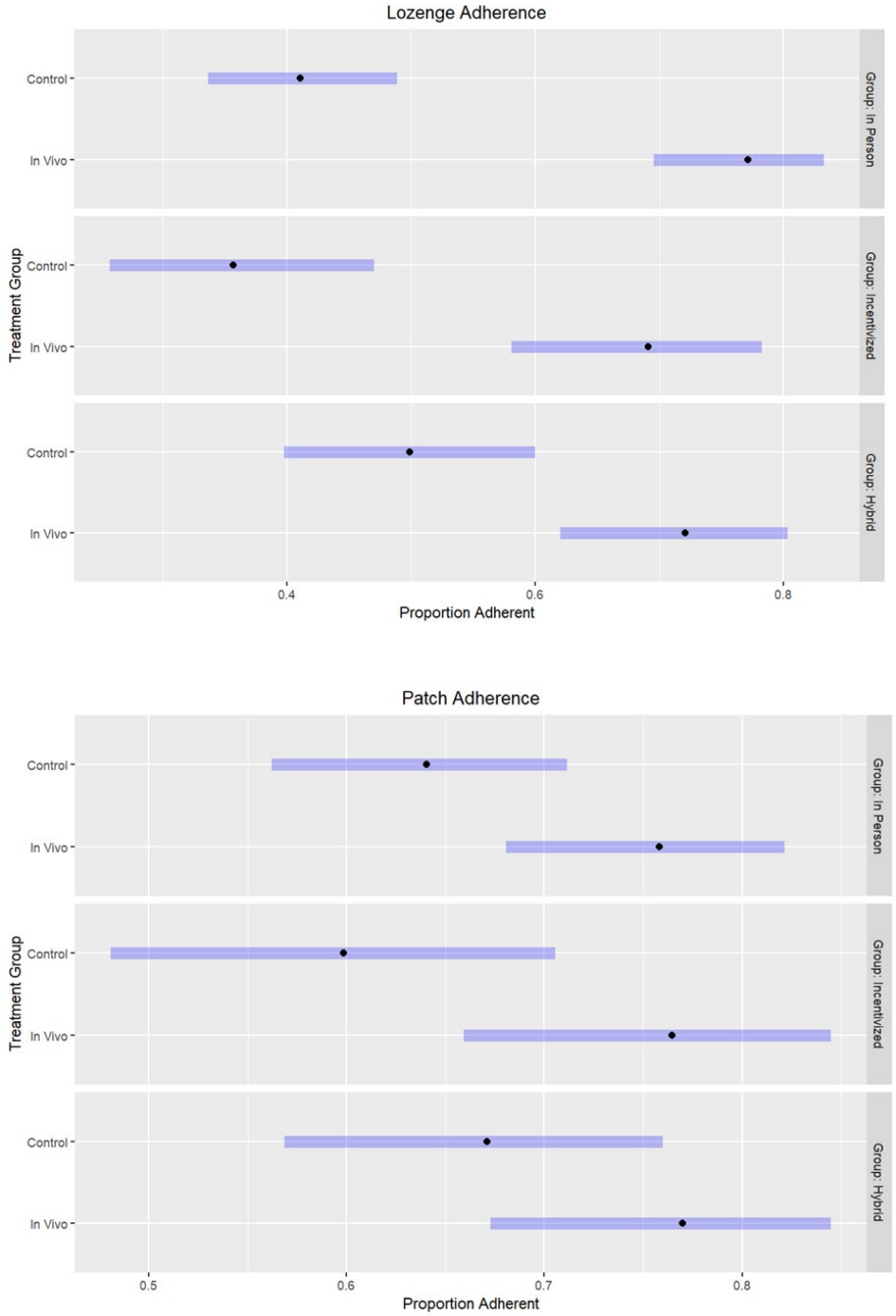

Figure 2. NRT Adherence at S4.