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Goal-directed versus outcome-based financial incentives for smoking cessation among low-income, hospitalised patients: rationale and design of the Financial Incentives for Smoking Treatment II (FIESTA II) randomised controlled trial

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ABSTRACT

Introduction Smoking remains the leading preventable cause of death in the USA. Low utilisation of treatments for smoking cessation remains a major barrier for reducing smoking rates. Financial incentives represent an innovative approach to increasing use of therapies for smoking cessation. This paper will describe the rationale and design of the Financial Incentives for Smoking Treatment II (FIESTA II) study, a randomised controlled trial to evaluate the effectiveness and feasibility of goal-directed and outcome-based financial incentives to promote smoking cessation among hospitalised smokers.

Methods and analysis We are recruiting adult participants who smoked tobacco in the 30 days prior to initial interview and are contemplating quitting smoking. These participants will come from two hospitals in underserved communities in New York City and Los Angeles. They will be randomised into one of three arms. The first arm consists of goal-directed financial incentives plus enhanced usual care, which includes hospital-directed information about quitting smoking, nicotine replacement therapy and referral to a Quitline. The second arm involves outcome-based financial incentives plus enhanced usual care. The third arm consists of enhanced usual care alone. Multiple phone interviews with the participants will be completed after randomisation to assess smoking cessation. Participants will earn $20 for each follow-up interview completed and $30 for each smoking cessation test completed. Those who are randomised to the financial incentive groups can earn an additional $700. The participants in the outcome-based group will receive payments solely for exhibiting cessation, whereas the participants in the goal-based group are also eligible for receiving payments after meeting milestones such as speaking with a helpline coach.

Ethics Human research protection committees at New York University School of Medicine and the University of California Los Angeles (UCLA) David Geffen School of Medicine granted ethics approval.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This three-arm randomised control trial compares the effectiveness of two financial incentive strategies on smoking cessation among hospitalised patients who use tobacco.
⇒ The study examines the comparative effectiveness and cost-effectiveness of goal-directed versus outcome-based financial incentives.
⇒ The major limitation is uncertainty about the sustainability and acceptability of using financial incentives, though we believe these issues can be overcome based on prior studies that have been conducted.
⇒ We anticipate that the results of this study will inform the design of scalable financial incentive programmes to address smoking cessation in healthcare systems.

Protocol number: IRB#19-000084.
Trial registration number NCT03979885.

INTRODUCTION

Smoking remains the leading preventable cause of death and disease in the USA, and each year, more than 480 000 people die prematurely from smoking or second-hand smoke exposure.[1] The burden of smoking also exacerbates health disparities, as smokers have lower educational levels and incomes compared with non-smokers.[2] Because of smoking's enormous public health impact, the United States Preventive Services Task Force (USPSTF) recommends universal and routine tobacco screening for all patients treated in healthcare settings.[3] States have

both individually and collectively supported mass media campaigns,[4–6] raised tobacco taxes[7] and implemented policy changes to increase access to evidence-based behavioural counselling and pharmacotherapy.[8] However, a major barrier to further reducing smoking rates is the low utilisation of effective treatments. While 70% of smokers report wanting to quit,[9] only 25% of those who try will seek assistance and an even smaller proportion will use evidence-based methods.[10] For these reasons, it is critical to identify novel approaches to intensify utilisation of evidence-based methods for smoking cessation.

Hospitalised smokers represent an important population to target for effective smoking cessation interventions because they are typically hospitalised for conditions related to tobacco use,[11 12] experience a disproportionate burden of serious smoking-related illnesses, have high rates of relapse to cigarette use after discharge[12] and impose $110 billion in costs on the healthcare system annually.[13–16] Hospitalisation is a critical opportunity to encourage cessation and offer assistance. Patients have enforced abstinence while admitted and may be newly sensitised to health-related issues. This may be particularly advantageous because only 3%–6% of smokers annually successfully quit smoking.[17] While initiating treatment during hospitalisation and continuing for at least 1 month after discharge increases long-term cessation rates,[9] many inpatient interventions studied so far lack generalisability and feasibility outside of clinical trial settings.[18]

Financial incentives may be an effective intervention based on (a) microeconomic theory, because we expect hospitalised smokers to be motivated by gains and avoidance of losses, and (b) regret aversion, because individuals may be averse to feeling regret associated with loss of financial incentives they would have received had they used evidence-based smoking cessation therapies or successfully quit smoking.[19–21] If engagement in smoking cessation counselling and use of nicotine replacement therapy are successful, they may lead to increased self-efficacy to maintain these behaviours even after the financial motivator is no longer present.

While some theories of motivation have led researchers to raise concerns about the long-term durability of the extrinsic effects of financial incentives,[22 23] they have empirically been demonstrated to promote long-term smoking cessation when incentives are sufficiently large.[24 25] Furthermore, as health insurers and healthcare systems move towards bundled payments, financial incentives to promote smoking cessation may offer a favourable return on investment as smokers incur higher inpatient and outpatient costs compared with non-smokers. Therefore, financial incentives represent potentially both a sustainable and innovative way to promote smoking cessation.

With the exception of the original FIESTA trial (NCT 02506829; Ladapo Sherman AMJ 2020), prior studies of financial incentives for smoking cessation have only been tested in lower risk, non-hospitalised patients. No financial incentive studies have been performed in hospitalised smokers except for FIESTA. However, as the Consortium of Hospitals to Advance Research on Tobacco (CHART) studies have demonstrated, outpatient strategies for smoking cessation are not necessarily effective in the inpatient setting, so tailoring interventions to the hospitalised population may be valuable. Furthermore, prior studies of financial incentives for smoking cessation have emphasised outcome-based incentives—that is, incentives for successful achievement of an outcome, like successfully quitting.[15 25–27] It is unclear whether goal-directed incentives or outcome-based incentives are more effective, but a goal-directed approach may be more sustainable because it preferentially encourages the use of evidence-based cessation therapies. The goal-directed structure also provides earlier opportunities for success, which may increase self-efficacy and intrinsic motivation for smoking cessation. Moreover, the optimal incentive structure may differ from patient to patient, and personalising the incentive structure—by allowing patients to choose—could yield the most effective quit rates and return on investment.

The primary aim of FIESTA II is to compare the impact of two approaches for smoking cessation on smoking abstinence, use of evidenced-based therapy and quality of life. The secondary aim is to compare the short-term and long-term return on investment of using goal-directed and outcome-based financial incentives to evaluate the economic sustainability of these strategies. This paper serves to describe the design and rationale of the FIESTA II study.

METHODS AND ANALYSES

Study overview and design

The FIESTA II study is a three-arm randomised controlled trial to compare the effectiveness of two approaches to smoking cessation among hospitalised patients who use tobacco. Primary outcomes include smoking status, use of evidence-based smoking cessation therapies and quality of life measures. Our first hypothesis is that goal-directed financial incentives will most effectively promote bioconfirmed smoking cessation, use of evidence-based smoking cessation therapies and quality of life measures compared with outcome-based financial incentives (hypothesis 1a) or enhanced usual care (hypothesis 1b). Our second hypothesis is that patients randomised into the incentive structure per their preference prior to randomisation will be more likely to quit smoking. Our third hypothesis is that goal-directed financial incentives will have a more favourable return on investment and cost-effectiveness ratio compared with outcome-based financial incentives.

We are enroling adult patients hospitalised in two medical centres that serve low-income populations. There will be three study arms: goal-oriented, outcome-oriented and enhanced usual care. Participants in all three study arms will receive hospital-directed information about quitting smoking, nicotine replacement therapy and referral to a Quitline (this referral is the enhancement).

Participants who are randomised to the financial incentive groups can earn up to $700. The participants in the outcome-based group will receive payments solely for achieving bioconfirmed cessation, whereas the participants in the goal-based group will receive payments after meeting milestones such as speaking with a helpline coach or using evidence-based smoking cessation therapies. To maximise incentive efficacy, we incorporate concepts from behavioural economics, including immediacy of payments and framing feedback to elicit regret aversion. The study began on 15 February 2019 and is currently scheduled to end 31 December 2023.

Inpatient study population

We will recruit patients from Olive View-University of California Los Angeles (UCLA) Medical Centre in Los Angeles and Bellevue Hospital in New York City, with a goal of enroling 1058 participants who use tobacco and are hospitalised. Olive View-UCLA Medical Centre is operated by the Los Angeles County, Department of Health Services and receives approximately 11 000 admissions per year.

Smoking prevalence among hospitalised patients is approximately 20%. Bellevue Hospital is the flagship hospital for New York's primary safety net health system and receives approximately 20 000 admissions per year. The prevalence of smoking among hospitalised patients is approximately 25%. Both locations serve diverse, medically underserved populations.

The electronic health record (EHR) at both hospitals automatically generates lists of current smokers from nursing/physician assessments. Our research assistants (RAs) will approach these patients every weekday to describe the study, assess eligibility, offer enrolment and complete informed consent. Information about newly identified patients from this EHR-generated list and smokers previously identified but unavailable for enrolment initially (eg, not in the hospital room because of a test or procedure) will be sorted randomly every weekday morning to ensure that patients from all units within the hospital are equally likely to be approached for enrolment (this ameliorates possible bias if RAs are unable to approach all patients daily).

We will maintain a log of all patients identified as smokers through our EHR who do not enrol in the study and track reasons for non-enrolment. In this log, we will record demographics (ie, race/ethnicity, sex, age group, hospital service) but no individually identifying data. This log will allow us to determine if our enrolled cohort is representative of hospitalised smokers at our institutions, and will be used to adjust recruitment/enrolment techniques. We have successfully used hospital EHRs to identify smokers in prior studies, FIESTA and CHART. In CHART, we enrolled 9% of smokers that we approached at Bellevue. In FIESTA, our enrolment rate was 50% higher than in CHART, possibly because we incorporated incentives. Therefore, we should be able to meet our target of recruiting 3–4 patients per week at each site.

Sample size

Sample size was calculated based on the primary endpoint of smoking status at 6 months. We aim to enrol about 1058 smokers (529 smokers/site), or 14–15 patients/month per site for 36 months, with about 440 participants in each of the two main incentive arms. We also expect a 15% loss-to-follow-up rate at 6 months, based on attrition seen in the prior study, FIESTA. Our preliminary findings in FIESTA show that the 6 month bioconfirmed cessation rate (with cotinine or exhaled CO) is anticipated to be approximately 9% in controls versus 27% in incentive group (p=0.02). FIESTA uses a mix of goal-directed and outcome-based outcomes. Its design differs from that of FIESTA II, so while we expect a large effect of incentives versus controls, it is unclear what the differential effect of goal-directed versus outcome-based incentives will be. However, if we consider an absolute difference of approximately 9% in cessation rates to be clinically meaningful, and we deconstruct FIESTA's incentives into less effective outcome-based components (with an effect of 22%) and more effective goal-directed components (with an effect of 31%), this sample size will provide at least 80% power to detect a meaningful difference in smoking cessation rates between the outcome-based financial incentive arm and the goal-directed financial incentive arm (hypothesis 1a) with type-I error rate α=0.05. It will also provide at least 80% power between the enhanced usual care arm (expected smoking cessation rate of 5–10%) and goal-directed incentive arm (hypothesis 1b) with α=0.05.

Eligibility and enrolment

We will include English or Spanish-speaking hospitalised adult patients ≥18 years old who have smoked tobacco in the past 30 days from initial screening. To be eligible, patients must have an active US phone number and address. They must also be at least contemplative or undecided about quitting smoking, as assessed by the readiness to quit measure. Due to COVID-19 restrictions on research activities in the hospital, participants must also have access to a video calling device to complete remote bioconfirmation tests. We will exclude patients who use only smokeless tobacco, are pregnant or breastfeeding, are discharged to an institution that controls their smoking behaviour and/or are unable to provide informed consent.

Before any participant is consented, approval of both the protocol and the consent form(s) must be obtained. The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the IRB for review and approval. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent using a previously approved consent form.

Randomisation

Randomisation will be performed among eligible patients after informed consent is obtained and baseline survey instruments are completed. The randomisation process will be stratified on hospital site and patient preference for incentive structure (goal-directed vs outcome-based). It will be generated using a random number generator. These procedures will be managed and implemented by the study statistician, Dr Tseng. Stratified randomisation will be used to eliminate the confounding effect of hospital sites and patient preference for incentive structure, and block design will ensure that the three arms have consistent sample sizes over time and 2:2:1 randomisation will be used. Blinding is not possible due to the nature of the interventions.

Financial incentives intervention for smoking cessation

Trained RAs conduct all screening and study visits. RAs are students or graduates of health-related disciplines such as biomedicine, public health, health promotion, education and clinical research. To promote enrolment of Spanish-speaking patients, some RAs are required to have full native or professional Spanish proficiency. RAs receive at least 20 hours of standardised training in the responsible conduct of research, study protocols and cultural sensitivity. RAs observe and role play a series of study visits in both English and Spanish and can successfully demonstrate intervention delivery before conducting study visits.

Baseline study visit

If the patient agrees to join the study after completing screening, the RA will visit the participant in the hospital to complete the following in chronological order: informed consent, baseline survey, randomisation, educational folder content explanation and additional clarifications. In the informed consent process, the RA will explain the consent and HIPAA (Health Insurance Portability and Accountability Act) form in detail and ensure that the patient fully comprehends before asking them to sign both. Each participant will receive a physical copy of their forms and forms will also be uploaded to their EHR. A baseline survey will then be completed with the patient either inperson or via phone call to determine participants' sociodemographic, clinical characteristics and incentive preference. Afterwards, the patient will be randomised into a study arm and then given a folder with educational information on nicotine replacement therapies, referred smoking helpline, an activated incentive debit card with predetermined pin number and their study arm timeline. The RA will submit a referral to the state's helpline at the end of this visit.

Enhanced usual care arm

If a participant is randomised to the enhanced usual care arm, they will receive hospital-directed nicotine replacement therapy and counselling. Specifically, usual care includes nurse-led screening and counselling at both sites, with EHR prompts for provision of nicotine replacement therapy. At the time of discharge, patients will receive information about the California Smokers' Helpline and New York Smokers' Quitline, state services that provide free counselling and NRT (nicotine replacement therapy) for smokers. The RA will assist patients in completing the enrolment form or enter an EHR Quitline referral (this component represents the enhancement). The Quitline will make call attempts to reach the patient. Patients will also receive a list of local community resources, as recommended by Helpline/Quitline (eg, California Helpline provides a list at www.nobutts.org/county-listing). Participants will be encouraged to speak to their doctors about using varenicline and combination pharmacotherapy for cessation (dosed by physician).

At 2 weeks, 30 days, 2 months, 6 months and 12 months, participants will receive $20 compensation for completing each visit's survey and $30 for completing a cotinine saliva or expired air carbon monoxide test if they have quit smoking. To assess provision of therapy across hospitals, our chart abstraction process will capture inpatient use of nicotine replacement therapy and prescriptions at discharge. For patients recruited from Bellevue, those living outside New York State (eg, New Jersey) will have their information faxed to their state Quitline.

Outcome-based arm

If a participant is randomised to the outcome-based incentive arm, they will receive enhanced usual care and financial incentives for smoking cessation, confirmed with a cotinine saliva test or expired air carbon monoxide (CO≤7 ppm) at 2 weeks ($100), 30 days ($150), 2 months ($200) and 6 months after study enrolment ($250). Patients who report using nicotine replacement therapy will undergo measurement of expired air CO instead for bioconfirmation. These incentives are outcome-based, in the sense that patients will only receive incentives for achieving the outcome of smoking abstinence. Long-term cessation will be assessed by biochemical verification at 12 months.

Goal-directed arm

If a participant is randomised to the goal-directed incentive arm, they will receive enhanced usual care and be informed that they will receive financial incentives for speaking with a coach from the CA/NY Quitline at 30 days or 2 months ($150), completing three follow-up calls with a coach from California smokers' Helpline/NYS smokers' Quitline ($150), talking to a doctor about using varenicline ($150) and using nicotine replacement therapy ($100). Additionally, participants who state that they have quit smoking will undergo a cotinine saliva test or expired air carbon monoxide (CO≤7 ppm) at each visit to verify. All goal-directed activities require documentation, a practice we have successfully implemented in FIESTA. The first time point for assessment of goal reaching is early, at 2 weeks, because in our past work with CHART, we found that as many as 57% reported that they were already smoking again by the second week after

discharge. Patients will also have an opportunity to receive incentives for goal-directed activities at 2 months if not achieved earlier. Long-term cessation will be assessed by biochemical verification at 6 months and 12 months. We will confirm Helpline/Quitline participation directly with the programme or with signed letters from counsellors or other evidence of participation. For pharmacotherapy, participants must obtain medication over the counter or from their doctor/Quitline and submit a copy of their prescription for verification. We will require participants to present receipts and/or return used patches or gum or medication bottles for verification that they have ≥75% compliance for≥1 month.

Incentive payments

Incentives will be provided with a prepaid debit card (US Bank). US Bank debit cards allow for immediate digital transfer of payments and have a digital platform for tracking payments. Research staff will provide patients with an incentive schedule brochure and preactivated US Bank card at enrolment and, after each completed visit/activity, money will be added to it. US Bank cards can be used at all locations that accept credit cards and can be withdrawn for cash at ATMs (automated teller machines). Using prospect theory, we have structured the incentives as frequent payments that are immediate, which may be more motivating than larger payments that are delayed. To employ the behavioural economic concept of regret aversion, patients will be given feedback at each assessment point about the incentives they would have received had they used evidencebased smoking cessation therapies or achieved abstinence.

Intervention standardisation and fidelity

We implement fidelity monitoring procedures to ensure that the delivery of intervention components is standard across all study sites and RAs. Each site will be following the same procedures and methods approved by the Institutional Review Board (IRB). The study will go through UCLA with endorsement by Olive View Medical Center and Bellevue Healthcare.

Participant retention strategies

To increase participation and minimise attrition, patients will be given $20 for each completed follow-up call (at 30 days, 2 months, 6 months and 12 months) and $30 for supplying a saliva sample, independent of the intervention arm's financial incentives. A RA will collect observed saliva samples in a public location convenient to the patient or at the hospital in order to confirm the validity of the patient's sample. Due to restricted entry to hospitals during the COVID-19 pandemic, alternative follow-up options are available to participants: (1) they can complete saliva test strips over a video call with RAs or (2) return saliva test strips via mail. If a participant fails to return to the clinic or video visit, the site will make every effort to regain contact with the participant (where possible, three telephone calls, and if necessary, a certified letter will be sent to the patient's last known mailing address or local equivalent methods). When able to reach the participant, the site will reschedule the missed survey or interview and counsel the participant on the importance of maintaining the assigned interview schedule. Participants are free to withdraw from the study at any time on request.

Data collection and measures

Primary outcomes include smoking status, use of evidence-based smoking cessation therapies and quality of life measures. Assessments occur at 2 weeks, 1 month, 2 months, 6 months and 12 months. At these times, all participants will be asked to provide a saliva sample for confirmation of smoking cessation with a cotinine test (cotinine level<10 ng/mL). Patients who report using nicotine replacement therapy will undergo measurement of expired air carbon monoxide (CO≤7 parts per million) instead for bioconfirmation.

In addition, we will also be checking other related endpoint and non-safety assessments:

1. Smoking habits will be assessed using measures adapted from the California Tobacco Survey (CTS), including quit attempts, reduction in daily cigarette smoking, readiness to quit, use of e-cigarettes and use of hookah.
2. Nicotine dependence will be assessed using the two-item Heaviness of Smoking Index.[28]
3. The level of motivation to quit will be evaluated using the Readiness to Quit (4-point classification scheme).[29]
4. Measures from CTS will evaluate others' use of tobacco at home and restrictions on smoking at home.[30]
5. Other health habits will be evaluated using Alcohol Use Disorders Identification Test (AUDIT-C)[31 32] to assess alcohol use and Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) for other substance use disorders.[33 34]
6. As hospitalised patients may experience more psychological distress, the Brief Symptom Inventory (BSI-18) will be used as a valid instrument for assessing psychological distress across three dimensions: depression, anxiety and somatisation.[35]
7. Patient Health Questionnaire-2 (PHQ-2) will also be used to evaluate depressive symptoms.[36]
8. A COVID-19 questionnaire will be used to assess the financial impact caused by COVID-19.

Our site principal investigator (PI) will oversee each clinical site for quality management of study conduct, data collection, documentation and completion. All sites will follow a common quality management plan. Should independent monitoring become necessary, the PIs will provide direct access to all trial-related sites, source data/documents and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

The Data and Safety Monitoring Board will meet annually to ensure overall study safety and efficacy. In addition, the PI will monitor data and safety. As part of data management, data monitoring will be performed on a

regular basis to maintain the integrity of the data. Data management activities will include generating automated reports for the research team with lists of participants due for study calls. As data are entered into the system, data managers will perform regular checks in all of the clinical databases for recurrent missing documentation, data inaccuracies, errors in submitted data and missing data. These data problems will be sent to the study coordinators for corrections. Logs of these data issues will be maintained to identify problem areas with specific variables or with specific study teams, allowing us to proactively modify the data collection instruments or retrain study coordinator/data entry staff. Logs of communications with study coordinators with regard to data cleaning and management will also be maintained to keep track of corrected issues. Monthly reports will be provided to the PIs on patient accrual, study completion and early termination to ensure awareness of lags in recruitment or retention of study subjects. A progress report will be completed on regular basis to summarise patient demographics and other baseline criteria data.

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorised third party without prior written approval of the sponsor/funding agency. Additionally, all research activities will be conducted in as private a setting as possible, data will be deidentified and all consent forms will be stored separately from other study materials.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, institutional policies or sponsor/funding agency requirements. It is National Institute of Health (NIH) policy that the results and accomplishments of the activities that it funds should be made available to the public. The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality and security for data dissemination and reuse (eg, all data will be thoroughly deidentified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Data dissemination

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

- NIH Public Access Policy, which ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central on acceptance for publication.
- NIH-funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results from this trial will be submitted to ClinicalTrials.gov. Every attempt will be made to publish results in peer-reviewed journals.

Materials generated under the project will be disseminated in accordance with participating institutional and sponsor policies. Depending on such policies, materials may be transferred to others under the terms of a material transfer agreement. Access to databases and associated software tools generated under the project will be available for educational, research and non-profit purposes. Such access will be provided using web-based applications, as appropriate. Publication of data shall occur during the project, if appropriate, or at the end of the project, consistent with normal scientific practices. Research data that documents, supports and validates research findings will be made available after the main findings from the final research data set have been accepted for publication. Such research data will be redacted to prevent the disclosure of personal identifiers.

Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines are being used.[37]

Adverse events

All adverse events associated with the procedures of this study will be reported within 5 days to the UCLA IRB. Adverse events are defined as any untoward or unfavourable medical occurrence in a human subject temporally associated with the subject's participation in the research. Serious adverse events are any events resulting in the following: death, persistent or significant disability, inpatient hospitalisation or prolongation of existing hospitalisation, immediately life threatening, suicidal attempt or ideation requiring intervention. Research staff will notify the PIs within 7 days for adverse events and immediately for serious adverse events. The PIs will conduct EHR reviews, when necessary, to gather additional information about the event. They will determine the severity of the event, the expectedness of the event in relation to the study and the probability that the event was related to the study. This information will be documented in the study database. The PIs and project director will plan measures to prevent future occurrences, if warranted, and make changes to protocol and/or consent form if needed.

Statistical analysis

General approach

Primary outcomes include smoking status, use of evidence-based smoking cessation therapies and quality of life measures. The randomisation stratification variables of hospital site and patient incentive preference will be included as covariates in all regression analyses.

First, we will use descriptive analyses to summarise demographic and clinical variables at baseline to characterise the population, and summarise study outcomes at each follow-up for each randomised group. The generalised mixed-effect models for repeated measures will be used as the main analytic framework to evaluate the treatment effect for the primary and secondary endpoints.

Our primary analysis will use a complete case approach, only including people who were not lost to follow-up. Patients who report abstinence but do not provide saliva/CO will be considered smokers. While smoking cessation studies frequently treat non-respondents at follow-up as smokers (similar to a 'last observation carried forward' approach), this method has been criticised,[38] though we will utilise it as an alternative way to present our findings, largely to facilitate comparability with other smoking cessation trials.

Analysis of the primary endpoints

Mixed-effects logistic regression model will be used for the primary endpoint of smoking status. The fixed effects include treatment, time, treatment–time interaction and hospital site and patient incentive preference. The random effects include subjects. Appropriate contrast will be used to provide estimates and 95% CI of treatment effects at each follow-up. Wald test will be used to evaluate the treatment effect on 6 months smoking status. For the second hypothesis, models will include an indicator variable for whether a patient was randomised to an incentive structure consistent with his or her prespecified (before randomisation) preference. These models will allow us to test whether personalised incentives affect the likelihood of smoking cessation. Sex, as a biological variable, will be explicitly included in subgroup analyses and reporting.

Analysis of the secondary endpoints

Secondary endpoints that will be evaluated include (a) smoking status, with e-cigarette and hookah users considered non-abstinent, (b) financial distress, (c) subjective social status, (d) other substance use, including alcohol and (e) 30-day hospitalisation rates for smokers versus quitters versus non-smokers. We hypothesise that participants in the incentive arms will experience reductions in financial distress and substance abuse and improvements in subjective social status. We also hypothesise that patients experiencing greater financial distress will be more likely to quit smoking in response to financial incentives. These analyses will be performed similar to our primary analyses.

Cost effectiveness

Using health economic modelling methods that Dr Ladapo has previously applied in other economic evaluations,[39–42] we will estimate the return on investment and cost-effectiveness of financial incentives for smoking cessation using in-trial utilisation and cost projections of averted adverse health events.

We will estimate the cost of the programme to help guide employers and policymakers considering adopting the programme, and to provide inputs for our CE analysis, while adhering to recommendations of the Panel on Cost-Effectiveness in Health and Medicine.[43] We will estimate the return on investment (ROI) of our financial incentives intervention from the perspective of the healthcare system (hospitalisations, ambulatory care and medications) on a per-patient basis. Costs will be determined by (a) multiplying staff or employee wages from the hospital and Quitline (based on US Bureau of Labour Statistics values) by the time they spend on smoking cessation care (because time spent in implementing the intervention theoretically replaces other productive employee activities)[44] (b) estimating the cost of in-trial and post-trial hospital and ambulatory care using EHR data and nationally representative reimbursement levels from Medicare; (c) using the Red Book to estimate pharmacotherapy costs, based on the average wholesale prices[45] and (d) estimating bulk purchase prices for other physical materials provided to smokers. The return on investment will be estimated using the difference between the value of financial incentives provided and the incremental healthcare costs or savings, comparing the financial incentives arm to the enhanced usual care arm and the goal-directed arm to the outcome-based arm. To project long-term return on investment, we will modify an existing Markov model, the PI (Dr Ladapo) previously developed for smoking cessation interventions for patients hospitalised with acute myocardial infarction.[39] This model currently uses a 10 year time horizon.

Cost-effectiveness=cost per quit and cost per life-year gained

We will also estimate the cost-effectiveness of the intervention using the ratio of the difference in costs between each of the intervention and control arms to the difference in smoking cessation rates between each of the intervention and control arms. The general equation for a cost-effectiveness ratio (CER) is as follows:[46]

Where i is the ith time period of a patient's life, cost is determined by resources utilised in the provision of smoking cessation care in the intervention and control arms and effectiveness is measured by quit rates and

$$CER = \frac{\sum_i \left(Cost_{intervention,i} - Cost_{usual\ care,i}\right)}{\sum_i \left(Effectiveness_{intervention,i} - Effectiveness_{usual\ care,i}\right)}$$

Figure 1 General equation for a cost-effectiveness ratio.[54]

quality of life (determined with Patient-Reported Outcomes Measurement Information System-29). Costs will be determined as described above. In addition, to estimate potential cost-offsets, we will use data from our survey's sociodemographic questions about employment to evaluate changes in productivity. We will also perform non-parametric bootstrapping with 1000 random samples from our study arms to estimate CIs for cost-effectiveness ratios, and we will use the bias-corrected percentile method described by Efron and others.[47–49]

Patient and public involvement

We sought feedback from patients enrolled in a prior incentives study on their preferences for an incentive structure (ie, goal-directed vs outcome-based incentives for a preventive health behaviour) and used this feedback to inform FIESTA's framework and intervention design. Patients were not involved in the recruitment and conduct of the study. We assess the burden of the intervention among FIESTA participants during an exit interview. We will make a summary of the results available to the public after the study's conclusion and publication of the primary outcomes.

DISCUSSION

Limitations

A major challenge of our intervention design is that simultaneous use of multiple smoking cessation techniques limits our ability to compare efficacy between each intervention strategy. However, we will address this by using ad hoc analyses to identify the interventions with the highest response rates to incentive payments. Another challenge of our study design is maintaining follow-up appointment adherence. To support this, we will offer patients the option to complete visits over phone or video call and send out reminder paper slips, phone calls and/or text messages according to each participant's preference. We will also compensate patients with $20 to defray transportation costs and promote retention. These smaller payments may reduce our ability to detect the marginal impact of the incentives through their income effect, though this effect is likely minimal. Additionally, by setting the reward amount equally across both incentive arms at $700, cost-effectiveness may favour the outcome-based incentives if smoking cessation rates are similar between arms. In the goal-directed arm, participants may inflate their goal achievement in order to increase their incentive earnings, though our objective goal verification process should minimise this occurrence. Several of our measures are self-reported, which can introduce social desirability bias into the participants' responses. Our RAs are not blinded to the participants' intervention group after the baseline survey, which may cause measurements that inadvertently favour the RAs' preferred strategy. Our recruitment may also attract patients who are highly motivated to quit smoking rather than a more representative sample of hospitalised patients, therefore overestimating intervention effects on smoking cessation.

Public health and policy considerations

We view FIESTA's major limitation in the context of public policy to be uncertainty about the sustainability and acceptability of using financial incentives for smoking cessation. The key issues are whether sources of funding can be identified for these incentives, and whether these incentives can be viewed as fair and appropriate from a public perspective. In spite of these concerns, effective financial incentive programmes have already been implemented across the world. The NHS Tayside programme in Scotland offered pregnant smokers £50 per month in shopping vouchers for negative carbon monoxide breath tests.[50] Australia linked eligibility for social security payments, childcare rebates and other payments to immunisation in order to increase rates of childhood vaccinations.[51 52] Consumer Value Store (CVS) Health previously launched a financial incentive programme to help employees quit smoking.[53]

We believe that issues related to sustainability and acceptability can be overcome and we can design these incentive programmes in a manner that is considered fair and ethical. One approach is to broaden the number of individuals eligible for incentives, while tailoring the behavioural targets and incentive amounts to ensure individuals with the greatest need benefit the most. In terms of funding for incentives, early investment in selective programmes may be offset by future reductions in healthcare costs. Political opinions in the future may also be open towards shifting investments from public programmes to more targeted programmes that directly benefit individuals. In contrast to other public health interventions, FIESTA does not address population-based approaches to smoking cessation, such as reducing sales of cigarettes, but rather focuses on individual decision making.

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