

# **Social and Monetary Incentives for Smoking Cessation at Large Employers (SMILE Study)**

## **Study Protocol**

### **Principal Investigator:**

William H. Dow, PhD, University of California at Berkeley

### **Supported by:**

The National Institutes of Health  
Grant: R01-DA035384

### **Registered with:**

[www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)  
Identifier: NCT02421224

### **Approved by:**

University of California at Berkeley Institutional Review Board  
IRB #: 2012-11-4792

Mahidol University  
Protocol Number 2014/1-1-06

**Draft or Version Number: 2.2**

**Date Last Revised: April 29, 2019**

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## A. Key roles and contact information

### **Principal Investigator:**

William H. Dow, PhD  
University of California at Berkeley  
School of Public Health  
Tel: 510-643-5439  
wdow@berkeley.edu

### **Site Principal Investigator:**

Aree Jampaklay, PhD  
Mahidol University  
Institute for Population and Social Research  
999 Phuttamonthon 4<sup>th</sup> Road, Phutthamonthon  
Salaya, Nakhon Pathom 73170, Thailand  
Tel: +66 2441-0201-4 ext. 501  
aree.ude@mahidol.ac.th

### **Other Key Personnel:**

Justin S. White, PhD  
University of California, San Francisco  
Box #0936  
San Francisco, CA 94143  
tel: 1-415-476-8045  
Justin.White@ucsf.edu

Nucharee Srivirojana, PhD  
Mahidol University  
Institute for Population and Social Research  
999 Phuttamonthon 4<sup>th</sup> Road, Phutthamonthon  
Salaya, Nakhon Pathom 73170, Thailand  
Tel: +66 083-698-3588  
nucharee\_s@live.com

Suthat Rungruanghiranya, MD  
Srinakharinwirot University  
Faculty of Medicine  
Ongkarak, Nakhon Nayok 26120, Thailand  
Tel: +66 3739-5085 ext. 11003  
suthat109@gmail.com

## B. Background and rationale

Below, we review the evidence for several causal pathways mobilized in the proposed intervention.

### 1. Background

#### a. Tobacco use in low-resource settings

Smoking cessation services are not widely available in low-resource settings in the developing world, even though 82% of the world's 8.3 million tobacco-related deaths will occur in the developing world by 2030.<sup>1</sup> Standard treatment options—nicotine replacement therapy (NRT), pharmacotherapy, and professional counseling—are efficacious,<sup>2,3</sup> but are not presently feasible in many places, where trained health professionals are scarce, access to health services is limited, and treatment is relatively expensive. Of those smokers attempting to quit, 64% do not use a cessation aid in the US and 90% in Thailand.<sup>4,5</sup> In this study, we test a novel intervention for promoting smoking cessation in low-resource settings.

Adult male smoking prevalence exceeds 40% throughout most of Asia.<sup>6</sup> In Thailand, daily smoking prevalence among men fell from 56% in 1991 to 37% in 2006, thanks in part to comprehensive tobacco control policies.<sup>7</sup> Thailand's demand for quitting remains high, such that half of smokers reported a quit attempt in the prior year.<sup>5</sup> Smoking treatment programs in Thailand are limited to a handful of hospitals and community pharmacies, yet quit rates rose as high as 10% in 2007.<sup>8</sup> Global tobacco control efforts, already underway, are expected to have similar effects, spurring an increased demand for quitting, throughout the developing world in the coming years.

Thailand's early adoption of tobacco control policies, high demand for quitting, and low use of professional services for smoking cessation make it an excellent setting for testing innovative approaches to promote quitting. Lessons from the proposed study will provide timely evidence for Thailand and other low-resource settings, where affordable and effective approaches are needed to meet a growing demand for quitting. (Outside Thailand, incentive values can be scaled to a similar share of income.) Moreover, a similar approach is transferrable to other contexts, including in rural communities, in clinics, and via private health insurers.

#### b. Monetary incentives for health behavior change

Monetary payments have been used to promote a variety of health behaviors. One systematic review of randomized controlled trials finds that economic incentives improved health behavior 73% of the time.<sup>9</sup> For example, cash incentives have successfully promoted: gym attendance,<sup>10</sup> adherence to medication,<sup>11</sup> and many other behaviors. Contingency management—a substance abuse treatment that uses cash incentives to promote drug abstinence—raised compliance 30%

on average.<sup>12</sup> These studies document the successful effects of incentives on individual health behaviors.

Monetary reinforcement of health behaviors has not been uniformly successful. A systematic review on competitions and cash incentives for smoking cessation concludes that, although incentives raise short-term quit rates, these gains prove fleeting.<sup>13</sup> Many of these prior studies are under-powered. The review also covers multiple interventions—lotteries, competitions, contingent rewards, and commitment mechanisms—making it difficult to discern the impact of any one design. Nonetheless, cash incentives may crowd out one’s motivation to undertake a health-promoting activity, or may attract smokers who are financially motivated but unmotivated to stay abstinent. In either case, recidivism following the reward schedule is a concern.

A combination of cash incentives and commitment contracts differs from standard cash for quitting in two key respects. First, participants must deposit money up front, selecting for smokers who have a desire to be abstinent rather than those who are only motivated financially. We will measure the difference in program take-up across the incentives conditions and see if users of the incentive contracts are less likely to relapse. If so, commitment contracts may offer a more (cost-)effective way to target incentives. Second, the team bonus activates peer pressure to succeed. Very few studies address how people respond to incentives over joint outcomes. One exception, Babcock et al. (2011), finds that team incentives for gym attendance are as effective as equal-sized individual incentives, despite necessarily lowering the expected payoff.<sup>14</sup> However, the study tracked a small number of students for 1 month only (2 weeks post-enrollment) and did not measure outcomes after payments were made. We build on this promising design to test team incentives in a realistic field setting designed to have (and test) long-term effects in a large sample.

Incentives in Workplace Wellness Programs. Workplace wellness programs offer an important public health and policy opportunity to improve health, encourage prevention, and lower the cost of health care. However, the success of these programs is dependent on the level of participation. Voluntary participation in workplace wellness programs increases with the use of incentives, both financial and non-financial.<sup>15</sup> Many programs offer monetary incentives for participation, compliance with behavior change recommendations, and achievement of specific health goals.<sup>16</sup> The proposed study will contribute to the literature on building incentives into wellness programs to see if a cash bonus increases program take-up and, if so, among which types of employees.

### c. Commitment mechanisms

Behavioral economists find that people exhibit a number of behaviors that are consistent with self-control problems. The hallmark of a self-control problem, also known as present bias, is that a person prefers immediate gratification to longer-term considerations. Departure from long-run preferences diminishes a person’s well-being.<sup>17</sup> Recent studies link present bias to health-related behaviors such as smoking and exercise.<sup>18-20</sup> The behavioral model also suggests

that some individuals benefit from pre-commitments that prevent a person from indulging in bad behavior.<sup>21</sup> In a U.S.-based sample, 81% of smokers used a non-binding commitment mechanism during a quit attempt, such as avoiding friends who smoke or places with smokers in order to steer clear of temptation.<sup>22</sup>

Deposit contracts are binding, often financially-backed agreements designed to motivate a person to maintain self-control and achieve a specified goal. Recent literature finds that deposit contracts enhance an array of behaviors, such as exercise and smoking cessation,<sup>23, 24</sup> but the evidence is more mixed for preventive health savings and weight loss.<sup>25, 26</sup> Only one randomized controlled trial has assessed smoking cessation contracts. Giné, Karlan, and Zinman (2010) find that 11% of smokers in the Philippines took up the contracts.<sup>24</sup> Average cumulative deposits over a 6-month period amounted to 20% of one month's income, a nontrivial commitment. According to the results from a surprise visit six months after the deposit period ended, the contracts raised the 12-month quit rate by 3.5% points (38%) from an 8.9% base. The study has been influential, for example, cited by a recent NIMH panel as presenting a "novel" approach that might improve psychiatric treatment adherence.<sup>27</sup>

#### d. Peer pressure

Peer pressure has long been implicated as a cause of bad health behavior, especially among adolescents. In this study, we try to activate peer pressure to foster positive behavior. Social pressure is a strong regulating force for increasing willpower and motivation.<sup>28-30</sup> Researchers have documented the effects of peer pressure across a range of settings: in joint liability microcredit groups,<sup>31</sup> in the workplace,<sup>32, 33</sup> and in the voting booth.<sup>34</sup> The effects may be especially strong if peers know each other well.<sup>35, 36</sup> Babcock et al. (2011) show that peer pressure from team incentives motivate students to exercise as much as individual incentives. Only three empirical studies, all randomized controlled trials, examine the use of social pressure as a commitment mechanism for present-biased individuals. Dupas and Robinson (2013) conclude that social commitment stimulated savings among present-biased members of a formal savings group more than a strong financial commitment.<sup>25</sup> Kast, Meier, and Pomeranz (2010) find that self-help peer groups in Chile doubled savings when members had to publicly declare a weekly savings goal, whose attainment was publicly verified and acknowledged at a future meeting.<sup>37</sup> In the design most similar to ours, Jeffery et al. (1983) assigned individuals to a weight loss contract in which refunded deposits depended on either individual weight loss or mean group weight loss.<sup>38</sup> The group contract arm shed 5 more pounds weight than the individual contract arm, although group size is unreported and sample size is small. Our study adds to this nascent literature by clarifying the role peer pressure can play in adhering to health-promoting behavior.

#### e. Social support

Social support programs have strong links to health behavior change. Alcoholics Anonymous has assigned millions of new members to an experienced sponsor who provides guidance on

how to maintain sobriety. Weight Watchers also assigns members to dyads. One attraction of a buddy system is the low marginal cost of adding the component to an existing intervention. Team-based interventions have been used to promote physical activity and weight loss,<sup>39, 40</sup> although buddy interventions, a common adjunct to smoking treatment, typically have not enhanced the likelihood of quitting.<sup>41</sup> Partner interventions may raise short-term quit rates relative to individual therapy,<sup>42</sup> but rarely induce long-term effects.<sup>43</sup> Only one high-quality study, of which we are aware, has tested the use of financial incentives alone compared to incentives with group therapy. It finds that social support had an independent effect on quitting above and beyond the incentives.<sup>44, 45</sup> Many other studies employ a weak research methodology. By comparing depositors with and without a partner, we will re-examine the effect of social support in financial interventions.

## 2. Rationale

Tobacco use is a key contributor to premature death and morbidity in Thailand and other low- and middle-income countries. Within these settings, smoking cessation services are not widely available in many low-resource settings, because trained counselors are scarce, and pharmacological approaches are priced beyond the reach of many smokers. Monetary incentive programs for smoking cessation are a potentially scalable intervention within workplaces in many low-resource settings. While such programs have shown promise in high-income settings, they have not been tested in a middle-income country setting.

We will conduct a 9-arm cluster randomized trial of large worksites located in the Bangkok metropolitan area of Thailand, in order to rigorously test multiple incentive designs within a scalable workplace setting. Our study will provide unique evidence on the effectiveness of adding a cash bonus and social pressure to commitment contracts. The methodology may be transferrable to other health behaviors and other settings. The findings will be useful for low-resource areas where effective and cost-effective approaches are needed to meet the demand for quitting. The innovative scientific lessons are expected to be broadly portable, with the potential to influence tobacco policy across many contexts and to advance the literature on the use of deposit contracts and social and monetary incentives to improve health behavior.

## C. Study objectives

The SMILE Trial (Social and Monetary Incentives for Smoking Cessation at Large Employers) was designed to evaluate the impact of deposit contracts, individual bonuses, and team bonuses in isolation and in combination, relative to each other and a no-incentive control group.

The primary objective of this study is to compare the impact of multiple incentive designs versus usual care to increase smoking cessation among employees at participating worksites in the Bangkok metropolitan area of Thailand. The benchmark for effectiveness of the incentive

programs is usual care, offered in the form of brief group counseling and a text-messaging program for smoking cessation.

The secondary objectives of this study are to compare the net effects across study designs, taking into account program take-up, heterogeneous treatment effects, cost per quitter, and social spillovers.

## D. Study design

### 1. Study population

#### a. Eligibility criteria for worksites

Criteria for inclusion of companies in the study include:

- At least 200 workers
- At least 30 smokers employed at the worksite, according to estimates from worksite personnel
- Willingness to implement a randomly assigned intervention and to follow all aspects of the study protocol
- Being located in the Bangkok metropolitan area of Thailand

These criteria will be verified during conversations with a company officer prior to inclusion of the company in the study.

#### b. Eligibility criteria for participants

Inclusion criteria for study participants include:

- Being a full-time employee at a participating worksite
- Being an adult aged 18 years old or older
- Reporting having smoked at least 100 cigarettes in his or her lifetime
- Reporting smoking an average of at least 10 cigarettes per week
- Reporting wanting to quit smoking within the next 6 months

All of these criteria will be verified during a screening questionnaire, to be verified during an in-person baseline assessment.

Exclusion criteria:

- The individual expects to leave the company within the next year.
- The individual is unable to provide informed consent.
- The individual is currently pregnant.



- Pregnant women who smoke are not at higher risk from participating, but they belong under the supervision of a medical professional.

These criteria will not be formally incorporated into a screening survey. Rather, they will be communicated to company officers, stated in recruitment materials and on informed consent form(s), and reviewed by study personnel at enrollment.

## 2. Recruitment

### a. Recruitment of worksites

We aim to recruit 100 worksites, the unit of randomization. We will target companies in or near several industrial areas in the Bangkok metropolitan area. Most companies in these industrial areas are factories that employ a large percentage of blue-collar workers. The smoking prevalence among blue-collar workers is believed to be higher than the general population. The close proximity of worksites to each other in the industrial areas will make it easier on study personnel to coordinate travel and logistics.

The study will target large worksites located in or near six industrial areas in the Bangkok metropolitan area: Bang Puu, Lat Krabang, Samut Sakhon, Nawanakhon, Bang Kradee, and Sinsakhon. The study will also include companies in the surrounding areas of Samut Prakan, Pathum Thani, Lat Krabang, and Samut Sakhon. These locations cover areas to the northeast, southeast, and east of downtown Bangkok. The sample of worksites is expected to be broadly representative of industrial worksites in the Bangkok metropolitan area.

We will employ a convenience sampling strategy. Even if a sample from large Bangkok worksites does have direct external validity to other contexts of interest, the study is still designed to produce results of policy significance, based on innovative testing in a design with strong internal validity and sufficient statistical power. A key concern will be to meet the sample size target of 100 units of randomization. Prior randomized trials of workplace smoking cessation programs have predominantly been conducted in studies within single large U.S. firms.

Prior to recruitment, field personnel will meet with officials at the industrial agency that administers the industrial zone and the provincial industrial office. We will inform these industrial offices of our study and its aims, and invite them to serve as a formal or informal collaborator. Those who agree will be invited to attend a workshop of company officers and to act as an observer during meetings at selected worksites. We will also request a list of health officers or human resources personnel at the worksites within that industrial area.

Recruitment of companies will follow several steps:

1. Compile contact information for companies located in the targeted industrial areas.

2. During a phone conversation, give a brief introduction and request a brief in-person meeting to discuss the project.
3. Send a letter with the formal request to meet to the appropriate company official as an email attachment.
4. Attend an initial meeting at the worksite as an opportunity 1) to encourage the company officer to join the study and 2) to collect information about challenges and opportunities for recruitment at the company.
5. Hold a workshop to present additional information about the study to officials from worksites that agree to participate in the study.

#### b. Recruitment of participants

The recruitment of participants will occur in two batches of roughly 50 worksites each. The second batch will begin the intervention approximately three months following the start of the first batch. The staggered approach is designed to relieve some of the pressure on the field teams of having to be active in 100 worksites at once. It will also allow for minor changes in logistical planning to be adopted in Batch 2.

Prior to recruitment of participants, field personnel will make outreach visits to each worksite. During these visits, field personnel will set up a booth in a central location at the company, such as in the cafeteria during lunchtime, where they will provide information about the study and answer any questions.

The recruitment of participants at each company will proceed in three phases:

1. Identify all smokers who work at the company during a screening survey. Human resources and/or the health officer will assist with disseminating and collecting the screening surveys.
2. Conduct a baseline survey of all smokers who are eligible for the study, as determined in the screening survey.
3. Invite everyone who is eligible for the study to enroll as a participant in the study. We will send an invitation letter to each person, post flyers and posters around the worksite, and ask the health officer to assist with recruitment.

### 3. Interventions

The proposed study employs a cluster randomized controlled design with a 3-month intervention followed up 3, 6, and 12 months after enrollment. We will randomly assign participating worksites to treatment arms that vary on three cross-randomized components: 1) deposits or no deposits, 2) bonus size (none, small, large) and 3) teammate or individual.

#### a. Intervention components

In total, there are 4 main intervention components:

C1. Usual care. All participants will receive usual care consisting of two elements: in-person group cessation counseling and cessation support via text messaging. The group counseling will consist of 90 minutes of counseling delivered at each worksite by a trained smoking cessation counselor. The text-messaging program, developed by the Thai Health Professional Alliance against Tobacco, will provide 1-3 messages per day for 28 days, which will include advice, support, and encouragement for quitting smoking. Similar programs have been found to be efficacious.<sup>46</sup> All materials will be delivered in Thai. Participants who do not own a mobile phone will be able to designate a family member to whom the messages can be sent. If the person cannot identify a phone number, the person will not receive the text messages.

C2. Deposits. Participants in deposit programs will be asked to provide refundable deposits contingent on smoking abstinence. These participants will receive a personal deposit box to take home and will make an initial deposit of at least 100 baht in the deposit box at the enrollment meeting. The deposit boxes, made out of metal, are designed to be tamper-proof. They have a coin slot but no other opening. Until the follow-up assessment at 3 months, participants will be able to make additional deposits in a lockbox that will be kept at the company. All deposits will be returned at the 3-month meeting only if the person has been determined to have quit smoking. At the 3-month follow-up assessment, study personnel will open each box using a can opener and will record the total balance.

At the enrollment meeting, participants will be required to give an additional 150-baht in collateral that depends solely on returning an intact deposit box at 3 months. The money will be placed in a sealed envelope with the participant's name on it to be stored at the project office in a locked cabinet. If the deposit box is tampered with or not returned at 3 months, then the money in the sealed envelope will be forfeited to the project.

C3. Teammate. Participants in team-based programs will be randomly assigned to another participant from the same worksite as a teammate. Team assignment will be stratified by work shift and native language in order to facilitate opportunities for communication. Pairings will be announced at the enrollment meeting at each worksite.

C4. Cash bonus. Participants in small individual bonus programs will be eligible for a cash bonus of 600 baht for abstaining from smoking at 3 months. Participants in large individual bonus programs will be eligible for a bonus of 1,200 baht for abstinence at 3 months. This amount is roughly equivalent to one and two days' wages, respectively.

Participants in team bonus programs will be eligible for a team bonus of 1,200 baht each if both team members abstain from smoking at 3 months. The team bonus is designed to activate a sense of social commitment and peer pressure to quit. In teammate assignment strata with an odd number of participants, the "extra" participant did not receive a teammate and was, instead, eligible for a \$40 individual bonus.

## b. Randomization groups

In total, there are 9 arms or randomization groups. The nine randomization groups are: 1) control group (usual care only), 2) 600-baht individual bonus, 3) 1,200-baht individual bonus, 4) team bonus, 5) deposits, 6) deposits plus teammate (no bonus), 7) deposits plus 600-baht individual bonus, 8) deposits plus 1,200-baht individual bonus, 9) deposits plus team bonus (Table 1).

Groups 2 and 3 are similar to incentives for smoking cessation used in many studies.<sup>47</sup> Incorporating both allows for a test of whether larger bonuses were more effective, as some researchers have hypothesized.<sup>48</sup> Group 5 is a “pure” deposit contract that replicates the intervention group in the CARES trial in the Philippines.<sup>24</sup> Group 6, involving a teammate and deposits but no other team-based incentives, will allow for identification of the independent effect of buddy-based peer support. Finally, group 9 combines a deposit contract with the same 1,200-baht team bonus in Arm 4, replicating the intervention used in White, Dow, and Rungruanghiranya.<sup>49</sup>

Table 1. Crosswalk of randomization groups and intervention components

#	Randomization group	Intervention Component				
		Usual care	Deposits	600-baht bonus	1,200-baht bonus	Team
1	Control	X				
2	600-baht individual bonus	X		X		
3	1,200-baht individual bonus	X			X	
4	Team bonus	X			X	X
5	Deposits	X	X			
6	Deposits plus teammate	X	X			X
7	Deposits plus 600-baht individual bonus	X	X	X		
8	Deposits plus 1,200-baht individual bonus	X	X		X	
9	Deposits plus team bonus	X	X		X	X

## 4. Study procedures

### a. Consenting procedure

The study will request consent of participants at three separate points of the study: prior to screening, prior to baseline assessment, and prior to enrollment in the main intervention.

The informed consent form for the screening process will be provided along with the self-administered screening questionnaire. Consenting individuals will sign, date, and return the form along with their completed screening questionnaire.

The informed form completed prior to the baseline assessment will occur during an in-person interview with study personnel. Only those individuals deemed eligible based on the screening questions will be asked to sign and date the baseline consent form. It covers several study activities, including participation in the baseline assessment and the three follow-up assessments (urine test, survey, and brief counseling session) to be held at 3, 6, and 12 months. Participation in these activities will be independent of whether the individual decides to enroll in the main intervention.

The informed consent for enrollment in the main intervention will occur at the start of the enrollment meeting (discussed below). A different version of the consent form will be used for each arm of the intervention, corresponding to the different procedures used in each arm. Thus, the consent form will cover counseling at the enrollment meeting, entry into the text-messaging program, the deposit contract, bonuses, and teammate procedures. Written consent will be requested from candidates after study personnel have provided a study overview and given an opportunity for candidates to ask questions about participation. A study personnel member will counter-sign and date the form.

#### **b. Screening**

Human resources or the health officer at each worksite will distribute a self-administered screening questionnaire to workplace employees. The main purpose of the screening questionnaire is to determine eligibility for the study. Employees will be asked to return the completed questionnaire form within one week. Respondents will receive an in-kind gift with a retail price of 35 baht (about \$1). We will transfer the gifts to the company officer to distribute at the time that study personnel pick up the screening questionnaire forms.

#### **c. Baseline assessment**

For participants who are successfully screened for eligibility and are consented into the study, baseline assessments are executed so that we can measure against these at Months 6 and 12 to calculate study outcomes. They also ensure that the groups are balanced with respect to baseline characteristics.

Following the baseline consent process, an interviewer will begin the baseline survey administered on a computer tablet. The survey will be coded into the Qualtrics offline-compatible software application for tablets. The survey will include topics such as demographic characteristics, smoking characteristics, risk and time preferences, and contact information.

At the end of the baseline survey, study personnel will tell the respondent that he or she will receive an invitation letter to invite enrollment into the main intervention. We will provide an inconvenience gift worth 150 baht in cash or in kind to those who complete the baseline survey. In-kind gifts will consist of items such as a project t-shirt. In addition, respondents will receive educational brochures, stickers, and/or posters about quitting smoking.

A study personnel member will contact by phone the eligible smokers who were not available on the day of the baseline survey. During the call, the study team member will inform the person that the field team will make a return visit to the company on a certain day within the next week, and the study team member will ask if the person is willing to take the baseline survey on the return visit day and, if possible, to set an appointment time.

#### d. Enrollment

After all participants from the worksite have completed the baseline survey, excluding non-responders and attriters, we will send a personal letter to each respondent with details on the assigned intervention and an invitation to attend the enrollment meeting, which will take place about two weeks after the baseline survey. We will follow up with a phone invitation during the week of the enrollment meeting. In the invitation letter and during the reminder calls, we will emphasize the importance of arriving to the meeting on time.

The enrollment meeting will take place on the premises of each participating worksite, scheduled in consultation with human resources or the health officer at that site. The main activities to occur during the enrollment meeting include:

- Study overview tailored to each arm
- Informed consent
- Smoking cessation counseling
- Developing a quit plan
- Making an initial deposit (Arms 5-9)
- Introduction of teammates (Arms 4, 6, 9)

In order to accommodate the availability of employees, we may hold multiple meetings to take place at different times of day to accommodate different work schedules and work shifts. If the meetings occur during work hours, the coordinating officer at the company will need to inform supervisors at the company in an effort to get workers excused from their normal duties during the enrollment meeting.

At the start of the enrollment meeting, a study personnel member will give a brief study overview and describe the specific intervention to which that company has been assigned, including procedures for making deposits, assignment and communication with a teammate, and receiving a cash bonus. At the conclusion of the study overview, attendees will be asked to consent to participation in the main intervention. The consent form will cover the smoking

cessation counseling at the enrollment meeting, the enrollee survey, and, as appropriate, the deposits, the bonus, and having a partner.

Following the consent process, a trained smoking cessation counselor will provide group counseling about smoking cessation using a module developed by the Thai Health Professional Alliance against Tobacco.

At the end of the counseling session, participants will complete a Quit Plan. This will include setting a specific quit date, preferably within two weeks. Participants will also be asked to start thinking about their first smoke-free day, how they will handle the challenges, and which types of activities they will substitute for smoking.

Among worksites assigned to a deposit contract arm (Arms 4-7), study personnel will give each participant a personal deposit box. Each person will wait in line to provide to study personnel an initial contribution of at least 100 baht, or more if desired. Study personnel will encourage participants to contribute at least as much as they had typically spent on tobacco. In addition, participants will be asked to give the project an additional 150 baht as collateral for the safe return of the box, in order to deter tampering or theft. The collateral will be kept under the care of an appointed company representative. Each participant will sign a form to document that they have provided the initial contribution and collateral and will receive a deposit receipt.

Among worksites assigned to a teammate arm (Arms 3, 5, 7), study personnel will announce pairings. If a participant's teammate did not attend the meeting, study personnel will tell the person that he or she will be randomly assigned to another partner, and study personnel will contact the participant by phone within the next few days to inform him or her of the teammate's identity. Study personnel will instruct all pairs who are present to complete a Teammate Support worksheet that asks teammates to share with each other their quit plan, including their smoking habits, how often they would like to discuss quitting with each other, and how they would like to encourage each other to quit smoking.

At the end of the meeting, participants will receive an inconvenience gift of 150 baht in cash or in kind, whichever the person prefers.

#### e. Follow-up assessments

Follow-up assessments will take place at each worksite approximately 3 months, 6 months, and 12 months after the enrollment meeting. The date will be set in consultation with human resources or the health officer at the worksite. All participants will be contacted by phone during the week of the follow-up meeting to notify them of the upcoming visit.

Participants will complete two main activities during each follow-up assessment: a urine test and a follow-up survey.

We will use the COT One Step Cotinine Test, sold by Alfa Scientific Designs, an immunoassay that detects urine cotinine at a cutoff concentration of 200 ng/mL within about 10 minutes. The test was found to be easy to use and reliable during pre-testing.

Participants will be provided with a urine specimen cup, labeled with a unique ID number as they enter the restroom. Study personnel will stand outside of the restroom and will collect the full cup as each participant exits the restroom. The cups will be brought to a nearby designated room where testing will take place. The assessor of the biochemical urine test will be blinded to participants' randomization groups. The results of the urine test will be entered on a paper record and subsequently entered electronically. Following the follow-up survey described below, a trained smoking cessation counselor will share the urine test results with the participant and provide brief counseling.

After providing a urine sample, each participant will complete a short survey administered by study personnel on a portable tablet. A separate module will be administered for self-reported quitters and self-reported continuing smokers, as determined at the start of the questionnaire. All respondents will be asked questions related to smoking behavior and quit attempts since the prior meeting. Participants will also be asked additional questions about their behavior during the intervention period and their perceptions related to the intervention.

At the end of the follow-up visit, each participant will receive an inconvenience gift worth 150 baht. Participants may choose to be paid in cash or in kind.

A field team member will contact by phone the participants who do not attend the follow-up visit to ascertain their self-reported smoking status. The reason for non-attendance will be recorded. If a participant reports having abstained, a field worker will schedule a time within the next 48 hours to provide a urine sample for biochemical verification. Those who provide the urine sample will receive the inconvenience gift worth 150 baht.

## 5. Randomization

After baseline surveys are completed, worksites will be randomly assigned in equal proportion to one of the nine randomization groups. The cluster randomized design mitigated concerns of within-worksites contamination and is expected to be viewed by employers as more acceptable than person-level randomization. We will follow a covariate-adaptive procedure, in which we will minimize the  $p$ -value from a joint  $F$ -test as a balance criterion implemented over 1,000 iterations.<sup>50</sup> In Monte Carlo simulations, minimization has been found to facilitate covariate balance.<sup>51</sup> The randomization procedure will include the following worksite-level covariates, which we will also include in the adjusted regression analyses: province, mean age, mean proportion born in Thailand, mean cigarettes per week, mean proportion who want to quit smoking within 6 months, number of employees, and estimated smoking prevalence based on baseline data.



A study investigator will implement the random allocation sequences using computer-generated random numbers, concealing the sequence from field staff, company employees, and participants until after the baseline survey has been completed. Participants will be informed of their assignment in an enrollment invitation letter sent following the baseline survey.

## 6. Outcomes

The primary outcome is biochemically-verified 7-day point-prevalence smoking abstinence obtained 12 months after enrollment, more than 9 months after all incentives were awarded. To be classified as having abstained, participants will have to self-report having abstained for the 7 days prior to the test and to test negative for nicotine and its metabolite cotinine using a rapid urine test. Participants who do not complete a survey or urine test will be assumed to be continuing smokers as part of the intent-to-treat analysis, as is the standard practice in the literature.<sup>52</sup> At each end point, we will record whether the participant indicated active use of nicotine replacement therapy or e-cigarettes to aid in smoking cessation. In awarding incentives and in analyses, users of nicotine replacement therapy or e-cigarettes who reported smoking abstinence were treated as abstinent.

Secondary end points include biochemically verified 7-day point-prevalence abstinence at 3 months (end of intervention) and at 6 months (3 months after the incentives end). Another secondary outcome will be program take-up of interventions, defined as attending the on-site enrollment meeting, consenting to enter the trial, and if applicable, making at least the minimum deposit contribution.

## 7. Data management

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the PIs. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete.

Survey data will be collected electronically through Qualtrics. Data on outcomes assessment will be recorded on paper and subsequently entered electronically.

The crosswalk with personal identifiers will be transferred to the PI at the termination of fieldwork; the copy in Thailand will then be destroyed, and the PI will retain it for up to one year following the end of the study in case a scientific need arises for follow-up. Deidentified electronic files will be retained indefinitely.

## 8. Statistical considerations

### a. Sample size and statistical power

The proposed sample size is 6,000 participants drawn from 100 worksites. This sample size is larger than previous studies that use incentives or commitment contracts for smoking cessation. For example, the sample size is more than double all but one study included in a recent systematic review of competitions and monetary incentives for smoking cessation.<sup>13</sup>

A preliminary survey of 37 firms who attended a workshop in September 2011 indicated that the median firm has 800 employees, roughly 20% of whom smoke. Of the 37 firms, 35 (95%) expressed an interest in joining the project, implying that the target of recruiting 100 worksites is feasible. Based on the survey data and the pilot study, we expect trial take-up to vary from 10% of smokers in the control arm to 70% in the larger individual bonus arm, and quit rates conditional on take-up to vary from 20% in the control arm to 45% in the deposit contract with a team bonus.

Using Optimal Design Software,<sup>53</sup> we computed the minimum detectable effects for a binary abstinence measure as a function of a cluster-randomized binary treatment using a multi-level equation (person at level 1, worksite at level 2) with a random effect for each worksite. We estimated that we will be able to detect absolute differences of at least 7.5 percentage points in abstinence rates for pairwise comparisons between any of the incentive-based arms versus the usual-care control group. This calculation assumed an abstinence rate of 6.0% in the control group (10% conditional on 60% program take-up), 60 participants per worksite, Type-I error  $\alpha = 0.05$ , and 80% power ( $\beta = 0.20$ ).

Our reported detectable effect sizes are conservative in that they do not adjust for stratification variables used for firm-level randomization (i.e., firm size, industry type, and smoking prevalence) or baseline control variables, both of which will reduce the variance of parameter estimates and, thus, the detectable effect size.

### b. Planned statistical analyses

We will conduct descriptive analyses as components of standard data analyses. To evaluate balance across groups achieved by randomization, baseline values of all control variables will be compared across the 9 arms using *t*-tests.

We will use generalized linear mixed-effects models to estimate the intent-to-treat effect of each arm and each intervention component on program take-up and smoking abstinence. The generalized linear mixed-effects models will include a logit link for the binary outcome and a random intercept at the worksite level to adjust for the clustering of participants within a worksite. The primary outcome variable will be verified abstinence, treating reported NRT or e-cigarette use for cessation as abstinent as long as no cigarettes were used. We will report risk

differences from unadjusted and adjusted models. The adjusted models will include prespecified variables known to be related to the outcomes, including baseline demographic characteristics and smoking history. Demographic characteristics will include age (18-25, 26-35, 36-45, ≥45), gender, household income per capita, educational attainment (0-3, 4-6, 7-12, ≥13 years), marital status (married, not married), any children, and place of childhood (urban Thailand, rural Thailand, foreign country). Smoking characteristics will include average cigarettes per day, moderate-to-high nicotine dependence (Fagerström Test for Nicotine Dependence score ≥5), number of past quit attempts, number of years since initiating smoking, and quit intentions (want to quit within 3 months or not).

In sub-analyses, we will pool Groups 2-9 to compare the average effect of receiving usual care plus any incentive program, compared with usual care (Group 1), using similar adjusted and unadjusted mixed-effects models to those described above. We will also investigate interaction effects between intervention components, using the same adjusted mixed-effects models as above. We will also investigate whether those in a bonus group or deposit group are more likely to relapse following the end of the incentive period.

We will perform four sensitivity analyses to assess the robustness of the estimated intervention effects. First, we will conduct the analysis on a per-protocol basis, that is, among those who had accepted their assigned intervention. Second, we will use complete outcome data without assuming that missing cases had smoked. Third, we will exclude from the analysis the outcome data from participants who reported currently using NRT or e-cigarettes. Fourth, we will perform multiple imputation using chained equations to impute missing outcome data at each end point.

In further statistical analyses, we will explore the relationship between time preferences measured at baseline and trial outcomes, as well as the peer effects that teammates have on each other and that participants have on non-participants who complete the baseline survey.

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