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SPECIAL ARTICLE

A Pragmatic Trial of E-Cigarettes, Incentives, and Drugs for Smoking Cessation

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RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
SD, 2018	RCT	?? ?	+	?	?	?

Characteristics of studies

SD, 2018

Population

1. METHODS We randomly assigned smokers employed by 54 companies to one of four smokingcessation interventions or to usual care.

Intervention

1. METHODS We randomly assigned smokers employed by 54 companies to one of four smokingcessation interventions or to usual care.
2. The four interventions consisted of usual care plus one of the following: free cessation aids (nicotine-replacement therapy or pharmacotherapy, with e-cigarettes if standard therapies failed); free e-cigarettes, without a requirement that standard therapies had been tried; free cessation aids plus $600 in rewards for sustained abstinence; or free cessation aids plus $600 in redeemable funds, deposited in a separate account for each participant, with money removed from the account if cessation milestones were not met.
3. Participants in the intervention groups were also notified that they were being offered one of four additional programs: free cessation aids, which included all forms of nicotine-replacement therapy, bupropion or varenicline, and ,Äî for participants who reported lack of success with initial standard therapy ,Äî free NJOY e-cigarettes (including battery sticks, a USB charger, and up to 20 chambers with 1.0 to 1.5% nicotine per week in participants' chosen flavors); free e-cigarettes without the requirement that standard therapies had first been tried; a reward incentive worth $600 for sustained smoking abstinence, plus all options in the free cessation aids group; or a deposit account worth $600, redeemable by participants who become abstinent, plus all free cessation aids.

Outcomes	1. The primary outcome was sustained smoking abstinence for 6 months after the target quit date. 2. Secondary outcomes included the point prevalence for quitting at 1 month and sustained abstinence rates at 3 months and 12 months (i.e., 6 months after the end of the assigned intervention). 3. CONCLUSIONS In this pragmatic trial of smoking cessation, financial incentives added to free cessation aids resulted in a higher rate of sustained smoking abstinence than free cessation aids alone.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomization and Interventions Participants were randomly assigned on an individual basis to one of five groups, with stratification according to employer. 2. 6,10,11 If participants did not opt out by notifying trial staff before the enrollment date, they were enrolled (a design known as " opt-out consent ") and were randomly assigned to an intervention or to usual care (Fig. 1). 3. METHODS We randomly assigned smokers employed by 54 companies to one of four smokingcessation interventions or to usual care.
Allocation concealment	high/unclear	1. 6,10,11 If participants did not opt out by notifying trial staff before the enrollment date, they were enrolled (a design known as " opt-out consent ") and were randomly assigned to an intervention or to usual care (Fig. 1). 2. Randomization and Interventions Participants were randomly assigned on an individual basis to one of five groups, with stratification according to employer. 3. In addition , the response rates to the 1-month survey were higher among participants assigned to the financial-incentives groups than among participants in the other groups.
Blinding of participants and personnel	high/unclear	1. 6,10,11 If participants did not opt out by notifying trial staff before the enrollment date, they were enrolled (a design known as " opt-out consent ") and were randomly assigned to an intervention or to usual care (Fig. 1). 2. 16,17 All samples were evaluated by laboratory technicians who were unaware of the group assignments. 3. The 54 companies were of different sizes and in different sectors of the economy and contributed a median of 59 participants (interquartile range, 38 to 130) to the trial.
Blinding of outcome assessment	high/unclear	1. 6,10,11 If participants did not opt out by notifying trial staff before the enrollment date, they were enrolled (a design known as " opt-out consent ") and were randomly assigned to an intervention or to usual care (Fig. 1). 2. At the time of randomization, all participants were notified of usual-care resources that they could access through the wellness websites for their companies, including information regarding the health benefits of smoking cessation, strategies to promote cessation, and the opportunity to register for the SmokeFreeTXT program of the National Cancer Institute, a free textmessaging program that gives encouragement, advice, and tips for stopping smoking. 3. The 54 companies were of different sizes and in different sectors of the economy and contributed a median of 59 participants (interquartile range, 38 to 130) to the trial.