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JNCI J Natl Cancer Inst (2022) 114(10): djac127

https://doi.org/10.1093/jnci/djac127
First published online July 12, 2022
Article

A Randomized Trial of Telephone-Based Smoking Cessation Treatment in the Lung Cancer Screening Setting

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Abstract

Background: Lung cancer mortality is reduced via low-dose computed tomography screening and treatment of early-stage disease. Evidence-based smoking cessation treatment in the lung screening setting can further reduce mortality. We report the results of a cessation trial from the National Cancer Institute's Smoking Cessation at Lung Examination collaboration. **Methods:** Eligible patients (n = 818) aged 50-80 years were randomly assigned (May 2017-January 2021) to the intensive vs minimal arms (8 vs 3 phone sessions plus 8 vs 2 weeks of nicotine patches, respectively). Bio-verified (primary) and self-reported 7-day abstinence rates were assessed at 3, 6, and 12 months post random assignment. Logistic regression analyses evaluated the effects of study arm. All statistical tests were 2-sided. **Results:** Participants reported 48.0 (SD = 17.2) pack-years, and 51.6% were not ready to quit in less than 30 days. Self-reported 3-month quit rates were statistically significantly higher in the intensive vs minimal arm (14.3% vs 7.9%; odds ratio [OR] = 2.00, 95% confidence interval [CI] = 1.26 to 3.18). Bio-verified abstinence was lower but with similar relative differences between arms (9.1% vs 3.9%; OR = 2.70, 95% CI = 1.44 to 5.08). Compared with the minimal arm, the intensive arm was more effective among those with greater nicotine dependence (OR = 3.47, 95% CI = 1.55 to 7.76), normal screening results (OR = 2.58, 95% CI = 1.32 to 5.03), high engagement in counseling (OR = 3.03, 95% CI = 1.50 to 6.14), and patch use (OR = 2.81, 95% CI = 1.39 to 5.68). Abstinence rates did not differ statistically significantly between arms at 6 months (OR = 1.2, 95% CI = 0.68 to 2.11) or 12 months (OR = 1.4, 95% CI = 0.82 to 2.42). **Conclusions:** Delivering intensive telephone counseling and nicotine replacement with lung screening is an effective strategy to increase short-term smoking cessation. Methods to maintain short-term effects are needed. Even with modest quit rates, integrating cessation treatment into lung screening programs may have a large impact on tobacco-related mortality.

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Lung cancer screening with computed tomography and treatment of early-stage disease can lower lung cancer mortality by 20%-24% (1-3). An estimated 14.5 million Americans are eligible for lung screening, and nearly one-half currently smoke cigarettes (3-5). To realize the maximum benefit of lung screening, individuals undergoing screening who smoke need to receive evidence-based smoking cessation treatment (6-8). As part of the National Cancer Institute's Smoking Cessation at Lung Examination collaboration (9), the goal of the Georgetown Lung Screening, Tobacco, and Health (LSTH) trial was to conduct a scalable and cost-effective phone-based cessation intervention for future implementation in lung screening settings.

The LSTH trial built on previous work (10-13) and was guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) Framework (14), a model developed to increase the reach and effectiveness of health promotion

Received: March 1, 2022; **Revised:** May 6, 2022; **Accepted:** June 28, 2022

interventions. Proactive telephone counseling for smoking cessation treatment is well suited to the lung screening setting because its effectiveness has been demonstrated with older (50+) adults (15-18), those not ready to quit (19-22), and those not seeking treatment (21,23). It is also intensive enough to provide tailored support to assist individuals who are ready to quit (23-27). Further, as a remotely delivered intervention, telephone counseling can reach people during the teachable moment that may be provided by lung screening (28-32) as well as counteract the reduced motivation that can follow a normal screening result (33). The LSTH trial personalized tobacco-related health risks within an evidence-based cessation intervention and maximized generalizability with broad inclusion criteria, including the large proportion undergoing lung screening who were not ready to quit (22).

We hypothesized that an intensive intervention would yield improved cessation outcomes relative to a minimal intervention while maintaining the potential for widespread implementation. Moreover, we expected that an intensive (vs minimal) intervention would be superior among individuals who may have more difficulty quitting (ie, less ready to quit, higher nicotine dependence, a normal lung screening result). The results can guide the evaluation of the costs and population impact of these approaches for implementation at a nationwide scale (34-37).

Methods

Overview

The LSTH trial accrued participants in partnership with 8 lung screening sites located in geographically diverse community-based hospitals and academic medical centers (Table 1). Each site had a thoracic tumor board and provided diagnostic work-ups and treatment as needed. The study was approved by the Georgetown University Medical Center Oncology IRB (IRB of Record) and the Lahey Hospital and Medical Center IRB. Clinicaltrials.gov registration is NCT03200236 (38). Study enrollment (May 2017-January 2021) and the 3-, 6-, and 12-month follow-up outcomes are described here. The study design and methods were described previously (39).

Study Participants

Inclusion was based on the National Comprehensive Cancer Network's broad eligibility criteria for lung screening (40): 1) aged 50-80 years and 2) 20+ pack-year smoking history. Additional criteria included 3) enrolled before undergoing lung screening; 4) smoked cigarettes, cigarillos, or little cigars within the past 7 days; and 5) English- or Spanish-speaking. Exclusion criteria were history of lung cancer and hearing or cognitive impairment preventing study engagement. Previous lung screening, current cessation treatment, and readiness to quit were not exclusion criteria.

Study Procedures

We conducted manualized staff training at each site to recruit and consent participants (Supplementary Methods, available online). We reviewed enrollment procedures monthly with each site. Site coordinators made up to 10 calls to eligible individuals with a scheduled lung screening exam (Figure 1) to assess eligibility, obtain verbal consent, and complete the 15-minute baseline (T0) assessment before their screening exam. Following enrollment, Georgetown staff mailed or e-mailed the consent and HIPAA forms for signature. Individuals who declined were approached for participation once more at their next annual screen. The denominator used to calculate reach was all trial-eligible individuals who underwent lung screening during the study enrollment period at each of the lung screening programs (Figure 1). Sites communicated the Lung-RADS® (Lung Imaging Reporting and Data System) results (41) via phone, letter, or in-person consultation. Referring providers contacted patients with results suspicious for lung cancer to discuss follow-up procedures. We offered the intervention (intensive arm) to those diagnosed with lung cancer (n = 10) but excluded them from the trial.

Georgetown tobacco treatment specialists (TTSs) made up to 10 attempts to complete the 20-minute postscreening phone assessment (T1). Participants who had quit smoking for at least 8 days were excluded before random assignment and withdrawn from the trial (N = 11).

Following the postscreening assessment (T1), using a password-protected program, a Georgetown TTS conducted 1:1 random assignment in blocks of 4, stratified by site, readiness to quit (next 30 days vs next 6 months or not considering quitting), lung screening result (Lung-RADS® 1 or 2 vs 3 or 4), and language (English or Spanish). The TTS then provided brief advice to quit and encouraged participants to return the consent form. Randomly assigned participants who did not sign the consent (after 10 reminders) were ineligible for the intervention but remained in the intent-to-treat analyses (Figure 1). The same TTS conducted the T1 assessment and all counseling calls.

Georgetown research assistants completed the 15-minute telephone follow-up assessments at 3 (T2), 6 (T3), and 12 months (T4) post random assignment (42) and were blinded to study arm. Participants received a $15 gift card (increased to $25 during the study) after completion of each assessment.

Within 2 weeks of self-reported 7-day point-prevalence smoking abstinence, participants completed bio-verification using a carbon monoxide (CO) test (43) conducted at the lung screening site, a mailed NicAlert (44) or NicoTest (45) saliva strip (for persons using marijuana or unable to use the iCO during COVID-19), or a mailed iCO (46) remote device to measure CO. The standard abstinence cutoffs were less than 30 ng/mL for NicAlert and NicoTest and less than or equal to 6 ppm for CO (47). Parking costs and a $25 gift card were provided. The equivalence between NicAlert and CO has been demonstrated (43,45).

The TTSs received training at an Association for the Treatment of Tobacco Use and Dependence–accredited program (48), weekly supervision for protocol adherence, and monthly supervision from a motivational interviewing expert. All calls were audio-recorded. Protocol adherence, assessed by coding a random selection of 10% of the intervention calls (49), was very high in both arms: M = 94.5% (88–100) in the intensive arm and M = 95.5% (89–100) in the minimal arm. Interrater reliability, calculated for 20% of the coded calls, showed high overall agreement: M = 95.0% (80–100) (Supplementary Methods, available online).

We mailed letters to referring providers notifying them of their patients' study enrollment and 6-month smoking status. The letters also reminded providers to discuss smoking at each visit, consider pharmacological aids when appropriate, and provide support for relapse prevention.

Intervention Procedures

Both arms included empirically validated behavioral and motivational interviewing intervention methods (15,23,50,51). Core

Table 1. Baseline characteristics

Characteristics[a]	Intensive arm No. (%)	Minimal arm No. (%)	Total No. (%)
Total No.	409	409	818
Demographic and clinical characteristics			
Age			
Mean (SD), y	63.6 (5.87)	63.7 (5.84)	63.6 (5.86)
50-54 y	6 (1.5)	2 (0.5)	8 (1.0)
55-59 y	116 (28.4)	111 (27.1)	227 (27.8)
60-69 y	212 (51.8)	219 (53.5)	431 (52.7)
70-80 y	75 (18.3)	77 (18.8)	152 (18.6)
Sex			
Female	212 (51.8)	218 (53.3)	430 (52.6)
Male	197 (48.2)	191 (46.7)	388 (47.4)
Race			
African American	34 (8.3)	31 (7.6)	65 (7.9)
Other (American Indian, Asian, not reported)	11 (2.7)	13 (3.2)	24 (2.9)
White	364 (89.0)	365 (89.2)	729 (89.1)
Ethnicity			
Hispanic origin	23 (5.6)	28 (6.9)	51 (6.2)
Non-Hispanic origin	386 (94.4)	380 (93.1)	766 (93.8)
Language			
English	402 (98.3)	404 (98.8)	806 (98.5)
Spanish	7 (1.7)	5 (1.2)	12 (1.5)
Marital status			
Married/living as married	207 (50.7)	198 (48.6)	405 (49.7)
Not married	201 (49.3)	209 (51.4)	410 (50.3)
Missing	1	2	3
Education level			
High school/GED or less	143 (35.1)	143 (35.2)	286 (35.2)
Associate degree/ vocational school	165 (40.5)	162 (39.9)	327 (40.2)
Bachelor's degree or more	99 (24.3)	101 (24.9)	200 (24.6)
Missing	2	3	5
Health insurance			
Private	193 (53.6)	201 (56.5)	394 (55.0)
Public (Medicare, Medicaid)	137 (38.1)	117 (32.9)	254 (35.5)
Combined (public and private)	18 (5.0)	23 (6.5)	41 (5.7)
None	12 (3.3)	15 (4.2)	27 (3.8)
Missing/refused	49	53	102
Tobacco-related comorbidities			
Mean (SD)	1.6 (1.02)	1.6 (1.05)	1.6 (1.03)
0	62 (15.6)	74 (18.4)	136 (17.0)
1	134 (33.8)	119 (29.6)	253 (31.7)
2	105 (26.4)	113 (28.1)	218 (27.3)
3+	96 (24.2)	96 (23.9)	192 (24.0)
Missing	12	7	19
First-degree relative with lung cancer			
No/does not apply	302 (77.6)	303 (78.9)	605 (78.3)
Yes	87 (22.4)	81 (21.1)	168 (21.7)
Missing	20	25	45
Lung cancer screening-related variables			
Screening result, no. (%)			
Lung-RADS® 1	125 (30.6)	116 (28.4)	241 (29.5)
Lung-RADS® 2	245 (59.9)	250 (61.1)	495 (60.5)
Lung-RADS® 3	23 (5.6)	24 (5.9)	47 (5.7)
Lung-RADS® 4	16 (3.9)	19 (4.6)	35 (4.3)
Follow-up procedures recommended			
No	360 (88.0)	358 (87.5)	718 (87.8)
Yes	49 (12.0)	51 (12.5)	100 (12.2)
Lung cancer screening site			
Anne Arundel Medical Center (E. Maryland)	11 (2.7)	10 (2.4)	21 (2.6)
Baptist Hospital of Miami (S. Florida)	38 (9.3)	38 (9.3)	76 (9.3)
Georgetown Univ. Medical Center (DC)	17 (4.2)	16 (3.9)	33 (4.0)
Hackensack Univ. Medical Center (New Jersey)	45 (11.0)	39 (9.5)	84 (10.3)
Hartford Hospital (Connecticut)	18 (4.4)	19 (4.6)	37 (4.5)
Lahey Hospital and Medical Center (Massachusetts)	179 (43.8)	185 (45.2)	364 (44.5)
MedStar Shah Medical Group (S. Maryland)	15 (3.7)	15 (3.7)	30 (3.7)
UnityPoint Health (W. Illinois)	86 (21.0)	87 (21.3)	173 (21.1)
NCCN group			
Group 1 (55-80 y, 30+ pack-y)	391 (95.6)	392 (95.8)	783 (95.7)
Group 2 (50-80 y, 20+ pack-y + risk factor)	18 (4.4)	17 (4.2)	35 (4.3)
Annual vs baseline LDCT screening			
Annual	233 (57.0)	240 (58.7)	473 (57.8)
Baseline	176 (43.0)	169 (41.3)	345 (42.2)
Cigarette smoking-related characteristics			
Pack-years			
Mean (SD)	48.2 (17.29)	47.8 (17.05)	48.0 (17.16)
20-29	9 (2.2)	8 (2.0)	17 (2.1)
30-39	107 (26.2)	113 (27.6)	220 (26.9)
40-49	155 (37.9)	157 (38.4)	312 (38.1)
50+	138 (33.7)	131 (32.0)	269 (32.9)
Cigarettes per d			
Mean (SD)	17.0 (9.50)	16.9 (8.60)	16.9 (9.06)
Median (range)	15.0 (1–60)	17.0 (1–45)	16.0 (1–60)
Missing	3	1	4
Mean age started smoking cigarettes daily (SD), y	17.0 (4.0)	17.3 (4.2)	17.1 (4.1)
Time to first cigarette, no. (%)			
Within 5 min	120 (29.7)	126 (31.1)	246 (30.4)
6 to 30 min	166 (41.1)	170 (42.0)	336 (41.5)
31 to 60 min	72 (17.8)	54 (13.3)	126 (15.6)
After 60 min	46 (11.1)	55 (13.6)	101 (12.5)
Refused/missing	5	4	9
Fagerstrom test for nicotine dependence[a]			
Mean (SD)	4.4 (2.1)	4.4 (2.1)	4.4 (2.1)
Missing/refused	36	43	79
Lives with current smoker			
No	271 (66.4)	286 (70.3)	557 (68.3)
Yes	137 (33.6)	121 (29.7)	258 (31.7)
Missing	1	2	3

(continued)

(continued)

Table 1. (continued)

Characteristics[a]	Intensive arm No. (%)	Minimal arm No. (%)	Total No. (%)
Readiness to quit			
Not considering quitting (1–5)	131 (32.0)	131 (32.0)	262 (32.0)
Next 6 mo (6)	78 (19.1)	82 (20.0)	160 (19.6)
Next 30 d (7–10)	200 (48.9)	196 (47.9)	396 (48.4)
Motivation to quit (1 = low, 10 = high)			
Mean (SD)	6.7 (2.32)	6.7 (2.25)	6.7 (2.28)
Median	7.0	7.0	7.0
Missing	4	4	8
Confidence to Quit (1 = low, 10 = high)			
Mean (SD)	5.9 (2.51)	5.8 (2.58)	5.8 (2.54)
Median	6.0	6.0	6.0
Missing	12	8	20
24-h quit attempt in past 7 d			
No	366 (89.9)	363 (88.8)	729 (89.3)
Yes	41 (10.1)	46 (11.2)	87 (10.7)
Missing	2	0	2
Evidence-based treatment in past 7 days			
No	364 (89.0)	355 (86.8)	719 (87.9)
Yes	45 (11.0)	54 (13.2)	99 (12.1)
Health and substance use[c,d]			
Health Index Scale (0 = worst/ 100 = best)			
Mean (SD)	69.2 (20.29)	70.7 (18.7)	69.98 (19.53)
Missing/refused	5	4	9
Alcohol frequency (past year)			
Never	115 (28.4)	106 (26.2)	221 (27.3)
Monthly or less	89 (22.0)	104 (25.7)	193 (23.8)
2-4 times per mo	66 (16.3)	68 (16.8)	134 (16.5)
2-3 times per wk	58 (14.3)	61 (15.1)	119 (14.7)
4+ times per wk	77 (19.0)	66 (16.3)	143 (17.7)
Refused/missing	4	4	8
Intervention engagement and satisfaction			
Median days from lung scan to random assignment: median (range)	13 (2–155)	14 (2–79)	13 (2–155)
Median days from random assignment to Call #1 (range)	8 (1–62)	9 (1–81)	9 (1–81)
Counseling session engagement			
Mean (SD)	5.0 (3.04)	1.9 (1.2)	3.5 (2.8)
Median	6.0	3.0	3.0
None/low: intensive (0–5); minimal (0–2)	184 (45.0)	200 (48.9)	384 (46.9)
High: intensive (6–8); minimal (3)	225 (55.0)	209 (51.1)	434 (53.1)
NRT engagement, No. of wk[d]			
Mean (SD)	4.2 (3.06)	1.5 (0.89)	1.4 (1.3)
Median	4	2	1
Intensive: (2–8 wk); minimal: (2 wk)	333 (81.4)	299 (73.1)	632 (77.3)
None: (0 wk)	76 (18.6)	110 (26.9)	186 (22.7)
Participant satisfaction with counseling			
Not at all satisfied	15 (6.8)	20 (12.3)	35 (9.2)
A little satisfied	15 (6.8)	25 (15.4)	40 (10.5)
Somewhat satisfied	61 (27.9)	43 (26.5)	104 (27.3)
Very satisfied	128 (58.4)	74 (45.7)	202 (53.0)
Participant satisfaction with NRT			
Not at all satisfied	2 (0.7)	8 (2.9)	10 (1.8)
A little satisfied	10 (3.4)	15 (5.5)	25 (4.4)
Somewhat satisfied	35 (11.9)	64 (23.4)	99 (17.5)
Very satisfied	247 (84.0)	186 (68.1)	433 (76.4)

[a]The FTND total score was not used in the analyses because 10% were missing 1 or more items that make up the total score. Lung-RADS®= Lung Imaging Reporting and Data System; NCCN = National Comprehensive Cancer Network; LDCT = low-dose computed tomography; FTND = Fagerstrom test for nicotine dependence; NRT = nicotine replacement therapy.
[b]Supplementary Table 5 (available online).
[c]Supplementary Table 6 (available online).
[d]A box of NRT contains 14 patches (2-week supply).

components included discussion of smoking-related goals, nicotine patch use, strategies to address smoking triggers, readiness to quit, and confidence and motivation to quit (Supplementary Methods, available online). These elements used motivational interviewing informed open-ended questions and reflections in a nonjudgmental atmosphere (52). Participants set a quit date only once they were ready. Those who quit focused on relapse prevention during the remaining calls.

To capitalize on the screening result as a potential teachable moment (6,29), the intervention began shortly post random assignment (Table 1). TTSs proactively called participants for all sessions (scheduled at participants' convenience), which were completed within 3 months post random assignment. Participants received educational materials for use during and outside of the calls.

Participants were offered free nicotine replacement therapy (NRT; NicoDerm CQ 21-mg, 14-mg, and 7-mg patches) express-mailed in 2-week batches to interested participants. Participants not interested in patches were encouraged to discuss other FDA-approved pharmacological aids with their provider (Supplementary Methods, available online).

The Intensive Arm

This arm included eight 20-minute phone sessions and 8 weeks of nicotine patches. During the first 3 calls, the TTS initiated a discussion of the screening results and any follow-up procedures to address thoughts that reflected minimization of the need to quit and/or the lung screening process as a potential motivator to stop smoking (Supplementary Methods, available online) (29). To encourage counseling engagement, each 2-week supply of NRT was mailed only after completion of subsequent calls.

The Minimal Arm

This arm included three 20-minute phone sessions and one 2-week supply of nicotine patches designed to emulate what was currently offered by state quitlines (53). TTSs did not initiate a discussion of lung screening results in the minimal arm.

Measures

Table 2 describes the electronic health record data provided by the lung screening sites, measures included in the baseline and

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follow-up telephone assessments, and the process data regarding the intervention delivery (39). We also measured intervention delivery costs to evaluate cost-effectiveness; those data are the subject of another report (34).

Statistical Analyses

All analyses were based on the intent-to-treat principle. The outcomes of those lost to follow-up were imputed as continuing to smoke. All statistical tests were 2-sided. We used descriptive statistics and bivariate analyses (*t* tests and χ^2 tests) to describe the associations of baseline characteristics with the outcomes and potential moderators and to evaluate those lost to follow-up.

We used logistic regression models to compare the study arms on bio-verified (primary) and self-reported abstinence (7-day point prevalence) at 3, 6, and 12 months. We conducted separate logistic regression models to assess the hypothesized moderators (readiness to quit, screening result, engagement with treatment, and nicotine dependence) at 3 months. All analyses controlled for baseline demographic and clinical characteristics that were statistically significantly associated with the outcome. Finally, we conducted sensitivity analyses to determine if the lung screening site with the largest number of study participants had an undue influence on the results.

As a result of COVID-19, screening sites were closed for several months and we were unable to randomly assign the planned number (1,200, 600 per arm) despite an additional 8 months of accrual beyond the intended end date (Supplementary Table 1, available online). At a statistical significance level of .05, with 403 per arm (after accounting for attrition), we had at least 80% power to detect differences in bio-verified abstinence rates for planned comparisons at 3, 6, and 12 months, ranging from 4% to 8% (when the minimal arm abstinence rate ranged from 1% to 15%). All analyses were conducted using SAS version 9.4 (54).

Results

Descriptive Characteristics

On average, participants were 63.6 years old, had 48 pack-years, and currently smoked 16.9 cigarettes per day (SD = 9.06; Table 1). Most participants were White (89%), smoked within 30 minutes of waking (71.9%), and were not ready to stop smoking in 30 days or less (51.6%). Only 2.1% had 20-29 pack years and 0.98% were 50-54 years old; thus, the sample closely matched those eligible for screening under the 2013 United States Preventive Services Task Force (USPSTF) guidelines.

Counseling engagement was similar by study arm, with 55% completing 6-8 of the intensive arm sessions and 51.1% completing all 3 sessions in the minimal arm. NRT use was proportional to study arm: 81.4% and 73.1% in the intensive arm vs minimal arm, respectively. Satisfaction with the intervention was high (Table 1).

Figure 1 presents the reach and retention rates (see also Supplementary Table 2, available online). In univariate analyses, we found that compared with White participants, African American participants were statistically significantly more likely to enroll and to be retained in the trial.

Cessation Outcomes

At 3 months, the intensive arm had statistically significantly higher quit rates compared with the minimal arm for self-reported (14.3% vs 7.9%, respectively; odds ratio [OR] = 2.00, 95% confidence interval [CI] = 1.26 to 3.18) and bio-verified rates (9.1% vs 3.9%, respectively; OR = 2.70, 95% CI = 1.44 to 5.08). At 6 and 12 months, the study arms no longer differed statistically significantly (Table 3). Exploratory analyses suggested that repeated point-prevalence abstinence (55) was higher in the intensive (vs the minimal) arm when comparing assessment points (Supplementary Figure 1, available online).

Regarding hypothesized moderators (Table 4), compared with the minimal arm, the intensive arm was more effective at 3 months among those with normal screening results (OR = 2.58, 95% CI = 1.32 to 5.05), greater nicotine dependence (OR = 3.47, 95% CI = 1.55 to 7.76), high engagement in counseling (OR = 3.03, 95% CI = 1.50 to 6.14), and receipt of NRT (OR = 2.81, 95% CI = 1.39 to 5.68). Because of small cell sizes in the minimal arm, there was suggestive evidence that readiness to quit moderated the intervention (OR = 10.54, 95% CI = 2.42 to 46.01). The site contributing the largest sample had similar bio-verified quit rates as the other sites combined (Table 4). Quit rates among those who completed at least 1 counseling session and those who completed the follow-up assessments were slightly higher compared with the entire sample (Supplementary Tables 3 and 4, available online).

Discussion

This randomized clinical trial provides evidence to support the value of integrating smoking cessation treatment with lung cancer screening programs. The results demonstrated that intensive telephone counseling and NRT statistically significantly increased short-term quit rates compared with minimal telephone counseling and NRT. The intensive treatment was especially effective among those with higher nicotine dependence, normal lung screening results, and individuals who were not ready to quit.

This trial extends the evidence for the efficacy of the combined cessation treatments of telephone counseling and NRT (23) to older adults in the lung cancer screening setting. Proactive telephone counseling is compatible with the lung screening setting, because both telephone counseling and nicotine replacement can reach people quickly, within or outside the radiology clinic, and during the time when individuals may be most receptive to engaging in treatment (28-33). Although the effectiveness of phone counseling has been demonstrated with similar populations, including older adults (15-18), those not ready to quit (19-22), those not seeking treatment (21,23), and those who are ready to quit (23-27), we are aware of only 1 published phone-based trial conducted in any setting that included all these important trial components (56). The authors reported 14% (intervention arm) vs 12.6% (control arm) self-reported point-prevalence abstinence at 12 months (56), comparable with the LSTH self-reported 12-month rates (12.1% and 10.0%, respectively). The LSTH trial adds to this literature by using broad inclusion criteria and a standard cessation intervention, increasing the likelihood of greater reach and implementation in other lung screening settings.

Engagement with telephone counseling and NRT use was robust, suggesting that participants considered these treatment modalities to be beneficial. Further, those who were highly engaged with either intervention had statistically significantly higher abstinence rates than those who were less engaged. Despite the promising findings at the 3-month assessment, there was no statistically significant difference between arms at 6 or 12 months. Additional research is needed to assess potential methods of maintaining short-term effects, such as the use of booster

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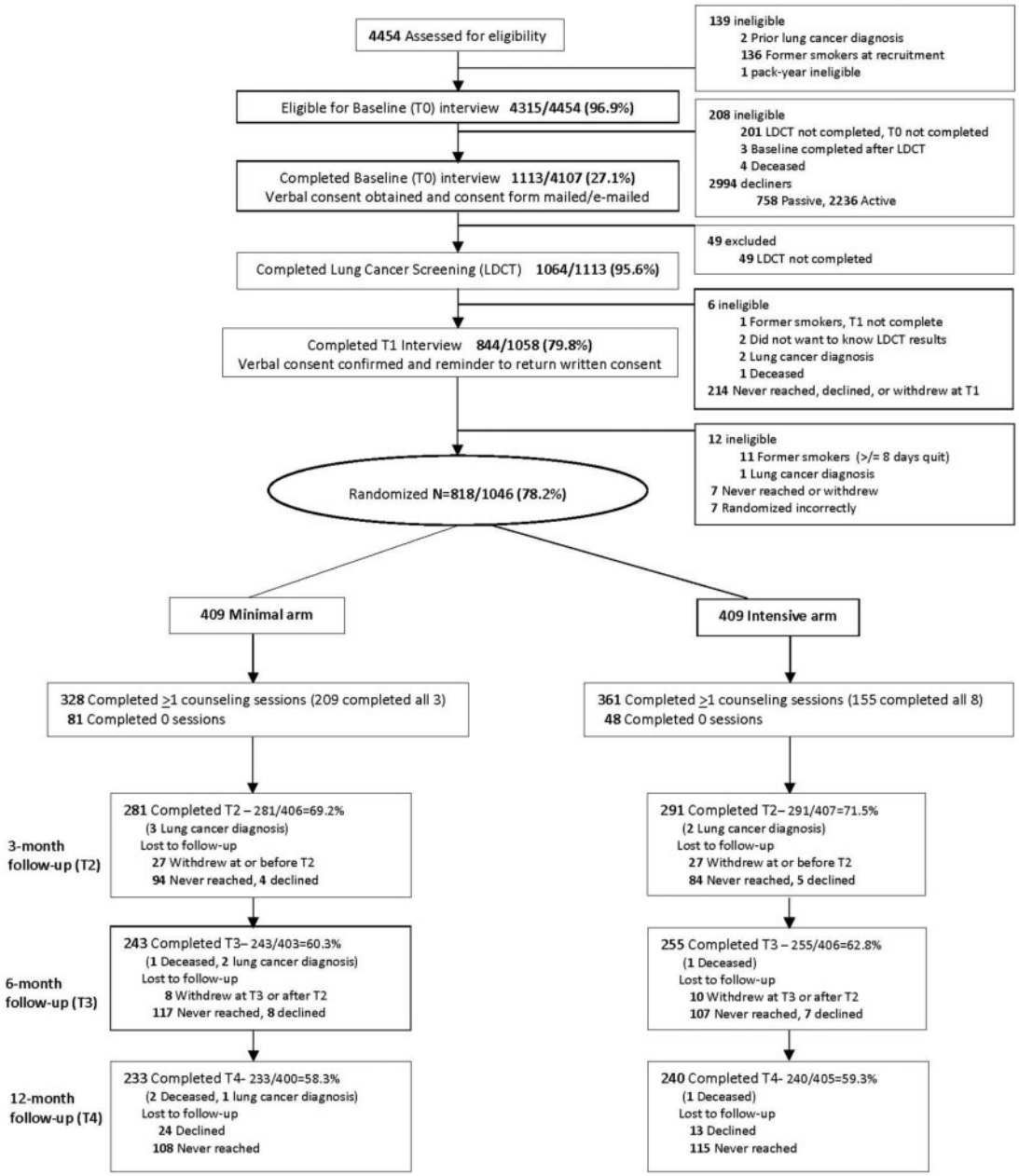

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram. LDCT = Low-dose computed tomography.

sessions, particularly for those less motivated to quit (26), the addition of video-based phone interventions (57), or longer-term combined NRT or other pharmacotherapies (58). Further, a stepped care approach (ie, if NRT does not result in quitting) may be appropriate given the greater expense and expertise required for prescription medications. These issues may also be addressed by ongoing Smoking Cessation at Lung Examination trials (9).

Further, although the intensive arm was statistically significantly more efficacious than the minimal arm at 3 months, the bio-verified quit rates were, as expected, somewhat lower than self-reported rates (11). The low quit rates may be partially explained by the fact that this trial was designed to reach a broader and more heterogeneous sample than is recruited in most smoking cessation trials (eg, trials recruiting highly motivated volunteers) (26). Thus, the intensive intervention was not equally effective in all participants, such as those with lower nicotine dependence, normal screening results, less readiness to quit, and undergoing their baseline scan. Improving the tailoring and targeting of interventions to better assist these groups is particularly important because they represent a large proportion of individuals undergoing lung cancer screening (5).

Several caveats should be considered in evaluating our trial results. First, despite the broad inclusion criteria, such as those not currently ready to quit, a lack of diversity remained among participants at disproportionate risk for lung cancer, such as lower socioeconomic groups. This limitation is largely a reflection of the current population undergoing lung screening, and efforts are needed to reach more diverse patients (59,60). Importantly,

Table 2. Summary of measures and assessment points

Measuresa	Screening site and EHR	T0, T1 (baseline)	T2, T3, T4 (3, 6, 12 mo)
Demographic and clinical information			
Age, sex, language, date of birth, insurance coverage (64,65)	Yes	No	No
Race and ethnicity (another race include Asian, American Indian, Alaska Native, Native Hawaiian) (64,65)	Yes	Yes	No
Marital status and education level (64,65)	No	Yes	No
Tobacco-related comorbid illnesses (COPD, stroke, heart attack, high blood pressure, diabetes, asthma, chronic bronchitis) (1,64,65)	Yes	Yes	No
Family history of lung cancer (first-degree relative) (1,64,65)	No	Yes	No
Lung cancer screening			
CT scan results (EHR) (41,64,65)	Yes	No	No
Recommended follow-up procedures (lung biopsy, sputum cytology, bronchoscopy, follow-up CT scan in 3, 6, or 12 mo, follow-up PET scan, appointment with pulmonologist or PCP) (64,65)	Yes	Yes	Yes
Final diagnosis: lung cancer, other cancer, nondiagnostic, alternate benign diagnosis (64,65)	Yes	No	No
Smoking and cessation history			
Cigarettes per d (64-66)	No	Yes	Yes
Other tobacco/nicotine use (pipes, cigars, smokeless, e-cigarettes) (64-66)	No	Yes	Yes
Fagerstrom test for nicotine dependence (64,65,67)	No	Yes	Yes
Pack years (no. of years smoked × packs per d) (64,65)	Yes	No	No
Smoking/tobacco outcomes			
Readiness to quitb, (64,65,68)	No	Yes	Yes
Confidence and motivation to quit (10-point scale, 0 = least confident or motivated, 10 = most confident or motivated) (64,65,69)	No	Yes	Yes
24-h quit attempts within past 7 d (64,65)	No	Yes	Yes
Evidence-based treatment in past 7 d (pharmacotherapy, counseling, or electronic interventions)	No	Yes	Yes
Self-reported 7-d abstinence (42,55,64,65,70)	No	Yes	Yes
Biochemical verification: NicAlert and NicoTest saliva test, expired CO (in person) and iCO (remote test) (42,55,64,65,70)	No	No	Yes
Health and substance use			
Alcohol use frequency (never, monthly or less, 2-4 times per mo, 2-3 times per wk, 4+ times per wk) (71)	No	Yes	No
Health Index Scale (0 = worst, 100 = best health) (64,65,72)	No	Yes	Yes
Treatment engagement and satisfaction			
Engagement (no. of counseling sessions completed and amount of NRT requested (box contains 2-week supply of patches)	No	No	Yes
Satisfaction with telephone counseling and nicotine patches (not at all satisfied, a little satisfied, somewhat satisfied, very satisfied) (64,65)	No	No	Yes

[a]CO = carbon monoxide; COPD = chronic obstructive pulmonary disease; CT = computed tomography; EHR = electronic health record; NRT = nicotine replacement therapy; PCP = primary care provider; PET = positron emission tomography.
[b]1-10 scale; 10 = already quit smoking, 9 = made changes in smoking but need to keep working , 8 = begun to make changes in smoking, 7 = plan to quit in the next 30 d, 6 = plan to quit in next 6 mo, 5 = often think about quitting but have no plans yet, 4 = sometimes think about quitting and have no plans yet, 3 = rarely think about quitting and have no plans to quit, 2 = do not think about quitting, 1 = decided to continue smoking.

the percentage of eligible African American participants who enrolled and who were retained was greater than among African Americans who declined or dropped out, respectively, indicating the potential for similar interventions to have an impact among African Americans (Supplementary Table 2, available online). The identification and referral of lung screening–eligible individuals must become more widely integrated in primary care to increase participant diversity along with opt-out methods for cessation treatment that are known to improve reach to historically underserved patients (61,62). Further limitations include lower than anticipated study enrollment, which was worsened by COVID-19. As a result, the moderation analyses should be interpreted with caution because of limited cell sizes. Retention rates at follow-up and bio-verification completion rates were also lower than expected.

This study has several strengths, including the large, geographically diverse sample and the wide inclusion criteria that provide generalizability to the broad population of patients eligible for lung screening who smoke. We did not exclude participants based on their motivational readiness to quit, behavioral health diagnoses, or concurrent smoking cessation treatment. Second, the study enrollment rate was based on the denominator that included all trial-eligible patients who underwent lung screening at each site during the recruitment period. This population-based approach is important when considering implementation on a broader scale. Third, the necessity of bio-verification of smoking status was confirmed for populations in which follow-up may be difficult and when high-risk status may impact self-report (42). Other strengths include the

Table 3. Biochemically verified and self-reported 7-day point prevalence abstinence rates

Smoking abstinence among all randomly assigned participants (intention-to-treat analysis)	Intensive arm[a] No. (%)	Minimal arm[a] No. (%)	OR (95% CI)
Biochemically verified[b,c]			
3 mo	37 (9.1)	16 (3.9)	2.7 (1.44 to 5.08)
6 mo	29 (7.1)	24 (5.95)	1.2 (0.68 to 2.11)
12 mo	34 (8.4)	25 (6.3)	1.4 (0.82 to 2.42)
Self-reported[d]			
3 mo	58 (14.3)	32 (7.9)	2.0 (1.26 to 3.18)
6 mo	42 (10.3)	38 (9.4)	1.1 (0.70 to 1.76)
12 mo	49 (12.1)	40 (10.0)	1.3 (0.82 to 2.00)

[a]The total numbers for each arm at each assessment differ because of the exclusion of patients diagnosed with lung cancer or deceased before the assessment (intensive arm: n = 407, 3 months; n = 406, 6 months; n = 405, 12 months; minimal arm: n = 406, 3 months; n = 403, 6 months; n = 400, 12 months). CI = confidence interval; OR = odds ratio.
[b]Methods of verification: NicAlert, NicoTest, expired carbon monoxide (CO) conducted in person, expired CO using iCO remote device.
[c]Covariates included for biochemically verified abstinence rates at: 3 months = recommended follow-up lung biopsy and computed tomography (CT) scan in 3 months, number of tobacco-related comorbid conditions; 6 months = recommended follow-up CT scan in 3 months and number of tobacco-related comorbid conditions; 12 months = race.
[d]Covariates included for self-reported abstinence rates at: 3 months = number of tobacco-related comorbid conditions and the age when first started smoking cigarettes every day; 6 months = no covariates; 12 months = race and number of cigarettes per day at T1.

rigorous randomized design, bio-verification, and TTSs' excellent protocol adherence.

Overall, this trial provides important evidence about an efficacious, scalable approach to deliver smoking cessation to older individuals undergoing lung cancer screening, including those who may not be ready to quit or who may not be seeking cessation treatment (16-21,25,26). Telephone counseling with nicotine replacement addresses the behavioral and dependence aspects of cessation treatment at a time when individuals may be amenable to receiving support for quitting. Our approach considers feasibility, because telephone counseling is provided outside of busy lung cancer screening settings that typically have limited staffing. Remote interventions are critical because Centers for Medicare & Medicaid Services (CMS) does not require screening practices to provide cessation counseling within the radiology clinic (8). Remote telephone counseling and mailed nicotine replacement is an efficient modality for intervention implementation. Telehealth approaches can provide broad reach and are likely to remain an important feature of cessation interventions going forward (57).

Because the intensive arm was statistically significantly more effective than the minimal arm only in the short term, it will be important to address relapse prevention in the intensive arm and to determine if the added costs are offset by the higher quit rates and long-term effects on mortality. In a separate article, we report the costs associated with intervention delivery and a cost-effectiveness analysis to guide future implementation and maintenance of cessation programs in the lung screening setting (34). Even with modest quit rates, the long-term population impact of effective cessation interventions delivered with lung cancer screening can be substantial (35,63).

Table 4. Moderation effects at 3 months for biochemically verified 7-day point prevalence abstinence[a]

Moderators	Intensive arm (n = 407) No. (%)	Minimal arm (n = 406) No. (%)	Adjusted OR (95% CI)
Lung screening result			
Lung-RADS® 1-2	32 (8.6)	14 (3.8)	2.58 (1.32 to 5.03)
Lung-RADS® 3-4	5 (13.5)	2 (5.0)	3.85 (0.56 to 26.45)
Readiness to quit (T1)			
Next 30 d	18 (9.1)	14 (7.2)	1.44 (0.67 to 3.10)
Next 6 mo/not considering quitting	19 (9.1)	2 (0.9)	10.54 (2.42 to 46.01)
Time to first cigarette (T1)			
≤30 min	26 (9.1)	9 (3.1)	3.47 (1.55 to 7.76)
>30 min	10 (8.6)	7 (6.4)	1.50 (0.52 to 4.31)
Engagement with phone counseling sessions			
None/low[b]	3 (1.6)	3 (1.5)	1.15 (0.23 to 5.83)
High[c]	34 (15.2)	13 (6.3)	3.03 (1.50 to 6.14)
Engagement with NRT			
None (0 wk)	4 (5.3)	3 (2.7)	1.82 (0.39 to 8.56)
Any NRT[d]	33 (10.0)	13 (4.4)	2.81 (1.39 to 5.68)
Site			
Largest site (Lahey)	16 (9.0)	7 (3.8)	3.12 (1.19 to 8.24)
Other 7 sites combined	21 (9.2)	9 (4.1)	2.41 (1.05 to 5.54)
Baseline vs annual scan			
Baseline	13 (7.4)	7 (4.1)	2.01 (0.76 to 5.36)
Annual	24 (10.3)	9 (3.8)	3.31 (1.44 to 7.62)

[a]The logistic regression analyses adjusted for recommended follow-up procedures for lung biopsy, recommended CT scan at 3 months, and number of tobacco-related comorbid conditions. CI = confidence interval; CT = computed tomography; Lung-RADS® = Lung Imaging Reporting and Data System; NRT = nicotine replacement therapy; OR = odds ratio; T1 = postscreening assessment.
[b]Intensive: 0-5 sessions; Minimal: 0-2 sessions.
[c]Intensive: 6-8 sessions; Minimal: 3 sessions.
[d]Intensive: 2-8 wk; Minimal: 2 wk.

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Funding

This study was supported by the National Cancer Institute at the National Institutes of Health (grant numbers R01CA207228 to KT and R01CA207228-S1 to KT).

Notes

Role of the funder: The funder had no involvement in the design of the study, analysis of the data, the writing of the manuscript, and the decision to submit the manuscript for publication.

Disclosures: The authors have no conflicts of interest to declare. JM, a *JNCI* Associate Editor and coauthor on this article, was not involved in the editorial review or decision to publish this manuscript.

Author contributions: Conceptualization—KLT, CS, RN, DA. Data curation—RMW, LS, TL. Formal analysis—GL, TL, RMW, LS. Funding acquisition- KLT, GL, JM, RM, EDA. Investigation—LS TL. Methodology—KLT, CS, RN, DA. Project administration—KLT, RMW, LS. Supervision—KLT, KMD, RMW, LS. Validation—

RMW, LS. Visualization—LS, RMW. Writing—original draft: KLT, RMW, LS, GL, TL. Writing—review & editing: KLT, RMW, TL, GL, LS, KMD, TL, CS, RN, DA, JM, JJ, RM, JJ, PC, EDA.

Acknowledgements: The authors gratefully acknowledge the contributions of the Lung Screening, Tobacco, and Health (LSTH) trial collaborators (alphabetical order): Ryan Anderson, BS, Shacoria Anderson, MPH, Juan Batlle, MD, Chavalia J. Breece, NP, Claudia Campos, MA, Lisa Charles, BS, Marisa Cordon, MPH, Danielle E. Deros, MS, Ellen Dornelas, PhD, Daisy Dunlap, BS, Joanne Ebner, BSN, OCN, NCTTP, Ellie Eyestone, MPS, Shelby Fallon. MPH, Jennifer Frey, PhD, Julia Friberg, BS, Lucia Galleno, Ph.D., Maria M. Geronimo, RN, Darilyn Gould, BA, Charlotte Hagerman, PhD, Harry Harper, MD, Melissa Harris, Judith Howell, RN, Sarah Hutchison, Jen-Yuan Christine Kao, Emily Kim, BS, Andrea Borondy-Kitts, MS, MPH, Yamile Leon, MSN, RN, Andrea McKee, MD, Brady McKee, MD, Vicky Parikh, MD, Margaret Pless, MS, Michael Ramsaier, BA, Shawn Regis, PhD, Nicolas Rojas, BA, Diana Ruiz, RN, Andrew Salner, MD, Jennifer Stephens, MS, and Felice Yang, MPH.

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author. Please see https://doi.org/10.7910/DVN/0O31JY for a description of the available data and to request access.

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