Stress, depression, sleep problems and unmet social needs: Baseline characteristics of low-income smokers in a randomized cessation trial

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ABSTRACT

Background: Low-income Americans smoke cigarettes at higher rates and quit less than other groups.
Methods: To increase their engagement in and success using evidence-based cessation methods, we tested two interventions using a 2x2 randomized factorial design: (1) telephone navigation to reduce financial strain and address social needs such as food, rent and utility payment; and (2) a specialized tobacco quitline designed for low-income smokers. From June 2017 to November 2020, we enrolled 1,944 low-income smokers in Missouri, USA, recruited through the Missouri 2-1-1 helpline, into the trial. This paper describes recruitment, key characteristics and life circumstances of this high-risk population.
Results: After eligibility screening, 1,944 participants completed baseline and were randomized. Participants were racially diverse (58% African American), poor (51% < $10,000 annual pre-tax household income) and many reported less than high school education (30%). They reported a mean of 2.5 unmet social needs, especially childcare and paying bills, had high rates of stress, depressive symptoms and sleep problems, and most were in fair or poor health. There were few differences between these variables, and no differences between tobacco use and cessation variables, across the four study groups and between participants recruited pre and during the COVID-19 pandemic.
Conclusions: Trial recruitment through the 2-1-1 helpline is feasible for reaching a population of low-income smokers. Low-income smokers face myriad daily challenges beyond quitting smoking. Cessation interventions need to account for and address these life circumstances.
Trial registration: Clinicaltrials.gov NCT03194958.

1. Introduction

Compared to other Americans, those with lower incomes are more likely to smoke and less likely to quit [1,2], with greater nicotine dependence and lower self-efficacy and readiness for quitting [3–9]. Smoking-related health problems disproportionately affect people who are poor [10], and smoking deepens poverty in low-income households by increasing financial stress and food insecurity and lowering standard of living [11–13].

Free tobacco quitlines are available in every state to help low-income smokers quit [14]. Systematic evidence reviews show telephone counseling such as that provided by quitlines is effective in helping people quit smoking [15–17], although little of that evidence is derived from studies among low-income smokers [18,19], who are less likely to know about and use evidence-based cessation methods [8].

One explanation for low awareness and use of evidence-based cessation methods is people living in poverty often have such overwhelming needs in other areas of life that disease prevention is secondary to addressing those priorities [20,21]. Finding a job, paying rent, and feeding one's family may supersede any interest in quitting smoking. This is not just a matter of prioritization, but also because experiencing scarcity – such as having unmet social needs – can diminish one's

cognitive capacity to focus on other goals [22], sometimes leading to shorter term thinking, leading to decisions and actions focused on immediate need, rather than long-term goals [22–26].

It is also possible standard smoking cessation services do not adequately address unique challenges faced by low-income smokers, including effects of social networks and other environmental cues. Although smoking prevalence is declining and smoking is prohibited in many public spaces in the U.S., it remains normative and acceptable in social networks of low-income smokers [27,28], where it is not uncommon for half or more of one's friends, family members and co-workers to smoke [29,30]. This can increase exposure to cues that prompt smoking while reducing social pressure to quit [31]. Low-income smokers also tend to have less control over exposures to tobacco at work [32] and are more likely to encounter tobacco and tobacco promotion in retail outlets near their homes [33]. Finally, many standard tactics used in cessation programs may not be feasible for low-income smokers. For example, seemingly simple advice to buy hard candy or straws to chew on to stave off smoking cravings may not be wise or even possible for those with severe resource constraints.

To address these challenges, we developed two interventions to help low-income smokers quit [34]. The first aims to reduce social needs and financial strain through social needs navigation, while the second provides specialized quitline services designed for low-income smokers. The specialized quitline and social needs navigation interventions were informed by a conceptual model described in prior reports [35–37]. According to the model, having unmet social needs contributes to stress, depression, problems with sleep, mental and physical health, all of which affect cognitive processing and executive function, and interfere with one's ability and motivation to change risky health behaviors, including smoking. Accordingly, we propose that health interventions for people who experience unmet social needs will be more effective if they account for, and help resolve social needs, as well as addressing unique contextual challenges to behavior change.

This manuscript examines baseline data from participants in a randomized trial evaluating the relative and combined effectiveness of the two interventions to increase cessation. Participants – low-income adult daily smokers who were interested in quitting – were recruited through the Missouri 2-1-1 helpline, an information and referral service that receives over 250,000 requests for social needs assistance by phone each year. We describe prevalence of unmet social needs in a statewide sample, and test for differences in participant characteristics across four randomized study groups to confirm group equivalence. Because the study period included a potential historical confound in COVID-19, we also examine sample differences before and during the pandemic. Longitudinal follow-up in the trial is ongoing at time of writing.

2. Study objectives

This paper addresses the following questions: (1) To what extent are potential smoking cessation barriers such as social needs (housing, food, safety, utilities, transportation, childcare), stress, depressive symptoms, sleep problems and co-morbid chronic conditions present in a statewide sample of low-income smokers interested in quitting? (2) What patterns of smoking and quitting behaviors are reported in the sample, including use of evidence-based cessation approaches, quit aids such as nicotine replacement, and different forms of cessation support received from others? (3) Are both sets of factors distributed equally at baseline among the four groups in the randomized trial? (4) Do these factors differ among low-income smokers recruited before and during the COVID-19 pandemic?

3. Materials and methods

This randomized controlled trial (RCT) uses a 2 x 2 factorial design to compare the independent and combined effects of two interventions – a specialized tobacco quitline (vs. standard quitline services) and social

needs navigation (vs. none) – to help low-income smokers quit. Details of the study design and methods were previously published in the study protocol [34]. The group receiving standard quitline services without social needs navigation is considered the usual care control group. The primary study outcome for the RCT is 7-day point prevalence abstinence measured at 6-month follow-up. Some participants participated in a biochemical validation sub-study by completing either a breath test that measured CO or a urine test that measured cotinine to confirm self-reported abstinence [38]. Study outcomes will be reported in a future paper when participants have completed follow-up. All study materials and methods were approved by the Human Research Protection Office at Washington University in St. Louis.

3.1. Setting

Participants were recruited from Missouri 2-1-1, a statewide telephone helpline used primarily by low-income individuals seeking help with social needs such as food, rent and utility payments [39]. Calls to 2-1-1 are answered by live operators who listen to caller concerns and provide them with referrals to local agencies that can help address their needs. 2-1-1 is a federally-designated 3-digit number that serves all 50 states and receives 12–13 million requests per year nationally [40], including over 250,000 in Missouri [41]. Standard and specialized quitline services for the study were provided by the Missouri Tobacco Quitline through its contract with Optum, the largest provider of quitline services in the U.S.

3.2. Participants

After receiving standard service from 2-1-1, a random sample of callers was screened for initial study eligibility by the 2-1-1 operator. Callers were asked about smoking status, readiness to quit, and willingness to be contacted by the university research team about participating in a quit smoking study. Adult callers (18 years and older) who reported daily tobacco smoking, readiness to quit smoking in the next 30 days, and willingness to be contacted were then called by the research team, screened for additional eligibility criteria (people were ineligible if they were pregnant or breastfeeding, not comfortable speaking English, had private insurance that included a Quitline benefit, were currently enrolled in a Quitline, or were not planning to remain a Missouri resident for the next 30 days). From June 1, 2017 to November 15, 2020, 1,944 participants provided informed consent, were enrolled in the study, and completed a baseline telephone interview.

3.3. Recruitment and randomization

Randomization to study groups occurred after participants completed the baseline interview. In blocks of 500, a list of computer-generated numbers was used to assign participants in equal proportions to four groups: (1) standard quitline only (control); (2) specialized quitline only; (3) standard quitline + social needs navigation; and (4) specialized quitline + social needs navigation.

3.4. Interventions

A detailed description of the study interventions is available in the study protocol paper [34]. The *standard quitline* is Optum's *Quit For Life®* tobacco cessation program, which includes a series of four 10–15 min telephone sessions with trained quit coaches, unlimited calls initiated by the participant to the quitline, access to internet- and text-based programs, a printed Quit Guide, and up to two weeks of nicotine patch or gum, where appropriate.

The *specialized quitline* intervention adapted *Quit for Life* to address low-income smokers' financial strain, smoking exposures and norms, and cessation literacy. Specialized quit coaches were trained to understand the lives of low-income smokers, unique aspects of their smoking

behavior, distinctive ways they may process cessation information and communicate with a coach, and attributes of trusted information sources. Counseling sessions can last longer to provide more time for rapport building, coaches make more attempts to reach participants for each call, and if phone numbers seem to be disconnected (sometimes due to running out of minutes on a prepaid mobile phone) attempts to reach them continue to be made. A targeted, plain language Quit Guide is also provided for participants in this arm.

The *social needs navigation* intervention is designed to help participants address needs such as food, housing, utilities, employment, or childcare. This phone-based intervention is delivered by trained social services professionals and available for three months post-baseline, with interaction frequency determined by participant need and willingness to be assisted. Navigators help participants identify and prioritize their needs, jointly generate solutions, and put in place specific steps to reach solutions. The steps include finding available services, determining participant eligibility for services, advocating for the participant, arranging transportation, and following up to evaluate progress. Navigators provided no cessation advice or assistance; if participants raised the subject of quitting smoking, navigators referred them to the Quitline.

3.5. Measures

Baseline interviews assessed key variables from our conceptual model: social needs, perceived stress, depressive symptoms, sleep problems, chronic diseases and mental health conditions, self-rated health, smoking and cessation behaviors, nicotine dependence and demographics.

Social needs were assessed using 10 items based on Segal's Personal Empowerment Scale [42], studies by Blazer and colleagues [43], and used in prior trials and large studies [44]. Items assessed the likelihood that, in the next month, the respondent would: (1) have a place to stay; (2) be able to pay their current electric, gas or water bill in full; (3) have enough food to feed themselves and others in their home; (4) have reliable transportation to get to appointments, meetings, work, and getting the things they need for daily living; (5) have enough money for necessities like food, shelter and clothing; (6) have enough money to deal with unexpected expenses; (7) be threatened physically by another person; and (8) have trouble finding or paying for childcare. The childcare item was asked only of parents and guardians of children ≤18 years that needed or used childcare. Response options were "very likely/likely/unlikely/very unlikely." Also assessed were: (9) the amount of space in the home (too much/about the right amount/not enough); and (10) neighborhood safety (very unsafe/unsafe/safe/very safe).

In analyses, we report the proportion of participants for whom each social need is unmet. Responses of "very unlikely" and "unlikely" for items 1–6 were classified as unmet needs, as were responses of "very likely" and "likely" for items 7 and 8. Responses of "not enough space" for item 9, and "very unsafe" or "unsafe" for item 10 were classified as unmet needs. We also report the sum of all unmet social needs experienced by each participant (range 0–10).

Perceived stress was measured using Cohen's 4-item Perceived Stress Scale [45]; *depressive symptoms* were assessed using the PHQ-2 depression screener [46]; and *sleep problems* were assessed using two items adapted from the Pittsburgh Sleep Quality Index [47] measuring overall sleep quality in the past month (4-point scale, very bad to very good) and frequency of trouble sleeping (never, <1/week, 1–2 times/week, 3 or more times/week). Sum scores range from 0 to 16 on the Perceived Stress Scale, and 0–6 for both PHQ-2 and sleep quality. Higher scores indicate greater perceived stress, greater severity of depression symptoms and lower sleep quality.

Chronic disease and *mental health history* were assessed by asking if participants had ever been told by a doctor that they had each of 13 conditions (yes/no): asthma, cancer, COPD, heart disease, type I diabetes, and type II diabetes (chronic diseases); and ADHD, bipolar disorder, depression, drug or alcohol use disorder, generalized anxiety disorder, PTSD and schizophrenia (mental health). The number of conditions reported by each participant also was summed within categories. Single items assessed *self-rated health* (excellent/very good/good/fair/poor), type of insurance (Medicaid/Medicare/Dual eligible/Uninsured/Gateway to Better Health/Veteran's Affairs), and whether participants have one person they think of as a regular doctor (yes/no).

Smoking-related measures assessed participants' *age at smoking initiation* (in years), number of *cigarettes smoked* per *day*, and *other tobacco products* they have used in the past month (little cigar or cigarillo, cigar, pipe, spit or smokeless tobacco, e-cigarette, other tobacco products). *Nicotine dependence* was measured using the Heaviness of Smoking Index [48], with scores ranging from 0 (low) to 6 (high dependence). We also assessed whether they lived or worked with other smokers (both yes/no). Only those who reported current employment were asked the latter question. A single item assessed whether smoking was allowed inside their home (yes/no).

Cessation-related measures included whether they had *ever tried to quit smoking* (yes/no) and, if so, how long it had been since their *most recent quit attempt*. Those who reported a past quit attempt were asked if they had ever used any of seven *quit aids*: nicotine patches, gum, lozenges, nasal spray, inhalers, or prescription medicines like "Chantix" or "Zyban, bupropion or Wellbutrin" (all yes/no). Participants also were asked if they had ever *called a telephone helpline*, *joined a group*, *read printed materials*, or *searched online* for information about or help quitting smoking (all yes/no).

Demographic items assessed each participant's age, gender, race/ethnicity, level of education, annual pre-tax household income, whether they had children ages 18 or younger living in the home, and ZIP code, which we classified in rural/non-rural as defined by the Federal Office of Rural Health Policy [49].

3.6. Data management

Data on eligibility screening questions administered by 2-1-1 operators and participant contact information were transferred to the research team daily (M-F). Data from participant responses to baseline telephone interviews were captured in a FileMaker Pro database program custom-built for the study and used by interviewers on the research team.

3.7. Statistical analysis

Descriptive statistics are reported for all variables for the full sample and by study group. Differences by study group are evaluated using chi-square tests for categorical variables and ANOVA for continuous variables. Differences between participants enrolled pre-COVID, from June 1, 2017 to March 11, 2020, and during COVID, from March 12, 2020 to November 15, 2020, were evaluated using chi-square tests for categorical variables and independent samples t-tests for continuous variables.

4. Results

Between June 1, 2017 and November 12, 2020, a random sample of 80,869 callers were asked by 2-1-1 operators if they would be willing to answer a few questions. Nearly all (93%; n = 74,881) agreed. Of those, 13,527 reported that they smoke cigarettes every day (18%) and 8,636 reported that they smoke cigarettes some days (12%). Among the daily smokers, 48% reported that they were interested in quitting in the next 30 days (n = 6,445), and of those, 5,225 (81%) gave permission to 2-1-1 to share their contact information with the research team.

The CONSORT diagram in Fig. 1 shows the enrollment flow of potential participants through randomization and baseline assessment. Although research staff made up to 13 call attempts to contact potential participants, many (27%) were never reached. Among those who were reached and screened (n = 3,587), over half agreed to participate (54%). A total of 1,944 participants provided informed consent, completed a
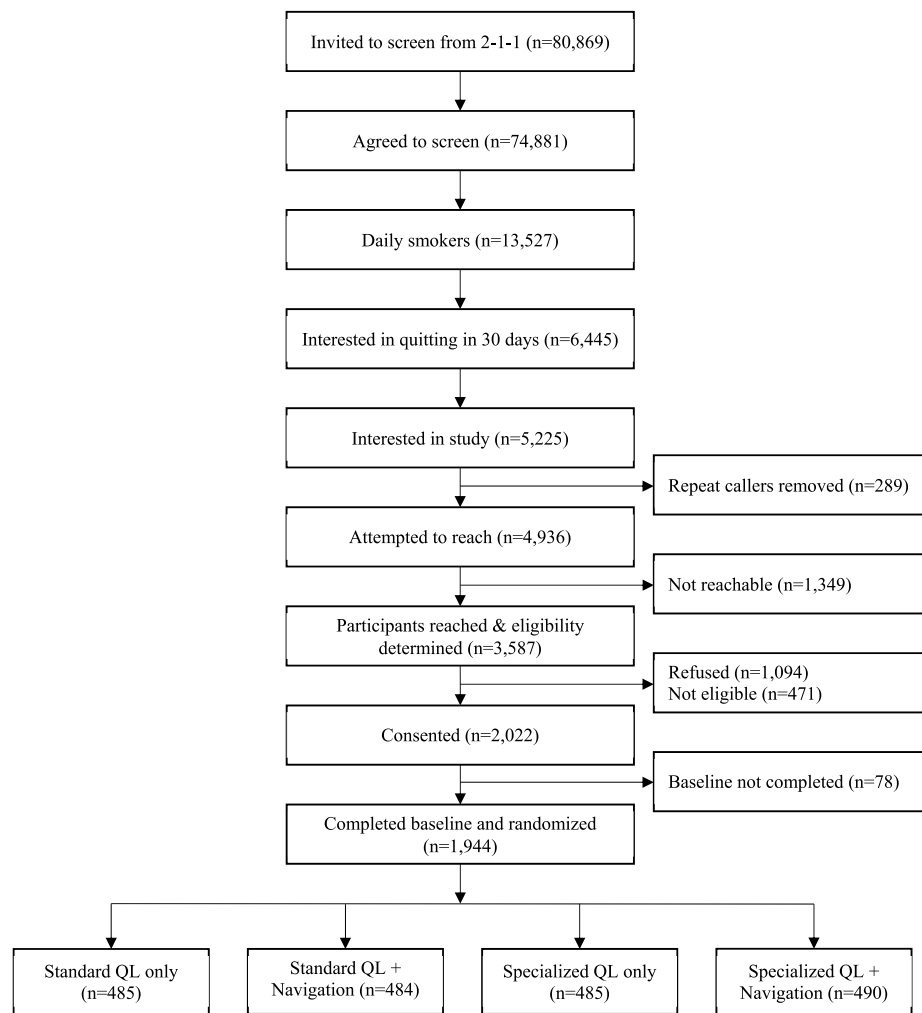
Fig. 1. CONSORT diagram of study recruitment, enrollment, and randomization to quitline (QL) and social needs navigation interventions.

baseline assessment, and were randomized to one of the four study groups.

Table 1 shows demographic characteristics and smoking and cessation histories of the sample. Participants' mean age was 48.4 years, most were women (72%), and 58% were African American. Half (51%) reported pre-tax annual household income below $10,000 and 30% reported completing less than high school education. Demographic characteristics did not vary by study groups (Table 1).

Participants' mean age at smoking initiation was 15.7 years. On average, participants smoked 15.6 cigarettes per day, and commonly reported living with at least one other smoker (40%). Among those who were employed outside the home (n = 501), 84% worked with other smokers. Three in four (74%) allowed smoking inside their home. Nearly all (88%) had tried quitting smoking at least once, and of those, nearly half (48%) had tried to quit within the last 12 months. Of those who had ever made a quit attempt, 71% reported having tried at least one pharmacological quit aid; past use of any NRT (67%) was much more common than past use of prescription medications like Chantix, Zyban, bupropion or Wellbutrin (29%, combined). Similarly, most reported having read printed materials about quitting such as pamphlets or booklets (61%), but fewer had sought assistance from a telephone helpline, group cessation program or the internet (6–26%). The four study groups did not differ by any of these smoking and quitting variables (Table 1).

Table 2 describes participants' social needs, health, stress, depressive symptoms and sleep problems. Participants had many unmet social needs. Of the 10 social needs assessed, the sample mean was 2.5 unmet needs; two-thirds of participants had two or more unmet needs. The most common unmet needs were having enough money for unexpected expenses (74% unmet), childcare (53%, among those with children), paying utility bills (46%), and having enough money for necessities (36%). These were followed by not having enough space in the home, living in an unsafe neighborhood, and not having reliable transportation (all 22%); 14% had unmet food needs. The mean number of unmet social needs and the proportion with two or more unmet social needs were not significantly different by study group. The only variable that differed by study group was having enough money for unexpected expenses. (Table 2).

Over half of the sample rated their health as fair (39%) or poor (17%), and many reported a history of chronic diseases or mental health conditions; 54% had at least one of the six chronic diseases assessed, and 71% had at least one of the seven mental health conditions assessed. Most common among the chronic diseases were asthma (28%), COPD (20%) and type II diabetes (15%); most common among the mental health conditions were depression (61%), anxiety (38%), PTSD (30%) and bipolar disorder (29%). Across the sample, the mean number of chronic diseases per participant was 0.8 and the mean number of mental health conditions was 2.0. One third of participants (35%) reported that they did not have a regular doctor. The only health condition that varied across study group was history of depression. (Table 2).

Participants reported high levels of stress, depressive symptoms and sleep problems. The sample mean score on the Perceived Stress Scale

Table 1
Demographic characteristics, smoking and cessation histories of participants at baseline, by study group.

Sample characteristics	Frequency (%)					
	All participants	Standard QL only	Standard QL + Navigation	Specialized QL only	Specialized QL + Navigation	p-value
	(n = 1944)	(n = 485)	(n = 484)	(n = 485)	(n = 490)	
Demographics						
Age in years, mean (SD)	48.4 (12.2)	48.2 (12.1)	48.6 (12.2)	49.0 (12.5)	47.8 (12.1)	0.49
Female	1396 (71.8)	349 (72.0)	334 (69.0)	357 (73.6)	356 (72.7)	0.42
Race						
Black or African-American	1111 (57.8)	268 (55.6)	275 (58.0)	278 (57.8)	290 (59.9)	0.83
White	666 (34.7)	179 (37.1)	166 (35.0)	164 (34.1)	157 (32.4)	
Other	144 (7.5)	35 (7.3)	33 (7.0)	39 (8.1)	37 (7.6)	
Hispanic	55 (2.9)	15 (3.1)	13 (2.7)	13 (2.7)	14 (2.9)	0.98
Annual pre-tax household income						
< $10,000	957 (51.2)	229 (49.4)	222 (47.5)	248 (53.6)	258 (54.3)	0.33
$10,000 - $19,999	572 (30.6)	144 (31.0)	155 (33.2)	140 (30.2)	133 (28.0)	
≥ $20,000	340 (18.2)	91 (19.6)	90 (19.3)	75 (16.2)	84 (17.7)	
Education						
< High school	588 (30.4)	148 (30.6)	147 (30.4)	151 (31.4)	142 (29.0)	0.43
High school/GED	580 (29.9)	148 (30.6)	128 (26.5)	154 (32.0)	150 (30.6)	
> High school	769 (39.7)	187 (38.7)	208 (43.1)	176 (36.6)	198 (40.4)	
Child ≤18 in home	663 (34.1)	173 (35.7)	168 (34.7)	149 (30.7)	173 (35.4)	0.32
Reside in rural ZIP code	151 (7.8)	34 (7.0)	31 (6.4)	42 (8.7)	44 (9.0)	0.36
Smoking and cessation history						
Age in years at first cigarette, mean (SD)	15.7 (5.6)	15.9 (6.1)	15.4 (4.8)	15.8 (6.3)	15.7 (5.2)	0.61
Cigarettes per day, mean (SD)	15.6 (9.2)	15.7 (9.4)	15.3 (8.8)	16.0 (9.3)	15.4 (9.3)	0.59
Heaviness of Smoking Index (0–6), mean (SD)	3.0 (1.3)	3.0 (1.4)	3.0 (1.3)	3.0 (1.4)	3.0 (1.3)	0.90
Use of other tobacco products	668 (34.4)	186 (38.4)	150 (31.0)	155 (32.0)	177 (36.1)	0.05
Live with other smokers	784 (40.4)	186 (38.5)	202 (41.7)	200 (41.4)	196 (40.0)	0.73
Workplace allows smoking[†]	353 (71.5)	90 (70.9)	94 (72.3)	76 (72.4)	93 (72.4)	0.98
Have coworkers who are smokers[‡]	397 (83.8)	104 (86.0)	107 (84.9)	79 (79.8)	107 (83.6)	0.64
Allow smoking inside the home	1428 (73.8)	366 (76.3)	349 (72.4)	342 (70.7)	371 (75.7)	0.15
Self-reported quit attempt, ever	1713 (88.2)	421 (86.8)	434 (89.7)	427 (88.0)	431 (88.3)	0.59
Self-reported quit attempt, last 12 months[‡]	799 (47.6)	200 (48.7)	194 (45.5)	210 (50.0)	195 (46.1)	0.52
Past use of any pharmacological quit aid[‡]	1216 (71.0)	291 (69.1)	306 (70.5)	308 (72.1)	311 (72.2)	0.72
Past use of printed materials[‡]	1047 (61.4)	247 (59.1)	258 (59.6)	277 (65.3)	265 (61.8)	0.23
Past use of online information[‡]	448 (26.3)	114 (27.3)	109 (25.2)	125 (29.5)	100 (23.3)	0.19
Past use of telephone helpline[‡]	255 (15.0)	67 (16.0)	53 (12.3)	69 (16.4)	66 (15.4)	0.32
Past use of group therapy[‡]	107 (6.3)	27 (6.4)	29 (6.7)	27 (6.3)	24 (5.6)	0.92

† Only asked of those who work outside the home (n = 501)

‡ Only asked of those who ever made a quit attempt (n = 1713).

was 8.0 (on a 0–16 scale).The mean score on the PHQ-2 was 2.7 (on a 0–6 scale), with nearly 40% of participants reporting little interest in doing things most days (39%) and feeling down and depressed most days (38%). Nearly half of participants (49%) reported that their sleep quality was "fairly bad" or "very bad", and over half (56%) reported trouble sleeping at least three nights per week. The mean sleep quality score was 3.7 (on a 0–6 scale). None of these mean scale scores were significantly different by study group (Table 2).

The last eight months of study recruitment occurred during the COVID-19 pandemic. With 2-1-1s experiencing dramatic increases in call volume [50], eligibility screening for the study was paused or slowed, and fewer potential participants were identified during this period. Average weekly enrollment in the trial dropped from 11.9 participants pre-COVID-19 to 6.3 participants during it. We found few differences between those enrolled before (n = 1,720) and during (n = 224) the pandemic. Those recruited during the pandemic were significantly more likely to report past use of pharmacological quit aids, specifically past use of NRT, and were more likely to have health histories of cancer, PTSD, and drug or alcohol use disorder, the latter two of which contributed to higher rates of mental health conditions overall (Appendix Tables A.1 and A.2). COVID-19-related items added to the baseline assessment during this period showed that 49% reported smoking more since the pandemic began and 6% reported smoking less (n = 148; data not shown).

5. Discussion

We successfully recruited a large, statewide sample of low-income smokers and described many of the myriad challenges they face daily, beyond quitting smoking. Many are in fair or poor health, experience acute financial strain in many aspects of daily living, and feel stressed and depressed. The mean stress score in the sample is well above population norms [51], and the mean depression score easily surpasses the threshold at which further depression screening is recommended [52]. Many participants report problems sleeping, and one in three does not have a regular doctor. Recent research suggests that quitting smoking is more difficult when social needs are unmet and psychological distress is present [53]. Many of the study participants were experiencing this combination at baseline, confirming a need for interventions such as those being tested. Our randomization procedure distributed nearly all key characteristics equally across the four study groups.

Participants' exposure to smoking also was high. On average, participants began smoking before age 16, 40% live with other smokers, and 74% allow smoking in their home. Most of those who are employed report that their workplace allows smoking (72%), and nearly all report that they work with other smokers (84%). These findings are highly similar to those reported in other recent tobacco research in low-income populations, especially mean age at smoking onset [54] and prevalence of living and working with other smokers [33,55]. Greater exposure to smoking through one's social network can decrease the likelihood of quitting [56,57] in part due to less pressure to quit [31].

Many (88%) had tried to quit smoking at least once before, 48% had

Table 2
Unmet social needs and health of participants at baseline, by study group.

Sample characteristics	Frequency (%)					
	All participants	Standard QL only	Standard QL + Navigation	Specialized QL only	Specialized QL + Navigation	p-value
	(n = 1944)	(n = 485)	(n = 484)	(n = 485)	(n = 490)	
Social needs						
Number of unmet needs (0−10), mean (SD)	2.5 (1.8)	2.5 (1.8)	2.4 (1.8)	2.5 (1.7)	2.6 (1.8)	0.32
0 unmet needs	241 (12.4)	62 (12.8)	66 (13.6)	54 (11.1)	59 (12.0)	0.42
1 unmet need	394 (20.3)	93 (19.2)	107 (22.1)	107 (22.1)	87 (17.8)	
2+ unmet needs	1309 (67.3)	330 (68.0)	311 (64.3)	324 (66.8)	344 (70.2)	
Type of need						
Not enough money for unexpected expenses	1395 (73.9)	335 (70.8)	330 (70.7)	366 (77.2)	364 (77.0)	**0.02**
Trouble finding or paying for childcare*	89 (53.0)	24 (49.0)	18 (46.2)	19 (57.6)	28 (59.6)	0.54
Cannot pay utility bills in full	846 (46.1)	205 (44.2)	211 (46.6)	208 (45.2)	222 (48.6)	0.56
Not enough money for necessities	674 (35.6)	160 (33.8)	155 (32.4)	173 (36.9)	186 (39.5)	0.10
Not enough space in your home	430 (22.3)	115 (23.9)	102 (21.4)	106 (22.0)	107 (22.0)	0.80
Unsafe neighborhood	423 (22.2)	120 (25.2)	104 (22.1)	87 (18.2)	112 (23.4)	0.07
No reliable transportation	417 (21.8)	108 (22.5)	100 (21.1)	99 (20.8)	110 (22.7)	0.85
Not enough food	276 (14.4)	61 (12.7)	68 (14.3)	73 (15.2)	74 (15.3)	0.64
No place to stay	182 (9.6)	40 (8.5)	51 (10.9)	49 (10.4)	42 (8.8)	0.51
Threatened physically	161 (8.4)	40 (8.4)	39 (8.3)	34 (7.1)	48 (10.0)	0.46
Health						
Health status (1 = poor-5 = excellent), mean (SD)	2.5 (1.0)	2.5 (1.0)	2.5 (1.0)	2.4 (1.1)	2.5 (1.0)	0.73
Excellent	81 (4.2)	24 (5.0)	19 (3.9)	21 (4.3)	17 (3.5)	0.55
Very good	197 (10.2)	39 (8.1)	54 (11.2)	53 (10.9)	51 (10.5)	
Good	573 (29.5)	154 (31.8)	143 (29.6)	126 (26.0)	150 (30.7)	
Fair	759 (39.1)	186 (38.4)	192 (39.8)	189 (39.0)	192 (39.3)	
Poor	330 (17.0)	81 (16.7)	75 (15.5)	96 (19.8)	78 (16.0)	
No regular doctor	676 (35.0)	174 (36.2)	173 (36.0)	160 (33.2)	169 (34.8)	0.76
Insurance						
Medicaid	665 (34.8)	165 (34.4)	156 (33.0)	165 (34.3)	179 (37.5)	0.80
Dual Medicaid and Medicare	360 (18.8)	102 (21.3)	82 (17.3)	89 (18.5)	87 (18.2)	
Medicare	214 (11.2)	51 (10.6)	58 (12.3)	56 (11.6)	49 (10.3)	
Uninsured	539 (28.2)	127 (26.5)	139 (29.4)	136 (28.3)	137 (28.7)	
Gateway to Better Health†	86 (4.5)	22 (4.6)	23 (4.9)	26 (5.4)	15 (3.1)	
Veterans Affairs	48 (2.5)	13 (2.7)	15 (3.2)	9 (1.9)	11 (2.3)	
Sum of chronic diseases (0–6), mean (SD)	0.8 (1.0)	0.8 (0.9)	0.8 (1.0)	0.9 (1.0)	0.8 (0.9)	0.26
At least one chronic disease	1039 (53.5)	252 (52.0)	253 (52.3)	270 (55.7)	264 (53.9)	0.64
Asthma	539 (27.8)	127 (26.3)	138 (28.6)	143 (29.6)	131 (26.8)	0.63
COPD	382 (20.0)	97 (20.3)	93 (19.6)	111 (23.2)	81 (16.7)	0.09
Heart disease	209 (10.9)	60 (12.5)	47 (9.9)	54 (11.3)	48 (10.0)	0.53
Cancer	150 (7.8)	28 (5.9)	33 (6.9)	41 (8.5)	48 (9.9)	0.10
Type I diabetes	50 (2.6)	9 (1.9)	17 (3.5)	12 (2.5)	12 (2.5)	0.43
Type II diabetes	292 (15.2)	67 (13.9)	65 (13.5)	80 (16.7)	80 (16.5)	0.38
Sum of mental health conditions (0–7), mean (SD)	2.0 (1.8)	2.0 (1.8)	1.9 (1.8)	2.1 (1.8)	2.0 (1.8)	0.27
As least one mental health condition	1380 (71.0)	342 (70.5)	333 (68.8)	357 (73.6)	348 (71.0)	0.42
Depression	1186 (61.4)	284 (59.0)	274 (57.0)	321 (66.5)	307 (62.9)	**0.01**
Anxiety	721 (37.6)	188 (39.1)	162 (34.0)	194 (40.7)	177 (36.7)	0.15
PTSD	571 (29.8)	135 (28.3)	125 (26.3)	153 (31.8)	158 (32.6)	0.11
Bipolar disorder	565 (29.3)	133 (27.8)	148 (30.7)	141 (29.3)	143 (29.5)	0.80
Drug or alcohol use disorder	375 (19.4)	101 (20.9)	91 (18.9)	93 (19.4)	90 (18.4)	0.79
ADHD	254 (13.2)	61 (12.7)	65 (13.7)	62 (12.8)	66 (13.6)	0.95
Schizophrenia	196 (10.2)	46 (9.6)	47 (9.8)	57 (11.8)	46 (9.5)	0.58
Depressive symptoms (0–6), mean (SD)	2.7 (1.9)	2.7 (1.8)	2.6 (1.8)	2.8 (2.0)	2.6 (1.9)	0.40
Perceived stress (0−16), mean (SD)	8.0 (3.2)	8.1 (3.1)	7.9 (3.1)	8.0 (3.2)	8.0 (3.3)	0.73
Sleep problems (0–6), mean (SD)	3.7 (1.9)	3.7 (1.9)	3.7 (1.8)	3.7 (1.9)	3.7 (1.9)	0.95

* Only asked of those who reported needing or using childcare for children in the household (n = 175).

† Gateway to Better Health is a health care program for uninsured adults in St. Louis City and County who are not eligible for Medicaid or Medicare.

tried in the past 12 months, and they had tried a variety of cessation aids. Over half of those who reported a prior quit attempt had tried using a nicotine patch (57%) or had read pamphlets or booklets about quitting (62%). After that, the drop off was sharp: 1 in 3 had used nicotine gum; 1 in 4 had sought help online; and 1 in 7 had ever called a tobacco quitline. These rates are higher than other reports that assessed cessation aid use during smokers' last quit attempt or during the past year for U.S. adults [58,59]. Further investigation into differences in factors associated with ever versus recent use of cessation aids is warranted [60].

5.1. Potential limitations

As found in prior research [61], smoking prevalence was high among 2-1-1 callers. Because participants were identified when calling 2-1-1, they likely have at least one acute social need they are trying to address. In one study comparing 2-1-1 callers to other low-income populations (e.g., Medicaid plan members), 2-1-1 callers reported about twice as many unmet social needs [44]. Thus, it is not clear how representative this sample is relative to all low-income smokers in the U. S.

This recruitment strategy is also a strength of the trial, however. It is an innovative approach for engaging low-income individuals with

unmet social needs in an intervention trial. During the COVID-19 global pandemic, when patients dwindled in clinical settings, calls for help to 2-1-1 actually increased significantly [50]. Thus, despite the last 8 months of recruitment occurring during the pandemic, we achieved 97% of the target enrollment (1,944 participants out of 2,000 target sample size). Even with slowed recruitment during COVID-19, randomization procedures successfully created four study groups that differed on only two factors examined here. We will control for these variables in future trial analyses examining differences between study arms.

Taken collectively, these findings help contextualize low-income smokers' lives and support the need for interventions that recognize and address social needs, and adapt the content and delivery of cessation counseling to maximize its appropriateness. We are eager to evaluate these interventions in the ongoing trial once participant follow-up is complete.

Ethics approval and consent to participate

The study was approved by the Human Research Protection Office at Washington University in St. Louis (201603150). All participants provided verbal informed consent and were age 18 years or older at enrollment. The trial was registered at www.clinicaltrials.gov (NCT03194958).

Availability of data and materials

Because study data are confidential, they are not publicly available. De-identified data or aggregate may be made available in response to reasonable requests to the corresponding author.

Competing interest

The authors employed at Washington University in St. Louis (Rachel Garg, Amy McQueen, Taylor Butler, Lauren Grimes, Jennifer Wolff, Tess Thompson, Charlene Caburnay, Jordyn Wartts, Cindy Charles, Matthew Kreuter) and those whose contributions were made during past employment at Washington University in St. Louis (Irum Javed, Christina Roberts) declare that they have no competing interests.

Kelly Carpenter declares that she is employed by Optum and has no other competing interests.

Valerie Howard declares that she is employed by the Missouri Department of Health and Senior Services (MDHSS) and has no other competing interests.

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Author contributions

MK is PI of the study. He collaborated with Co-PI AM and RG, CCa, CR and TT on developing the study design, interventions, assessments and other aspects of the research. He collaborated with RG to draft the manuscript, collect and integrate feedback from all authors, and submit the final version of the manuscript. RG also conducted statistical analyses and created data tables, and worked with IJ to manage and clean all study data. LG, TB, CR and JWo coordinated community partnerships with 2-1-1 and MDHSS, developed and implemented all study protocols, including recruitment, enrollment and data collection, and managed the efforts of interviewers and research assistants. KC and VH coordinated quitline involvement in the study, including integrating the baseline survey and quitline enrollment into a single assessment. JWa and CCh led bibliographic research for the paper. All authors read and

contributed to writing this paper and reviewed and approved the final version.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

List of abbreviations

PHQ-2   Patient Health Questionnaire 2-item screener for depression
COPD   chronic obstructive pulmonary disease
ADHD   attention deficit hyperactivity disorder
PTSD   post-traumatic stress disorder
NRT   nicotine replacement therapy
US   United States

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2021.100857.

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