

# Testing a Brief Quitline Intervention for Tobacco Cannabis Co-Users: A Randomized Controlled Pilot Study

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## ABSTRACT

**Background:** Tobacco cannabis co-use is common and becoming more prevalent. Frequent and heavy users of cannabis may struggle to quit smoking. Quitlines offer free cessation treatment in the United States and 25% of quitline callers may also be cannabis users. The present paper describes a randomized pilot study of a tailored intervention for cannabis and cigarette co-users. The intervention combines the quitline smoking cessation treatment with a motivational enhancement therapy-based cannabis intervention.

**Methods:** The randomized pilot study was conducted within four state-funded quitlines with quitline coaches as interventionists. 102 quitline callers who were cannabis and cigarette co-users were randomized to receive treatment as usual (TAU) or the new Quitline Check-Up (QLCU) intervention. Outcomes were collected 90 days post-randomization. Primary outcomes included feasibility and acceptability of delivering the QLCU in the quitline setting. Secondary outcomes included 7-day point prevalence tobacco abstinence, past 30-day cannabis use, and Cannabis Use Disorder Identification Test scores.

**Results:** Study participants were heavy cannabis users, averaging 25 days of use in the past 30; nearly 70% used at a level considered hazardous. Fidelity ratings indicated coaches were successful at delivering the intervention. Treatment engagement was high for both groups (TAU  $m = 3.4$  calls; QLCU  $m = 3.6$  calls) as was treatment satisfaction. Intent-to-treat quit rates (with survey non-responders classified as smokers) were 28.6% for the TAU control group and 24.5% for the QLCU group ( $P = .45$ ).

**Discussion:** Hazardous cannabis use rates were high in this sample of tobacco cannabis co-users calling quitlines to quit smoking. The intervention for co-users was acceptable and feasible to deliver. No improvements in tobacco cessation outcomes were observed. Pragmatic intervention development within a real-world clinical setting can streamline the intervention development process. More research is needed on tobacco cannabis co-users and who can benefit from a tailored intervention. Registered: ClinicalTrials.gov NCT04737772, February 4, 2021.

**KEYWORDS:** Tobacco, cessation, quitlines, cannabis, coaching, interventions

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**IRB STATEMENT** The Institutional Review Board (IRB) at the Office of Human Research Affairs (OHRA) through UnitedHealth Group approved the study protocol and documents and provided oversight over the study. The OHRA IRB approved a waiver of documentation of consent for this research. Verbal consent to participate was collected for each study participant using an IRB-approved consent document.

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## Background

Tobacco use remains the number one cause of premature death and disease in the United States. In 2021, cigarette smoking rates among adults in the United States (US) were estimated at 11.5%<sup>1</sup> and that rate leaves more than 30 million Americans still at risk for smoking-related diseases and premature death.<sup>1</sup> Furthermore, those who continue to smoke are often from disadvantaged or disparate groups: Groups who continue to have high rates of smoking include those with behavioral health conditions and those with other substance use disorders, such as cannabis use disorder.<sup>1–3</sup>

Cannabis is a widely used psychotropic substance. Although illegal in the US for many decades, as of 2023 non-medical

adult cannabis use has been legalized in 23 states and Washington DC and a 24th state, Ohio, approved legalization via ballot initiative in November 2023.<sup>4</sup> Concurrent with legalization, frequent (daily or near-daily) use and prevalence of Cannabis Use Disorders (CUD) has increased.<sup>5</sup> Recent studies have shown that, although there is a perception that cannabis is harmless, use at the level of a CUD is associated with significant psychosocial and health-related problems similar in scope to that of alcohol use disorders.<sup>6</sup>

Cannabis and tobacco co-use is common and increasing.<sup>7</sup> Cigarette dependence is more prevalent among cannabis users: more than 60% of adults who use cannabis are also cigarette smokers.<sup>7</sup> The reverse is also true: rates of cannabis use are



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higher in cigarette smokers than in the overall population and daily cannabis use is highly correlated with smoking cigarettes.<sup>8</sup> Furthermore, longitudinal data suggests cannabis users are more likely to start smoking cigarettes, continue to smoke over time (as opposed to quitting), and relapse once quit.<sup>9</sup>

Epidemiological research suggests that cannabis users, particularly those with CUD, are less likely to quit smoking over time.<sup>9</sup> The literature regarding the impact of cannabis use on tobacco cessation in the clinical setting (i.e., among those seeking to quit smoking), however, is less clear. Overall, the evidence that past 12-month cannabis use impacts planned tobacco cessation is inconclusive.<sup>10,11</sup> Rogers, et al<sup>11</sup> found that baseline cannabis use predicted quicker relapse to smoking and a lower likelihood of being abstinent at follow-up in treatment-seeking combustible cigarette smokers. Furthermore, several studies have found that specific subgroups may be more impacted by cannabis use. Daily cannabis use, for example, may interfere more with smokers' attempts to quit smoking as compared to less frequent use.<sup>12</sup> Factors such as gender may play a role (with males' quit attempts more likely to be impacted) and the purpose of cannabis use may also be important with non-medical use more likely to interfere with smoking cessation.<sup>12,13</sup> A recent review concluded that while the evidence is mixed regarding the impact of cannabis use on tobacco cessation outcomes, failing to address cannabis in the tobacco treatment setting could impede tobacco control efforts.<sup>10</sup>

Quitlines (QLs) deliver free evidence-based tobacco cessation services throughout the US. Although data regarding cannabis use in QL callers is scarce, one evaluation found that about 25% of QL callers in 3 states/districts with fully legalized cannabis (Oregon, Alaska, and Washington DC) reported past 30-day cannabis use.<sup>14</sup> These quitline callers used cannabis on average 14 days of the past 30 and more than a third of the sample who used cannabis used 20 or more days/month. The relationship between cannabis use and cessation outcomes in the context of tobacco QLs is understudied. One observational study found that cannabis users, including daily users, participating in an insurance-funded QL were equally as likely to quit smoking as those who only used tobacco.<sup>15</sup> Another observational study, however, in the publicly funded New York Quitline found that cessation rates decreased as frequency of cannabis use increased.<sup>16</sup> The difference in findings between these two studies could be explained by differences in the samples: McClure<sup>15</sup> studied insured adults who were referred to a commercial QL from primary care. Goodwin et al<sup>17</sup> studied self-referred callers to a publicly funded QL.

In recent years, clinicians and researchers working with QLs have developed tailored coaching programs for priority populations, including those with behavioral health conditions.<sup>16</sup> Tailored QL-based interventions must, of necessity, be brief, focused, and delivered remotely. To be disseminated, they must be effective when delivered by QL personnel and any supplemental features of the intervention must be accessible to QL populations who are often low-income.<sup>18</sup> As QL callers are

enrolling for tobacco cessation services and not cannabis cessation services, McClure, et al<sup>19</sup> suggest the utility of avoiding an abstinence-only approach and including a reduction in use as a valid goal (i.e., taking a harm reduction approach to cannabis) in the context of tobacco cessation treatment.

The purpose of the present study was to develop and test a novel coaching intervention for cannabis co-users trying to quit smoking in their state QLs. A randomized pilot study was conducted with primary outcomes of feasibility of QL delivery and acceptability to QL participants. Secondary outcomes targeted by the intervention included tobacco cessation and motivation to change (decrease or quit) cannabis use. This project also contributes to the literature by describing cannabis use patterns, including hazardous cannabis use, in this QL population.

## Methods

### *Study design*

This pilot study was a two-arm randomized controlled trial (RCT) evaluating feasibility, acceptability, and preliminary tobacco cessation and cannabis outcomes of a novel coaching intervention for dual tobacco and cannabis users as compared to QL tobacco cessation treatment as usual (TAU). Individuals who contacted one of the participating state-funded QLs and were both smoking cigarettes and using cannabis at the time of enrollment and who met other study criteria were randomized to either receive TAU, or the experimental intervention, the Quitline Check-Up Intervention (QLCU). Outcomes were collected at 3 months post-randomization.

The Institutional Review Board (IRB) at the Office of Human Research Affairs (OHRA) through UnitedHealth Group (UHG) approved the study protocol and documented and provided oversight for the study. The study was registered with ClinicalTrials.gov using the identifier NCT04737772, and described by the CONSORT for reporting of pilot and feasibility trials.<sup>20</sup>

### *Setting*

QLs are tobacco cessation services available throughout the United States provided by state health departments to their residents free of charge. QL services include phone-based coaching, online support, text messaging, and, in most cases, free nicotine replacement therapy (NRT). QLs are effective population-based cessation services, endorsed by US Public Health Guidelines.<sup>21,22</sup> The QLs utilized for this study were operated by Optum at the time of the study. Optum operated more than 20 publicly funded QLs and delivered more than 350,000 coaching calls per year.

### *Participants*

Participants in this study were individuals who called to enroll in one of the four participating state QLs: the Alaska Tobacco

Quitline, the District of Columbia Quitline, the Oregon Tobacco Quitline, or the Washington State Quitline. These locations have legalized medical and non-medical adult (21+) cannabis use. Recruitment ran from September 16, 2021, through July 30, 2022. Callers who met the following initial criteria were offered study screening: (1) Daily cigarette smoking; (2) ready to quit smoking in the next 30 days; (3) not pregnant or planning to become pregnant in the next 3 months; (4) at least 21 years old; (5) English speaking; and (6) did not report a diagnosis of schizophrenia. Those who met the initial criteria were given a brief study description (indicating the study was for those who use cannabis and who smoke cigarettes) and were invited to be screened for the study. Additional screening criteria included: (1) smoked at least 5 cigarettes per day; (2) used cannabis nine or more of the past 30 days; (3) did not use

cannabis solely for medical purposes; (4) consumed cannabis for its psychoactive and physiological effects; (5) read English; (6) had regular access to a telephone; (7) were willing to communicate over email; (8) and did not have another member in the household participating in the study. See Figure 1 for the consort diagram.

*Procedures*

QL enrollment agents at Optum screened incoming callers for study eligibility criteria. Eligible participants were then transferred to a study-trained QL coach who delivered the informed consent script and collected responses to baseline survey questions. Following the baseline survey, participants were randomized to the standard QL TAU or the experimental

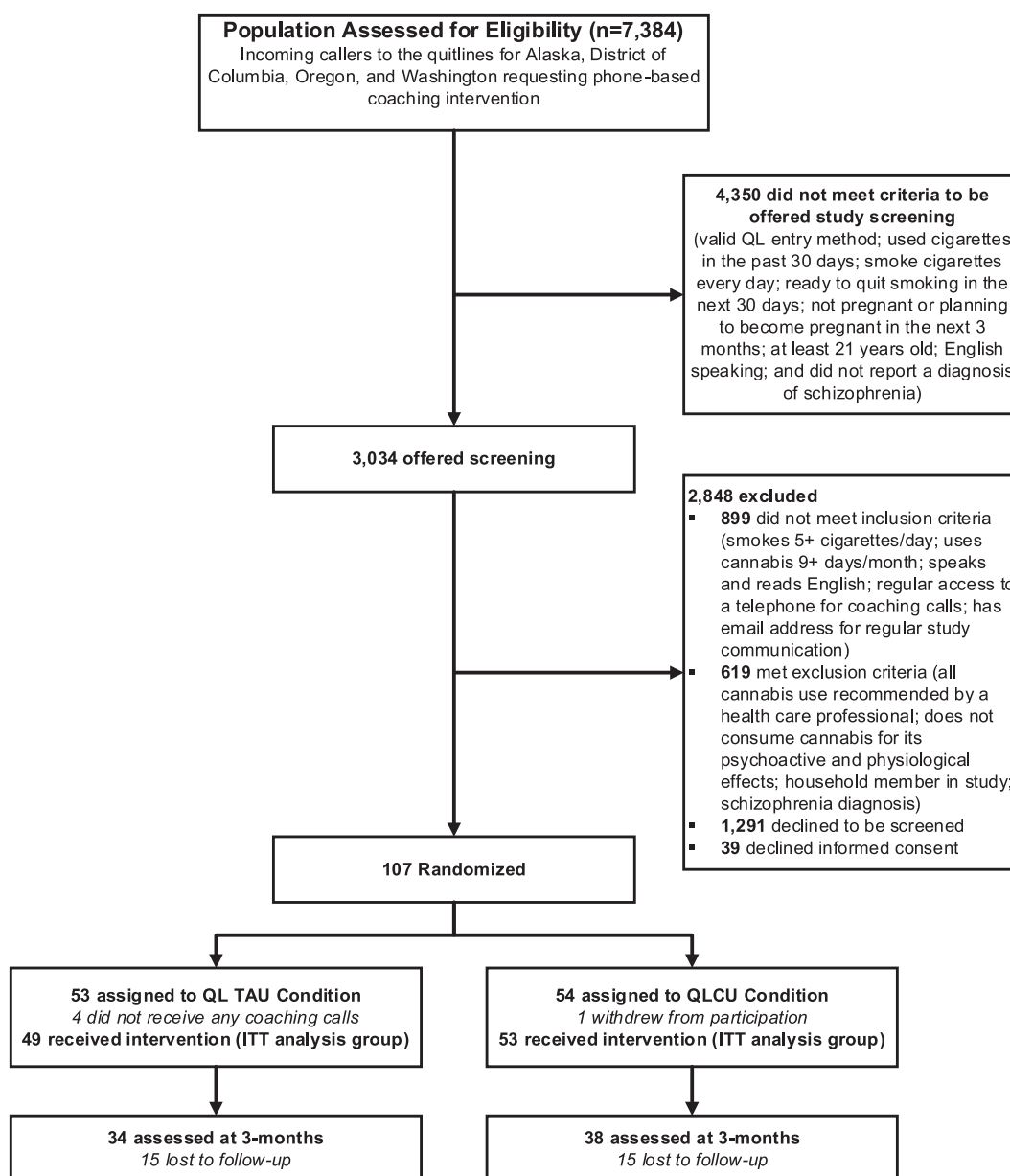


Figure 1. Consort diagram.

treatment (QLCU). Randomization occurred via the Optum software system pulling numbers from random number tables generated by the research team using the web-based generator, Research Randomizer.<sup>23</sup> Randomization was stratified by state and gender to achieve a similar proportion of males and females/nonbinary from each state into each treatment group. Participants were blind to their intervention condition, although they were aware that two different treatments were being offered.

Study-trained coaches provided the experimental intervention to participants or transferred participants to a non-study coach to provide TAU. Three months post-enrollment, participants received an email with a link to the web-based follow-up survey. For those who did not complete the online survey after two email reminders, an external survey group (blinded to treatment condition) attempted to reach the participant by phone to complete the survey. Those who reported seven-day tobacco abstinence were sent saliva test kits to test for the presence of cotinine, a nicotine metabolite. Participants sent the study team a picture of the result via email and also indicated whether or not they were using NRT at the time of the test.

Participants received a \$30 gift card after completing the baseline survey and the first coaching call, a \$20 gift card following the second coaching call, and a \$50 gift card for the outcome survey. Participants who were abstinent from smoking tobacco at follow-up received a \$20 gift card after completing biochemical verification.

### Interventions

*The standard quitline treatment as usual (TAU).* TAU included 5 proactive telephone coaching sessions (4 sessions for Oregon) with supplemental support delivered via text automated messaging and web-based information (see Table 1). All participating state QLs provided free nicotine replacement therapy (NRT), ranging from 2 weeks (Alaska and Washington DC) to 8 weeks (Oregon). Participants could also call into the QL for additional coach support. QL calls last 10–20 minutes on average and occur on the participant's schedule (typically every 1–2 weeks). Coaches discussed participant's tobacco use and dependence, prior quit attempts and successes, use of cessation medications, reasons for quitting, motivation, self-efficacy, and social support. In the first call, coaches worked with participants on a tailored treatment plan, established a date for quitting tobacco, discussed appropriate use of medications (e.g., NRT), and skills and strategies to cope with urges and cravings. Coaches briefly discussed social support and stimulus control strategies (i.e., "tobacco proofing") in call 1. In follow-up calls, coaches further discussed behavioral skills and coping strategies shown to help participants quit and stay quit (e.g., tobacco proofing, using medications, avoiding situations that trigger tobacco use, engaging in distracting activities, and managing stress).

The QL TAU is grounded in social cognitive theory,<sup>24</sup> incorporating the strategies for effective tobacco dependence

treatment outlined in the U.S. Public Health Service Clinical Practice Guideline.<sup>21</sup> Each call is designed to provide practical expert support to help participants develop problem-solving and coping skills, secure social support, and design a plan for successful cessation and long-term abstinence.

*Quitline Check-Up Intervention (QLCU).* The QLCU intervention was developed as part of the current research. The QLCU was based on the Marijuana Check-Up Intervention (MJCU) which was originally developed for non-treatment seeking cannabis users and was based on Motivational Enhancement Therapy (MET).<sup>25</sup> MET is a variation of motivational interviewing (MI) that includes an assessment of substance use patterns and problems and the provision of personalized feedback. In the QLCU, cannabis counseling was integrated and delivered simultaneously with QL tobacco cessation coaching (see Table 1). The intervention aimed to increase awareness of cannabis use as a risk factor for a tobacco quit, understanding of the relationship (if any) between use of cannabis and tobacco, and cannabis-related problems. In each coaching call, cannabis use patterns and modalities (i.e., eat, smoke, vape, dab, etc.), motivation to change, and cannabis goals (quit, reduce, or maintain level of use) were assessed. In addition, participants were asked what observations they had made on the relationship between their cannabis and tobacco use. In call 1, participants were provided with research-derived education on the risks of cannabis use during a tobacco quit. For example, heavy or frequent cannabis use may be associated with a less successful tobacco quit,<sup>19</sup> that cannabis use could increase tobacco cravings if substances are habitually used together,<sup>26</sup> and intoxication from cannabis (or other substances) could decrease inhibitions and make it less likely to maintain a tobacco-free goal.

Participants received a Personalized Feedback Report (PFR) via email and standard mail, which was reviewed during call 2. The PFR was generated individually for each participant based on their baseline cannabis and tobacco assessment data. Areas of feedback incorporated normative data comparing use of tobacco or cannabis with that of other adults in the United States, summaries of the participant's recent patterns of use, associated problems, and readiness rulers (assessing motivation to change). The PFR was reviewed with the coach utilizing motivational interviewing (MI) strategies throughout. MI techniques included open-ended questions, reflective listening, affirmation, support of autonomy, and selective reinforcement of participants' statements that favor change.<sup>27</sup> Coaches assessed each participant's behavior-change goals, self-efficacy, and motivation, and helped build a plan to enhance the ability to quit tobacco and achieve their goals regarding cannabis use.

Calls 3, 4 & 5 continued to focus on smoking cessation with an assessment of cannabis use and its impact on the tobacco quit. Participants were encouraged to set a cannabis goal for each call. Goals could be to reduce cannabis, quit cannabis, stay

**Table 1.** Intervention Descriptions: QL TAU<sup>1</sup> and QLCU Intervention.<sup>2</sup>

CALL NUMBER	QL TREATMENT AS USUAL (TAU) (CONTROL)	QLCU INTERVENTION ADDED TO QL TAU (EXPERIMENTAL)
Addressed in every call	Assessment of current tobacco use and challenges quitting. Assess medication usage and modify if needed. Set new quit date if needed	Current cannabis use (days, type, mode), problems, readiness for quitting or cutting back cannabis, relationship between cannabis and tobacco use
1: <i>Assessment &amp; Planning</i>	Program overview, assessment and planning with focus on setting a quit date, cessation medications, urge management, tobacco proofing and support. Quit guide mailed	Assessment of cannabis use, reasons for use, and readiness of change cannabis use. Psychoeducation regarding cannabis use as a barrier to quitting tobacco and relationship between cannabis and tobacco use.
2: <i>Quit date</i>	Motivational enhancement, reinforce quit plan. Review medication plan and likely triggers for relapse	Review PFR. Pros and cons of cannabis use, readiness to change and feedback based on PFR.
3-5: <i>Follow-up</i>	ACE model (avoid, cope, escape), social support, tobacco proofing, relapse prevention, practical problem solving	Assess cannabis use and readiness to change; deliver appropriate/tailored intervention by stage. Discuss cannabis use and nicotine withdrawal symptoms if any, set plan to be integrated with tobacco cessation treatment plan and goals, discuss relapse prevention, and plan for the future
NRT provision	Same for both groups. All are eligible for 2 or more weeks of NRT if they medically qualify and/or return a medical override letter from their doctor	
NRT dosing	Based on cigarettes per day prior to quitting, guided by an established dosing protocol	

QL TAU: Quitline Treatment as Usual; QLCU: Quitline Check-Up; QL: Quitline; PFR: Personal Feedback Report.

the same on cannabis use, or observe the interaction between cannabis use and tobacco cravings.

*Coach training.* Four tobacco cessation quit coaches delivered the QLCU intervention to study participants. All QL coaches receive 150 hours of tobacco cessation treatment training and get ongoing supervision and feedback as part of their employment at the QL. The four study coaches had previous training in research procedures and human subjects protection protocols and received 8 hours of study-specific training, including education about cannabis, motivational interviewing techniques, tailored behavioral support strategies, and specific methods of reviewing the PFR. In addition, coaches provided the study intervention to 10 participants in a proof-of-concept study before the randomized pilot, receiving individualized feedback on their calls from Drs. Walker and Carpenter.

### Measures

*Treatment acceptability: Treatment satisfaction.* Treatment acceptability and feasibility were the primary outcomes of this pilot study. Treatment satisfaction questions asked at follow-up included overall satisfaction with the QL, QL coach knowledge, if a tailored quit plan was developed, coach availability, timing of calls, and if the NRT was received. QLCU participants were also asked questions about their experience with the personalized feedback report and opinions about how talking about cannabis use influenced quitting tobacco. The program satisfaction scale was tailored for this study and based on previously used treatment satisfaction scales used in the quitline setting.<sup>16</sup> Treatment Engagement. Each coaching call completed was recorded by the call system and included both outgoing program calls and calls initiated by participants for additional support.

*Feasibility: Treatment fidelity.* Feasibility was measured by the ability of QL coaches to deliver the intervention as intended. The study team aimed to review at least 20% of experimental participants' calls and 5% of control participants' calls to ensure fidelity to the treatment condition. Fidelity measures were developed by the study team, pilot-tested in the 10-person proof-of-concept study, and then revised for the current randomized study. Experimental calls were reviewed for six call elements: (1) call introduction and purpose; (2) explore phase including assessing cannabis use, brief education about cannabis as a barrier to quitting tobacco, assessing cannabis as a barrier to quitting tobacco, and review of the PFR (2nd call only); (3) insight phase including a strategic summary of cannabis use and perceived impact on tobacco quit, (4) action planning phase including setting a cannabis goal; (5) call closing phase involving an action step review and next steps in the program; and (6) use of motivational interviewing techniques when discussing cannabis by using open-ended questions, reflections (especially around change talk), affirmations/autonomy support, and summaries throughout the call. Control group calls were

monitored for cannabis references and discussions to ensure that QLCU protocols were not being used.

*Tobacco measures: Tobacco use.* Tobacco use was measured during the QL enrollment process, baseline survey, and during the outcomes survey. Type of tobacco used, time of first use, and cigarettes per day used were asked during the enrollment call. Tobacco cessation was a secondary outcome and was measured by self-reported 7-day tobacco point prevalence abstinence (ppa) on the 3-month outcome survey. The outcome survey questions also included last time tobacco was used and cigarettes per day if not quit. Tobacco use questions were based on those in the North American Quitline Consortium's Minimal Dataset recommendations.<sup>28</sup> Cessation medication. Participants answered questions about cessation medication use during the outcome survey, including type of medication used, if any were used in combination, and if any were currently being used. Biochemical verification of tobacco abstinence. If a participant reported 7-day ppa during the outcome survey, a biochemical verification test (saliva test strip) for cotinine (a nicotine metabolite) was mailed along with instructions for use and submission of results to study personnel (NicoTests©). Participants were instructed to email a picture of their test result along with an included sheet of paper that included their study ID and a question regarding NRT use. At 3 months post-randomization, it was expected that participants would be continuing to use NRT which would cause a positive test result. The purpose of including this biochemical verification was to pilot-test these procedures.

*Cannabis use and related problems.* Cannabis use was assessed at eligibility, baseline, and follow-up. Questions included methods and reasons for use, days of use per month, and attitudes about quitting or reducing cannabis. On the outcomes survey, questions about cannabis use included time of last use, number of days used cannabis in the past 30 days, attitudes towards quitting and reducing use, quit goals, and cannabis use impacts on tobacco quit. Both the baseline and outcome surveys used the Cannabis Use Disorder Identification Test (CUDIT),<sup>29</sup> a brief, eight-item screening measure used as a tool to identify problematic cannabis use. Scores above 8 indicate hazardous cannabis use (i.e., use that could put the person or others at risk such as driving under the influence) and scores 13 or above indicate a need for further screening for a Cannabis Use Disorder.

*Psychosocial functioning and substance use.* Brief screening tools were used at baseline for depression, anxiety, and stress: the 2-item Patient Health Questionnaire (PHQ-2),<sup>30</sup> the Generalized Anxiety Disorder 2-item (GAD-2),<sup>31</sup> and the 4-item Perceived Stress Scale (PSS-4),<sup>32</sup> respectively. Alcohol use and other illicit drug use were assessed with validated single-item screeners.<sup>33,34</sup>

### Data analysis

We used summary statistics (means and proportions) with confidence intervals (CIs), standard errors (SE), and graphical

displays (histograms, pie charts, Box plots, etc.), as appropriate, to describe participant self-reported demographic characteristics, use of tobacco and cannabis, and other tobacco and cannabis variables measured at baseline and/or at each coaching call and at 3-months. We used Fisher's exact tests, t-tests, and Wilcoxon rank sum tests to compare intervention and control groups. Comparisons included mean number of calls completed, mean satisfaction ratings, mean change in cigarettes per day (CPD), and mean change in days of cannabis use. We also compared groups on changes over time in other cannabis measures, including hazardous cannabis use. We addressed the effect of missing values on estimated smoking cessation rates using sensitivity analyses for outcome measures: (1) we analyzed responders only, and (2) we imputed missing tobacco use as 'smoking'.

## Results

Participant demographics, mental health screening scores, and tobacco and cannabis use behaviors are shown in Table 2. Participants were 50% (n = 51), female, averaged 51.7 years of age (SD = 13.6), and were 85% (n = 87) heterosexual, 98% (n = 100) non-Hispanic, and 74% (n = 75) White. Thirty-four (33%) participants screened positive for depression (PHQ-2 score of 3+), and 33% (n = 34) screened positive for anxiety (GAD-2 score of 3+). Participants averaged a perceived stress score of 6.2 (SD = 3.2) on the 16-point PSS-4 scale. The TAU control group had more participants who screened positive for depression (41% [n = 20]; 26% [n = 14] QLCU) and anxiety (41% [n = 20]; 26% [n = 14] QLCU) and had a higher average score of perceived stress (6.8 [SD = 3.5]; 5.7 [SD = 2.7] QLCU), but these differences were not statistically significant.

**Table 2.** Participant Demographics, Mental Health Conditions, and Tobacco and Cannabis Use Behaviors at Study Enrollment (N = 102).

	TOTAL (N = 102)	QUITLINE TREATMENT AS USUAL (TAU) (N = 49)	QUITLINE CHECK-UP INTERVENTION (QLCU) (N = 53)
<b>Gender</b>			
Female	51 (50.0%)	25 (51.0%)	26 (49.1%)
Male	51 (50.0%)	24 (49.0%)	27 (50.9%)
Age; mean (SD)	51.7 (13.6)	50.4 (14.3)	52.9 (13.0)
<b>Sexuality</b>			
Heterosexual	87 (85.3%)	41 (83.7%)	46 (86.8%)
Gay or lesbian	5 (4.9%)	2 (4.1%)	3 (5.7%)
Bisexual or pansexual	4 (3.9%)	2 (4.1%)	2 (3.8%)
Something else	1 (1.0%)	0 (0%)	1 (1.9%)
Did not respond/Refused	5 (4.9%)	4 (8.2%)	1 (1.9%)
<b>Ethnicity</b>			
Non-hispanic	100 (98.0%)	49 (100%)	51 (96.2%)
Hispanic	2 (2.0%)	0 (0%)	2 (3.8%)
<b>Race</b>			
American Indian or Alaskan Native	2 (2.0%)	1 (2.0%)	1 (1.9%)
Native Hawaiian or Pacific Islander	1 (1.0%)	1 (2.0%)	0 (0%)
Black or African American	16 (15.7%)	7 (14.3%)	9 (17.0%)
White	75 (73.5%)	37 (75.5%)	38 (71.7%)
More than one race	8 (7.8%)	3 (6.1%)	5 (9.4%)
<b>Mental health screenings</b>			
Positive screening for depression (PHQ-2, score of 3+)	34 (33.3%)	20 (40.8%)	14 (26.4%)
Positive screening for anxiety (GAD-2, score of 3+)	34 (33.3%)	20 (40.8%)	14 (26.4%)
Perceived stress; mean (SD)			
(PSS-4, score out of 16 points)	6.2 (3.2)	6.8 (3.5)	5.7 (2.7)
<b>Tobacco use and behavior</b>			
Cigarettes per day; mean (SD)	16.3 (7.7)	17.4 (8.1)	15.2 (7.2)
<b>Time to first cigarette use</b>			
Within 5 minutes	34 (33.3%)	14 (28.6%)	20 (37.7%)
6-30 minutes	48 (47.1%)	26 (53.1%)	22 (41.5%)
31-60 minutes	13 (12.7%)	7 (14.3%)	6 (11.3%)
More than 60 minutes	7 (6.9%)	2 (4.1%)	5 (9.4%)
<b>Cannabis use, behavior, and readiness to change</b>			
Days of use within last 30 days; mean (SD)	24.8 (7.1)	25.7 (6.8)	24.0 (7.4)
Daily use (20+ days in last 30 Days)	80 (78.4%)	41 (83.7%)	39 (73.6%)
Cannabis Use Disorder Identification Test (CUDIT) score (range 0-22); mean (SD)	10.1 (4.7)	10.2 (4.9)	10.1 (4.4)
Hazardous cannabis use (CUDIT, score of 8+)	70 (68.6%)	33 (67.3%)	37 (69.8%)
Readiness to quit cannabis (1-10 scale, 10 = very ready); mean (SD)	3.3 (3.2)	3.4 (3.2)	3.3 (3.2)
Readiness to reduce cannabis use (1-10 scale; 10 = very ready); mean (SD)	4.2 (3.3)	4.2 (3.3)	4.1 (3.3)

**Table 3.** Treatment Satisfaction Outcomes at 3 Months After Study Enrollment (n = 71).

	TOTAL SAMPLE (3-MONTH SURVEY RESPONDENTS: N = 71)		QUITLINE TREATMENT AS USUAL (TAU) (3-MONTH SURVEY RESPONDENTS: N = 34)		QUITLINE CHECK-UP INTERVENTION (QLCU) (3-MONTH RESPONDENTS: N = 37)		P-VALUE
	%	95% CI	%	95% CI	%	95% CI	
Overall satisfaction with quitline							
Somewhat satisfied or higher	81.7	[72.7, 90.7]	82.4	[69.5, 95.3]	81.1	[68.6, 93.6]	.97
Likely to recommend quitline to others trying to quit smoking							
Somewhat likely or higher	90.0	[82.9, 97.1]	91.0	[81.4, 100.0]	89.0	[79.0, 99.0]	.90
Quit coaches listened to me and were responsive to questions							
Somewhat agree or higher	87.3	[79.5, 95.1]	85.3	[73.3, 97.3]	89.2	[79.2, 99.2]	.98
Quit coaches were knowledgeable about cannabis							
Somewhat agree or higher	56.3	[44.7, 67.9]	41.2	[24.7, 57.7]	70.2	[55.5, 84.9]	.052
Quit coaches were knowledgeable about quitting smoking							
Somewhat agree or higher	84.5	[76.3, 92.7]	76.5	[62.2, 90.8]	91.9	[83.8, 100.0]	.83
Program helped me develop a plan for quitting smoking							
Somewhat agree or higher	74.3	[64.1, 84.5]	67.6	[51.9, 83.3]	78.4	[65.1, 91.7]	.31
Quit coaches were available at times that were convenient							
Somewhat agree or higher	69.1	[58.3, 79.9]	73.5	[58.8, 88.2]	59.5	[43.6, 75.4]	.16
Talking about cannabis helped me quit or try to quit tobacco <sup>1</sup>							
Somewhat agree or higher	37.8 (14/37)	[22.1, 53.5]	N/A	N/A	37.8 (14/37)	[22.1, 53.5]	N/A
Talking about cannabis got in the way and made it harder for me to quit smoking <sup>a</sup>							
Somewhat agree or higher	21.6 (8/37)	[8.3, 34.9]	N/A	N/A	21.6 (8/37)	[8.3, 34.9]	N/A
I set a goal to quit or cut down on my cannabis use during the coaching program <sup>a</sup>							
Somewhat agree or higher	43.2 (16/37)	[27.3, 59.1]	N/A	N/A	43.2 (16/37)	[27.3, 59.1]	N/A

<sup>a</sup>Items were asked only of Quitline Check-Up Intervention (QLCU) participants at 3-month survey.

Tobacco and cannabis use behaviors at baseline (including cigarettes per day, time to first use, and days of cannabis use per month) did not significantly differ between groups. The average number of cigarettes smoked per day was 16.3 (SD = 7.7). Both groups had a high frequency of cannabis use, averaging 24.8 days of use in the past 30. The most common method of cannabis use was smoking (89%), followed by eating (40%). Most (78%; n = 80) participants were daily users (defined as 20 or more days per month by the US National Survey on Drug Use and Health), with the TAU group having slightly more daily users than the QLCU group (84% [n = 41] and 74% [n = 39], respectively). Participants averaged a score of 10.1 (SD = 4.7) on the Cannabis Use Disorder Identification Test (CUDIT), and 69% (n = 70) had a score of 8 or more, indicating hazardous cannabis use (67% [n = 33] TAU; 70% [n = 37] QLCU).

#### *Primary study outcomes were feasibility and acceptability*

Feasibility was measured by assessing the degree to which the QLCU intervention could be delivered in the QL setting by QL coaches. 58 of 166 (35%) of QLCU coaching calls were scored for fidelity by study investigators (Walker, Berlin, and Carpenter) and 47 (81%) of those achieved a passing score which was considered sufficient. In addition, (9%) of control condition calls were listened to for possible contamination. None of those calls contained elements of the QLCU intervention, although 4 (36%) of them had minor reference to cannabis (likely due to the extensive cannabis assessment given to participants at baseline).

Program acceptability was measured through QL engagement and satisfaction items. The primary method of assessing QL engagement is by the number of coaching calls each participant completes. Counting both outgoing program calls and



any incoming support calls, the control group averaged 3.4 calls (SD = 1.8) and QLCU participants averaged 3.6 (SD = 1.5). Overall QL satisfaction did not differ between groups (see Table 3): 82% of those who completed the outcome survey (n = 58) of participants were satisfied with the QL, and 90% (n = 64) would recommend it to others. Participants also gave similar ratings to quit coaches' listening and responsiveness (87% [n = 62] satisfied). Ratings differed for coaches' knowledge about cannabis (41% TAU [n = 14] vs 70% [n = 26] QLCU), knowledge about quitting smoking (77% [n = 26] TAU vs 92% [n = 34] QLCU); whether coaches helped the participant develop a plan to quit (68% [n = 23] TAU, vs 78% [n = 29] QLCU); and if coaches were available at convenient times (74% [n = 26] TAU vs 60% [n = 22] QLCU), but not significantly.

Within the QLCU group, most (75%; n = 28) were able to see their personal feedback report sent via email and mail, 70% (n = 26) had it available when talking to a quit coach, and 63% (n = 23) agreed the report was helpful. However, only 38% (n = 14) of those in the QLCU group agreed with the premise of the intervention: that talking about cannabis use helped with their tobacco quit. A minority (22%; n = 8) agreed that talking about cannabis made it harder to quit smoking. Less than half (43%; n = 16) reported setting a goal to quit or cut down on their cannabis use despite most being daily cannabis users.

Secondary outcomes in Table 4 include both self-reported respondent and intent-to-treat (assuming missing = smoking) 7dpp tobacco cessation rates. 70% (n = 72) of all participants responded to the outcome survey (69% [n = 34] TAU, 72% [n = 38] QLCU group). No significant differences were found

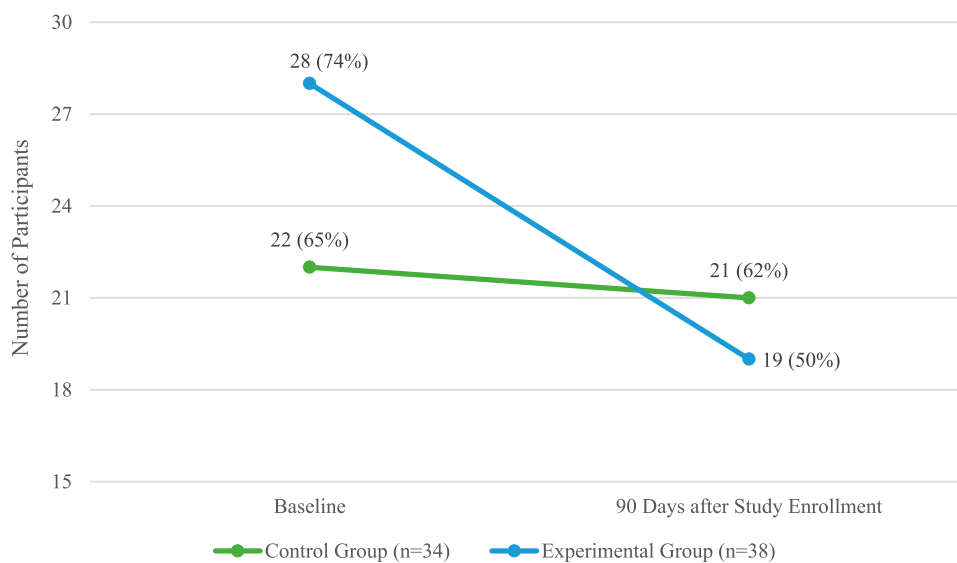
concerning tobacco quit rates given the study was not sufficiently powered to detect those differences. Respondent quit rates were 41% (n = 14) for the TAU and 34% (n = 13) for QLCU (P = .71), and intent-to-treat (missing = smoking) quit rates were 29% (n = ) for the TAU and 25% (n = 13) for QLCU (P = .45). At the follow-up survey, last 30 days of cannabis use decreased by an average of 3 days for the TAU and 3.8 days for QLCU, while cigarettes per day decreased by an average of 7.9 and 7.0 for TAU and QLCU, respectively. Figure 2 illustrates the change in the number of participants who were classified as hazardous cannabis use (CUDIT score of 8+) at baseline to 90 days after study enrollment (n = 72). Twenty-two participants (65%) in the TAU control group who responded to the follow-up survey indicated hazardous cannabis use at baseline, slightly decreasing to 21 participants (62%) at 90 days after study enrollment. Among respondents to the follow-up survey in the QLCU group, 28 participants (74%) indicated hazardous cannabis use at baseline, decreasing to 19 participants (50%) at 90 days after study enrollment. None of these differences in cannabis use were statistically significant.

Twenty-seven participants reported being quit from tobacco at their follow-up and were mailed a cotinine test kit. Ten of those participants returned results via an emailed photo of their results strip (37%; 7 from the QLCU group; 3 from the TAU control group). Seven of the ten participants returned pictures showing a negative result, confirming their quit. Two returned a picture of a positive cotinine test and reported continued NRT use. One returned a picture of a positive cotinine test and did not answer the question concerning NRT use.

**Table 4.** Participant Tobacco and Cannabis Use and Behaviors, Self-Reported 7-Day Point Prevalence Smoking Cessation Outcomes at 3 Months After Study Enrollment (n = 72).

	TOTAL SAMPLE (3-MONTH SURVEY RESPONDENTS: N = 72)		QUITLINE TREATMENT AS USUAL (TAU) (3-MONTH SURVEY RESPONDENTS: N = 34)		QUITLINE CHECK-UP INTERVENTION (QLCU) (3-MONTH RESPONDENTS: N = 38)		P-VALUE
	%	95% CI	%	95% CI	%	95% CI	
<b>Tobacco use and behaviors</b>							
Cigarettes per day <sup>a</sup> , among respondents	9.0 (4.9) (n = 46 respondents)		9.1 (5.2) (n = 20 respondents)		9.0 (4.7) (n = 26 respondents)		.95
Time to first use (within 5 mins) <sup>a</sup> , among respondents	29.8 (14/47)	[16.7, 42.9]	30.0 (6/20)	[10.0, 50.0]	29.6 (8/27)	[12.4, 46.8]	.99
<b>Cannabis use, behaviors, and readiness to change</b>							
Days of use within last 30 days, among respondents	21.1 (11.1)		23.2 (10.0)		19.1 (11.8)		.50
Daily use (20+ days in last 30 Days), among respondents	65.7	[54.7, 76.7]	73.5	[58.8, 88.2]	58.3	[42.6, 74.0]	.79
Cannabis use disorder identification test score (range 0-22); among respondents	8.1 (4.0)		8.9 (4.1)		7.4 (3.1)		.86
Hazardous cannabis use (CUDIT, score of 8+); among respondents	55.6	[44.2, 67.0]	61.7	[45.2, 78.2]	50.0	[34.1, 65.9]	.13
Readiness to quit cannabis (1-10 scale, 10 = very ready)	3.1 (3.1)		3.3 (3.4)		2.9 (2.9)		.91
Readiness to reduce cannabis use (1-10 scale, 10 = very ready)	4.3 (3.5)		4.0 (3.5)		4.5 (3.6)		.92
<b>Smoking status at 3-month survey (intent-to-treat analysis, missing response imputed as continued smoking)</b>							
Smoking abstinent 7+ days	26.5 (27/102)	[17.9, 35.1]	28.6 (14/49)	[15.9, 41.3]	25.5 (13/53)	[13.9, 37.1]	.45
<b>Smoking status at 3-month survey (3-month survey respondents)</b>							
Smoking abstinent 7+ days, among respondents	37.5	[26.3, 48.7]	41.2	[24.7, 57.7]	34.2	[19.1, 49.3]	.71

<sup>a</sup>Item asked only among those who reported continued smoking at 3-month survey. Note: Means and standard deviations are reported unless otherwise noted.



**Figure 2.** Number of participants reporting hazardous cannabis use (cannabis use disorder identification test – score 8+) at baseline to 3 Months after study enrollment (n = 72).

## Discussion

This randomized pilot study aimed to evaluate the feasibility and acceptability of a coaching intervention for tobacco cannabis co-users trying to quit smoking in the context of publicly funded tobacco QLs. This appears to be the first QL-based intervention targeting two substances (although tobacco remains the primary focus of treatment). QL callers are interested in quitting tobacco and are not necessarily thinking about their cannabis use when they enroll in QL services. Thus, a motivational enhancement approach to discussing cannabis use seemed appropriate. This new intervention was primarily aimed at assessing and discussing cannabis use patterns and highlighting those use habits with a negative impact on tobacco cessation goals. A secondary goal was to highlight problems related to cannabis use and provide feedback on comparing participants' use patterns to national norms, increasing motivation to decrease or quit cannabis.

This brief intervention was feasible to deliver using QL coaches who were provided modest amounts of training and supervision. Overall, participants were engaged with QL calls and were satisfied with the program, suggesting acceptability of integrating the intervention within state tobacco QLs. However, three-month results did not show any benefit to tobacco cessation from the intervention. The intervention was very brief and had to fit into the constraints of the publicly funded state QL format with calls averaging around 12 minutes. Only a minority of participants agreed with the premise of the intervention, that talking about cannabis use patterns might help them quit smoking. Given the low level of readiness to quit or reduce cannabis use at baseline, education about how cannabis use could interfere with quitting tobacco could have decreased self-efficacy. There is no evidence from this study that this type of discussion is helpful to co-users in general for increasing

cessation rates. Discussing cannabis use to increase tobacco cessation rates was a novel concept but may not increase cessation rates over and above a robust cessation program such as a QL program including multiple coaching calls and NRT.

Although only 9 days of cannabis use in the past 30 days was required to participate in the study, the average for the sample was 25 days of cannabis use in the past 30. Additionally, two-thirds of the sample reported hazardous cannabis use (defined as a score of 8 or higher on the CUDIT), which was higher than expected. All four of the participating quitlines were in locations with fully legalized cannabis use. Rates of cannabis use disorders have been reported to be increasing over time,<sup>35</sup> particularly in locations with fully legalized cannabis.<sup>36</sup>

Although this study was not powered to detect between-group differences in cannabis outcomes, the experimental intervention group did show some improvements in cannabis measures compared to the control group. It is difficult to measure cannabis use and days per month is a relatively crude indicator of use. However, participants in the QLCU groups decreased not only days per month of use, but there were also fewer daily users at follow up and the number of hazardous users decreased. While not statistically significant, results indicate the experimental intervention may have a clinical impact on decreasing hazardous cannabis use. These results need to be replicated in a larger study. The amount of time in the intervention spent on discussing cannabis use was quite brief and evidence-based components of the MJCU had to be condensed or removed to fit into the QL format. A more robust version of the intervention may see more impact on cannabis use.

This study recruited those who reported using cannabis by any method. In our clinical work with the participants, we noticed that those who exclusively used edible cannabis appeared a poorer fit for the intervention and did not want to

spend time discussing use. Edible-only users may be less likely to use cannabis in a way that affects tobacco use or smoking cessation.<sup>37</sup> On the other hand, smoking both cannabis and tobacco may increase risk as co-routes of administration, which may mean that each one serves as a cue or increases cravings for the other.<sup>38</sup> In addition to method of administration, reasons for use may also impact the need for an intervention like the one piloted here. For example, cannabis used specifically for sleep or nausea may be less likely to interfere with smoking cessation. In this pilot study, those who had a medical professional authorizing their cannabis use (and who did not report any non-medical use) were not included in the study. However, even when not authorized by a medical provider, some people may only use cannabis for a specific purpose. This study and future larger studies will shed light on who may need a tailored intervention.

Tailored QL interventions have been developed for other sub-groups of smokers, including for those with behavioral health conditions<sup>16</sup> and dual e-cigarette/conventional cigarette users.<sup>39</sup> Behavioral interventions are not often developed with practical dissemination in mind. Collins and colleagues<sup>40</sup> and others advise balancing intervention effectiveness with intervention affordability, scalability, and efficiency (EASE model). When interventions are developed with the end goal in mind (i.e., dissemination via the QL with QL coaches as part of a state funded QL program), they are more likely to meet criteria needed for a sustainable intervention (e.g., able to be delivered by QL coaches, brief, lower cost, acceptable to QL callers). However, this model has some limitations as discussed below.

The setting of the QL was both a strength and a limitation. While priming the intervention for dissemination, the intervention was of necessity very brief and conducted by tobacco quit coaches. It is unclear if a more intensive intervention conducted by treatment providers with more expertise in cannabis and in conducting motivational interventions might have different results. Similarly, as time was taken out of the tobacco intervention to include cannabis content, this could have diminished the impact of the intervention on tobacco cessation. Third, inclusion criteria for this study did not require participants to desire to change their cannabis use. In fact, readiness to change cannabis use was very low in both groups. As noted during call review, a few participants in the QLCU group were defensive about their cannabis use which may have impaired the coaches' ability to deliver the best tobacco intervention to those participants. Limiting this study to those open to changing their cannabis use may have had different results.

In conclusion, callers to QLs in four states with legalized cannabis who met criteria for a pilot study for cannabis tobacco co-users had high rates of daily cannabis use and low readiness to change their cannabis use. A brief motivational intervention integrated into a tobacco QL did not increase tobacco quit rates for cannabis co-users over and above the standard QL with nicotine replacement provided by the state, although it appeared

feasible and acceptable overall to QL participants. There was some promise that hazardous cannabis users who received the motivational intervention may moderate their use, although this was not statistically significant and needs to be replicated in a larger study. As more states fully legalize cannabis use, there may be a need for a similar coaching intervention for hazardous cannabis use.

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## Author contributions

KC, DW and BC conceived of the presented study. KC, DW, KM and HB drafted the manuscript. HB and KM developed tables and figures. KC, DW, BC and ES developed the experimental intervention. HJ designed the analysis and KM conducted the analyses. All authors provided critical feedback and contributed to the final manuscript.

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