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Tobacco use, cessation and related disparities among people living with substance use disorders and people living with mental illness

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Published in
Frontiers in Psychiatry

ISSN 1664-8714
ISBN 978-2-83252-133-5
DOI 10.3389/978-2-83252-133-5

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Tobacco use, cessation and related disparities among people living with substance use disorders and people living with mental illness

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Citation

Twyman, L., Kelly, P. J., Mathew, A. R., Taylor, G. M. J., eds. (2023). *Tobacco use, cessation and related disparities among people living with substance use disorders and people living with mental illness*. Lausanne: Frontiers Media SA. doi: 10.3389/978-2-83252-133-5

Table of contents

frontiers | Frontiers in Psychiatry

ORIGINAL RESEARCH
published: 06 April 2022
doi: 10.3389/fpsyt.2022.868550

Evaluating Simulation-Based Tobacco Treatment Scenarios for Providers Delivering Treatment for People Living With Mental Illnesses

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Background: People living with mental illnesses (PMI) experience elevated tobacco use and related morbidity and mortality. Despite the availability of effective and safe tobacco treatments along with evidence that PMI are motivated and able to quit successfully, few Mental and behavioral healthcare providers (MHPs) engage PMI in such treatment. MHPs may lack the confidence or skills to engage their clients in tobacco treatment. Currently, there are limited training modalities to prepare MHPs in delivering tobacco treatment for PMI. However, animated scenario-based simulated encounters can bridge this gap to effectively provide tailored MHP training to enhance treatment delivery. Hence, the purpose of this study was to evaluate simulated tobacco treatment education scenarios tailored to MHPs.

Methods: For this evaluation, we used a pretest-posttest design to assess changes in MHPs tobacco treatment knowledge and behavioral intentions after viewing simulated treatment encounters. We developed four animated scenarios, using brief tobacco treatment interventions, simulating treatment encounters with PMI. MHPs were primarily recruited from mental or behavioral healthcare facilities and were asked to complete a web-based questionnaire. Their knowledge, views, and experiences in providing tobacco treatment were assessed prior to viewing the animated scenarios. Participants were then asked to evaluate the desirability, acceptability, and applicability of the animated scenarios; and thereafter, their knowledge of and intentions to provide evidence-based tobacco treatment (i.e., ASK, ADVISE, ASSESS, ASSIST, ARRANGE) were again assessed.

Results: Participants ($N = 81$) were on average 41.0 years of age, mostly female (79.0%), and non-Hispanic White (86.4%). Nearly a quarter endorsed current tobacco use and few had tobacco treatment training (14.8%). Overall knowledge of tobacco treatment scores significantly increased before and after viewing the videos ($M = 3.5$ [SD = 1.0] to $M = 4.1$ [SD = 1.0], $p < 0.0001$). After viewing the simulated scenario videos, participants endorsed moderate to high mean scores (ranging from 4.0-4.2 on a 0 to 5 scale) on the desirability, acceptability, and applicability of the different animated scenarios. In addition, after viewing the scenarios the proportion of participants

OPEN ACCESS

Edited by:
Laura Twyman, Cancer Council New South Wales, Australia

Reviewed by:
Catherine Hayes, Boston University, United States
Masuma Pervin Mishu, University of York, United Kingdom

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Specialty section:
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

Received: *02 February 2022*
Accepted: *15 March 2022*
Published: *06 April 2022*

Citation:
Okoli CTC, Otachi JK, Seng S, Abufarsakh B and Williams LB (2022) Evaluating Simulation-Based Tobacco Treatment Scenarios for Providers Delivering Treatment for People Living With Mental Illnesses. Front. Psychiatry 13:868550. doi: 10.3389/fpsyt.2022.868550

who endorsed that they intended to occasionally/very often engage clients in evidence based tobacco treatment were high for ASK (94.9%), followed by ADVISE and ASSESS (84.7% each), followed by ASSIST (81.4%), and ARRANGE (74.6%). Evaluation scores significantly differed by type of animated scenario and participants' work settings and discipline.

Conclusions: These findings suggest that the use of brief animated scenarios may be a useful modality to enhance MHPs knowledge acquisition and treatment delivery intentions. Such approaches may be integrated into tobacco treatment trainings for MHPs.

Keywords: tobacco treatment, animated scenarios, mental health, behavioral health (BH) patients, substance use

INTRODUCTION

After over 50 years of promoting and testing tobacco control efforts in the United States (U.S.), there is equivocal science on what is most essential for successful tobacco control. These essential elements, summed up in the pillars of tobacco control endorsed by the Centers for Disease Control and Prevention (CDC), include preventing initiation, promoting cessation, eliminating secondhand tobacco smoke exposure, and de-normalizing tobacco use as a behavior (1). In terms of promoting cessation, healthcare delivery systems are strongly encouraged to adopt evidence-based tobacco treatment practices. These practices include multi-faceted approaches that support consumers by providing tobacco cessation pharmacotherapy, supporting behavioral counseling, and enacting organizational policies that promote best practices, such as tobacco-free policies (2). Adopting such strategies has been instrumental in curbing tobacco prevalence in the U.S., reducing the percentage of adult smokers from about 25% in 2002 to 14% in 2019 (3, 4).

Unfortunately, adoption of proven evidence-based practices has been particularly challenging within the mental and behavioral healthcare system in the U.S. Due to these gaps in integrating evidence-based tobacco treatment approaches within mental healthcare systems, people living with mental illnesses (PMI) experience disproportionate tobacco use prevalence, morbidity, and mortality as compared to the general population (5). For example, compared to people without mental illnesses, PMI have 2-3 times the tobacco use prevalence, higher rates of cardiovascular and lung disease, and die on average 10–25 years prematurely (5–8).

These disproportionate tobacco-related challenges among PMI persist despite the increasing evidence of the benefits associated with tobacco cessation on mental health outcomes (9). In fact, only 48.6% of mental healthcare systems in the U.S. have smoke-free policies and only 21.5–48.9% have treatment policies supporting evidence-based tobacco cessation interventions (10–12). Moreover, the delivery of evidence-based tobacco treatment within mental healthcare settings faces multi-faceted challenges including patient barriers (e.g., stressors that are relieved by tobacco use), mental healthcare provider (MHP) barriers (e.g., being poorly equipped to provide tobacco treatment and believing patients are not interested in quitting) and organizational barriers (e.g., lack of training for clinicians and staff) (13–15). Therefore, examining approaches that facilitate provider delivery of tobacco treatment may guide the development of effective strategies to enhance tobacco treatment engagement for PMI.

Prior research suggests that provider delivery of evidence-based tobacco treatment can be enhanced through targeted training (14, 16). In fact, targeted training in tobacco treatment increases healthcare providers' confidence in and delivery of tobacco treatment (17). Animated scenario-based simulated encounters may be an effective method to provide tobacco treatment education in mental health settings (18, 19). Simulation-based trainings may have the advantage of reaching a wide audience through cost-effective and resource efficient means, as compared to traditional face-to-face trainings (20–22). Developing and evaluating such simulated encounters can demonstrate their utility as training tools for MHPs.

The purpose of this study was to evaluate simulated tobacco treatment education scenarios tailored to MHPs. Specifically, we aimed to:

1) Assess providers' ratings on the desirability, applicability, and acceptability of simulated tobacco treatment scenarios, and
2) Examine changes in provider knowledge of tobacco use and treatment among PMI after engaging in the simulated treatment scenarios, and
3) Determine provider intentions to provide evidence-based tobacco treatment after engaging in the simulated treatment scenarios.

This evaluation may guide future research and practice regarding the use of simulated scenarios as tools for MHP tobacco treatment training.

METHODS

Study Design

This evaluation study employed a single-group pre/post-test design to examine changes in provider knowledge about tobacco use treatment among PMI after engaging in simulated scenario videos. In addition, a post-test only design was used to examine providers' intentions regarding delivery of evidence-based

tobacco treatment after watching the videos. A targeted sample of MHPs for the study was obtained through purposive sampling.

Study Population

Our research team contacted Key leadership within the Community Mental Health Centers (CMHCs) and targeted behavioral healthcare organizations to request permission to recruit providers for the evaluation. To determine the utility of the scenarios across disciplines and roles we targeted four different disciplines: prescribers, (e.g., physicians and nurse practitioners), counselors/therapists, nurses, and social workers for information. Our recruitment goal was 80 providers with a minimum of five from each discipline and role to obtain an estimated 20 providers per scenario. We recruited providers from 13 CMHCs, two outpatient behavioral health treatment programs, two inpatient behavioral health programs, and one substance use treatment programs for women. To support survey completion, the main contacts from each organization were sent an email reminder every two weeks throughout the data collection timeframe from June 1st to October 31st, 2021.

Intervention

Certified tobacco treatment specialists with extensive experience treating PMI and training other healthcare providers developed the four scenarios. Each scenario was developed to simulate the experience of an initial tobacco treatment encounter with a PMI. The scenarios were further tailored to specific PMI populations based on our extensive work on exploring the unique cessation needs voiced by PMI and MHPs who deliver care to them (14, 23–27). We then obtained face validity of the scenarios through review by other tobacco treatment specialists and healthcare providers for PMI.

Each scenario was ∼22–27 min in duration and comprised of two parts. Part A consisted of a 2–3 min general information regarding the prevalence of factors associated with tobacco use in specific PMI and treatment approaches for addressing tobacco dependence. The specific PMI populations were: Attention Deficit Hyperactivity Disorder (ADHD), Schizophrenia Spectrum Disorder (SSD), Major Depressive Disorder (MDD), and Substance Use Disorders (SUDs). Part B consisted of a 20–24 min animated scenario of a provider engaging a PMI in evidence-based tobacco treatment modeled after the 5As (Ask, Advise, Assess, Assist, Arrange) framework (28). Special care was taken to include diversity in terms of gender, age, ethnicity, and type of setting (i.e., inpatient psychiatric setting vs. outpatient setting) when developing the scenarios. The four scenarios can be viewed here:

1) SSD: https://www.youtube.com/watch?v=Tor9OIg5Ap0&list=PLYHtV_ZWwXeBtPD5ZjFRNLcjnQl24KR5E&index=4&t=0s
2) MDD: https://www.youtube.com/watch?v=_loAkQ3zDzM&list=PLYHtV_ZWwXeBtPD5ZjFRNLcjnQl24KR5E&index=6
3) ADHD: https://www.youtube.com/watch?v=g1BgpvVBVGI&list=PLYHtV_ZWwXeBtPD5ZjFRNLcjnQl24KR5E&index=4
4) SUDs: https://www.youtube.com/watch?v=YGxxyW1Bzxw&list=PLYHtV_ZWwXeBtPD5ZjFRNLcjnQl24KR5E&index=3~

Procedure

Approval was obtained from the relevant institutional boards governing the conduct of research with human subjects. We then sent a standardized email containing a link to the administrative staff of the participating organizations, who then sent the link through provider listservs. Participants were re-assured that their responses, recorded through the encrypted survey platform Qualtrics were anonymous. For those who indicated interest in participating, an informed consent form with detailed information about the study was provided to participants. If the participant clicked on "I consent" after reading the consent form, they were directed to the survey. Completion of the evaluation survey was ∼30–40 min, comprising of a pre-test questionnaire (∼5–7 min), the scenario (∼22–27 min), then completing a post-test questionnaire (∼5 min). Participants who completed the survey and evaluated the simulated scenarios were provided a $50 incentive.

To obtain a diversity of opinions while considering the salience of each scenario, we randomly distributed the four scenarios among the CMHCs to obtain information from this unique context. Each scenario was further sent to targeted settings given the specific population of interest in the scenario. For example, the scenario which depicted tobacco treatment with a patient with SSD being discharged from an inpatient hospital stay was sent to MHPs at two inpatient psychiatric settings and the scenario in which an adolescent with ADHD is being treated for use of juuls was sent to MHPs in a behavioral health program that specializes in the treatment of children, adolescents, and families. Furthermore, the scenario which depicts a young lady with MDD was sent to MHPs in outpatient behavioral health programs. Finally, the scenario of a young mother who has SUD was also sent to MHPs serving at residential substance use treatment programs for mothers.

Measures

Demographic data included age, sex, education (less than college vs. college graduate), race and ethnicity.

Provider and Practice Characteristics

Provider and practice characteristics included information on job role (Prescriber [MD/APRN], Nurse [LPN/RN] Social Worker [LSW/LCSW] vs. Psychologist/Counselor [LPCC/LMFT] vs. other), practice setting (CMHC vs. Outpatient Behavioral Health/Residential Recovery vs. Inpatient Behavioral Health vs. other), primary population served (adults vs. pediatrics vs. women) and work tenure in months.

Tobacco Use and Treatment Experience

Participants were also asked about their tobacco use in the last 30 days (yes vs. no), receipt of prior tobacco treatment training (yes vs. no), and the frequency of their delivery of the 5As on a scale of 0 = never to 3 = very often. For analysis, the frequency

of delivery of each component of the 5As were categorized into 0 = never/seldom and 1 = occasionally/very often.

Desirability, Applicability, and Acceptability Ratings of Animated Simulated Tobacco Treatment

To assess each component of the simulated scenario, we used measures similar to those used in a previous study (23). We asked the following question:

"We would like your opinions about this video we have developed to train providers on evidence-based tobacco treatment tailored to a patient/client living with [specific mental illness]. We would like you to rank the video on a scale of 0 to 5, based on how much you see it as desirable, applicable, and acceptable to you and other providers caring for people with [specific mental illness]. We explained desirable as "something you would want to hear/learn about"; applicable as "something that is useful to you/you could use" and acceptable as "something that would gain your interest/would make you seek more information". The mean scores on the desirability, applicability, and acceptability ratings of the information component (part A), the evidence-based tobacco treatment components (part B), and an assessment of the use of animation were used to evaluate the simulated scenarios.

Knowledge of Tobacco Use and Treatment in Specific PMI Populations

For each scenario, a five-item knowledge questionnaire was developed with 'true/false' response choices to elicit specific information provided in the part A of each scenario. For example, for the SSD scenario, the questions were as follows:

1. People with schizophrenia are equally as likely to use tobacco as compared to the general population.
2. Nicotine from tobacco use is not addictive and causes agitation for people with schizophrenia.
3. People with schizophrenia are more likely to use tobacco because of permissive attitudes of providers to tobacco use within behavioral health settings.
4. People with schizophrenia are unable to stop using tobacco because no evidence exists in ways to help them.
5. Tobacco use can reduce the effectiveness of medications used to treat schizophrenia.

Each question was tailored to the specific MI addressed in the corresponding video. The same questions were asked before and immediately after participants watched the videos. Mean summary scores of the questions were obtained. Also, proficiency measurements were derived by determining individuals scoring 4 of 5 questions correct (i.e., 80%).

Intentions to Provide Evidence-Based Tobacco Treatment

After watching the videos, participants were asked about their intentions to provide tobacco treatment using the 5 As model as follows: "In your practice role, how often do you anticipate that you will:

1. ASK patients/clients whether they smoke cigarettes or use other tobacco products?
2. ADVISE patients/clients who smoke or use tobacco products to quit?
3. ASSESS the readiness of patients/clients who smoke or use other tobacco products to quit or cut down?
4. ASSIST patients/clients in stopping smoking/tobacco use by providing medications and/or counseling?
5. ARRANGE for patients/clients to be referred to smoking/tobacco use cessation services or follow up with them on their abstinence?

Each question had a response choice of 0 = never to 3 = very often. For analysis, the frequency of anticipated delivery of each component of the 5As were categorized into 0 = never/seldom and 1 = occasionally/very often.

Data Analysis

Eighty-one participants provided response to the main outcomes of the evaluation survey. Of these respondents, 77 (95.1%) provided an evaluation of the scenarios and 59 (72.8%) provided complete responses to both the pre-test and post-test questions. Moreover, three participants did not provide their age, but provided their years of practicing in the discipline. Conservatively, we estimated their age by assuming they started practicing in their discipline at the age of 22. For example, a respondent who indicated that they had practiced in the discipline for 27 years but did not provide their age was assumed to be 49 years of age.

Descriptive statistics, including means with standard deviations or frequencies with percentages, were used to describe the sample as appropriate. Differences in demographic variables by the four scenarios among respondents were examined using Chi-Square analyses or Analysis of Variance (ANOVAs). Furthermore, differences in providers' scores on knowledge and practices regarding tobacco treatment by job role and work setting were examined using chi-square analyses and ANOVAs. Providers' ratings on the desirability, applicability, and acceptability of simulated tobacco treatment scenarios were examined by scenario, job role and practice setting using ANOVAs. Changes in provider tobacco treatment knowledge and proficiency scores before and after the simulated scenario training were assessed using paired-sample *t*-tests and McNemar tests, respectively. Finally, frequencies and percentages were used to describe providers' frequency of and intentions to deliver tobacco treatment prior to and after watching the simulated scenarios. Analyses were performed using IBM-SPSS Statistics version 28 (29) with a selected significance level of alpha = 0.05.

RESULTS

Sample Characteristics

Table 1 provides a description of the 81 respondents. Survey respondents were on average 40.1 (SD = 9.0) years of age and primarily female (79.0%), college graduates (96.3%), and identified as White non-Hispanic (86.4%). On average participants had worked for 101 (SD = 84.7) months in their discipline, worked in CMHCs (43.2%), were nurses (29.6%) or social workers (27.2%), and served adult populations (69.1%).

TABLE 1 | Sample characteristics by simulated scenario.

	Total ($N = 81$)		ADHD ($n = 18$)		Depression ($n = 17$)		Schizophrenia ($n = 22$)		SUD ($n = 24$)	
	n	%	n	%	n	%	n	%	n	%
Female	64	79.0	11	61.1	16	94.1	16	72.7	21	87.5
College graduate	78	96.3	17	94.4	16	94.1	22	100.0	23	95.8
Ethnicity/race										
White Non-hispanic	70	86.4	17	94.4	14	82.4	17	77.3	22	91.7
Black Non-hispanic	7	8.6	1	5.6	2	11.8	3	13.6	1	4.2
Asian/pacific islander	4	4.9	0	0.0	1	5.9	2	9.1	1	4.2
Job role/License										
Prescriber[a] (MD/APRN)	17	21.0	5	27.8	7	41.2	1	4.5	4	16.7
Nurse (LPN/RN)	24	29.6	3	16.7	3	17.6	12	54.5	6	25.0
Social worker (LSW/LCSW)	22	27.2	5	27.8	4	23.5	5	22.7	8	33.3
Psychologist/counselor (LPCC/LMFT)	12	14.8	4	22.2	2	11.8	5	18.2	2	8.3
Other (administration/peer specialist)	6	7.4	1	5.6	1	5.9	0	0.0	4	16.7
Tobacco treatment training	12	14.8	3	16.7	3	17.6	1	4.5	5	20.8
Practice setting* **										
CMHC	35	43.2	14	77.8	7	41.2	3	13.6	11	45.8
Outpatient behavioral health/residential recovery	11	13.6	2	11.1	3	17.6	1	4.5	5	20.8
Inpatient behavioral health	28	34.6	2	11.1	5	29.4	18	81.8	3	12.5
Other (Health Clinic/Private Practice)	7	8.6	0	0.0	2	11.8	0	0.0	5	20.8
Primarily populations* **										
Adults	56	69.1	10	55.6	13	76.5	21	95.5	12	50.0
Pediatrics	11	13.6	8	44.4	2	11.8	1	4.5	0	0.0
Women	14	17.3	0	0.0	2	11.8	0	0.0	12	50.0
Current use of tobacco products	18	22.2	4	22.2	4	23.5	4	18.2	6	25.0
Age in years (M/SD)	40.1	9.0	37.1	8.8	42.4	8.3	38.9	9.8	41.7	8.6
Work tenure in months (M/SD)	101.1	84.7	102.4	90.8	96.4	69.2	76.5	69.3	126.1	99.4

[a]*Only two physicians/psychiatrists responded to the survey among prescribers. The remaining respondents were APRNs.*

****p < 0.0001 (based on Chi-square analyses for categorical variables or ANOVAs for continuous variables).*

MD, Doctor of Medicine; APRN, Advanced Practice Registered Nurse; LPN, Licensed Practical Nurse; RN, Registered Nurse; LSW, Licensed Social Worker; LCSW, Licensed Clinical Social Worker; LPCC, Licensed Professional Clinical Counselor; LMFT, Licensed Marriage and Family Therapist.

Few participants had tobacco treatment training (14.8%), and nearly a quarter were current tobacco users. There were significant differences in practice setting and populations served by simulated scenarios. A larger proportion of respondents evaluating the ADHD scenario were from CMHCs and the majority of those evaluating the schizophrenia scenario served the adult population.

Provider's Ratings on the Desirability, Applicability, and Acceptability of Scenarios

Our analyses of the tobacco use and mental illness specific information per scenario revealed moderate to high scores on each of providers' desirability, applicability, and acceptability for the information about tobacco use and mental illness (i.e., part A), the evidence-based components of each of the scenarios, and the use of animation for the videos. However, mean scores were lowest on the *overall use of animation* for the Schizophrenia videos. There were significant differences in the total mean rating scores of the simulated scenarios in the ASK and ARRANGE components of the videos (see **Table 2**).

Changes in Provider Knowledge of Tobacco Use and Treatment

Among participants who responded to both the pre- and post-test knowledge questions ($n = 59$), we found significant increases in knowledge and proficiency scores (see **Table 3**). By scenario type, there were significant improvements in knowledge scores in the schizophrenia and SUD scenarios, and proficiency scores improved in the schizophrenia scenario. By work setting, there were significant increases in knowledge and proficiency scores in the inpatient setting only. Finally, among providers, nurses had an overall significant increase in knowledge scores.

Providers Intentions to Practice Evidence-Based Tobacco Treatment

Among participants who responded to both the pre- and post-survey questions ($n = 59$), the proportion of reported current practice (occasional/very often) of evidence-based tobacco

TABLE 2 | Mean rating scores on simulated scenarios by scenario type ($n = 77$).

		Part A: Information about tobacco use and mental illness	Part B: Evidence-based tobacco treatment components					Overall use of animation for the scenarios
Scenario	**n**	**mean (SD)**	**ASK mean (SD)**	**Advise mean (SD)***	**Assess mean (SD)**	**Assist mean (SD)**	**Arrange mean (SD)***	**Mean (SD)**
ADHD	17	4.1 (0.8)	4.2 (0.8)	4.2 (0.8)	4.3 (0.8)	4.4 (0.7)	4.2 (0.7)	4.2 (0.9)
Depression	16	4.0 (1.0)	4.3 (0.8)	4.3 (0.7)	4.4 (0.6)	4.3 (0.6)	4.4 (0.7)	4.1 (0.8)
SSD	21	4.0 (0.6)	3.8 (0.6)	3.6 (0.7)	4.0 (0.7)	3.9 (0.6)	3.7 (0.8)	3.6 (1.0)
SUD	23	4.3 (0.5)	4.2 (0.8)	4.2 (0.8)	4.1 (0.9)	4.1 (0.8)	4.1 (0.8)	4.2 (1.1)
Total	77	4.1 (0.7)	4.1 (0.8)	4.1 (0.8)	4.2 (0.7)	4.1 (0.7)	4.1 (0.8)	4.0 (1.0)

*ADHD, Attention Deficit Hyperactivity Disorder; SSD, Schizophrenia Spectrum Disorder; SUD, Substance Use Disorder. *$p < 0.05$.*

TABLE 3 | Pretest and posttest knowledge and frequency of providing tobacco treatment scores by scenario, setting, and provider type ($n = 59$).

		Knowledge score		Proficiency	
Scenario type	**n**	**Pretest *M* (SD)**	**Posttest *M* (SD)**	**Pretest *n* (%)**	**Posttest *n* (%)**
ADHD	14	3.8 (1.1)	3.9 (1.1)	10 (71.4)	9 (64.3)
Depression	16	3.8 (0.7)	4.3 (0.8)	11 (68.8)	13 (81.3)
SSD**†	13	3.2 (1.0)	4.4 (1.1)	5 (38.5)	11 (84.6)
SUD*	16	3.4 (1.2)	4.0 (1.1)	8 (50.0)	11 (68.8)
Work setting					
CMHC	25	3.9 (0.9)	4.1 (1.1)	19 (76.0)	17 (68.0)
Outpatient	10	3.5 (0.7)	4.0 (1.1)	4 (40.0)	7 (70.0)
Inpatient***††	19	3.1 (1.0)	4.2 (1.0)	8 (42.1)	16 (84.2)
Other	5	3.4 (1.5)	4.2 (0.8)	3 (60.0)	4 (80.0)
Provider type					
Prescriber	11	3.7 (0.6)	4.2 (0.9)	7 (63.6)	8 (72.7)
Nurse**	18	3.3 (1.0)	4.2 (1.0)	9 (50.0)	14 (77.8)
Social worker	16	3.9 (1.0)	4.3 (1.0)	11 (68.8)	14 (87.5)
Psychologist/counselor	8	3.6 (1.2)	3.9 (1.2)	6 (75.0)	4 (50.0)
Other	6	2.8 (1.0)	3.8 (1.2)	1 (16.7)	4 (66.7)
Total*†	**59**	**3.5 (1.0)**	**4.1 (1.0)**	**34 (57.6)**	**44 (74.6)**

*Based on paired sample t-tests for knowledge scores *$p < 0.05$; **$p < 0.01$, ***$p < 0.001$.*
Based on McNemar tests for proficiency scores †$p < 0.05$, ††$p < 0.01$.
ADHD, Attention Deficit Hyperactivity Disorder; SSD, Schizophrenia Spectrum Disorder; SUD, Substance Use Disorder.

treatment was highest for ASK (86.4%), followed by ASSESS (72.9%), followed by ADVISE and ASSIST (64.4% each), and ARRANGE (54.2%). After engaging in the simulated scenario, the proportion of those who intended to practice evidence-based tobacco treatment increased in each component (see **Figure 1**).

DISCUSSION

The purpose of this study was to evaluate a pilot intervention designed to improve MHPs' knowledge about tobacco use and mental illnesses and evidence-based practice in tobacco treatment. To our knowledge, ours is the first study to assess the use of animated simulated scenarios to enhance knowledge and intentions to provide tobacco treatment. This evaluation of the intervention yielded acceptable scores, suggesting that the intervention is desirable, acceptable, and applicable to MHPs. Moreover, engagement in the intervention resulted in overall increased knowledge scores, proficiency, and intentions to provide evidence-based practice. These findings provide preliminary support for use of simulated tailored tobacco treatment scenarios as an avenue for provider education and training.

Participants provided moderate to high mean scores on the desirability, acceptability, and applicability scale. Our findings are consistent with a prior qualitative study that used similar scales to evaluate the components of tailored tobacco treatment programs for patients with SSD (23). Furthermore, the lowest quality rating

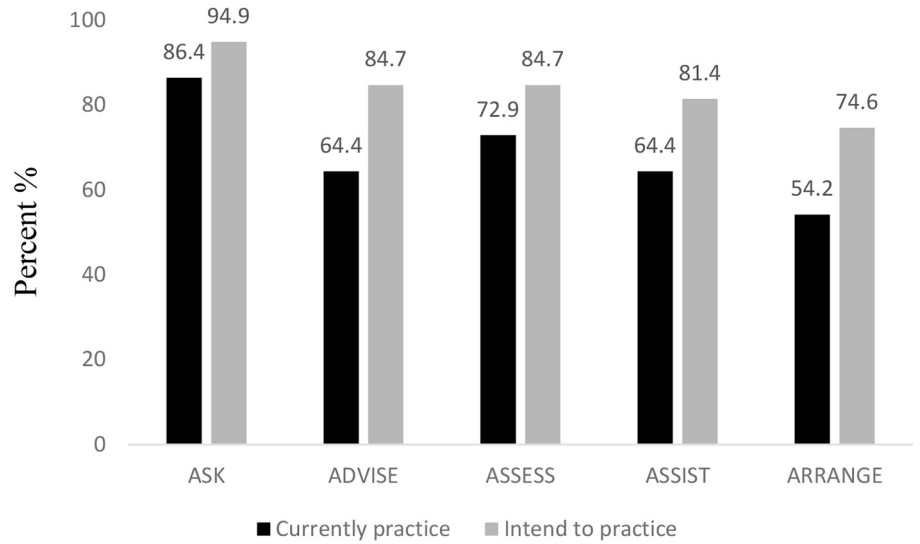

FIGURE 1 | Providers' current and intended practice (occasional/very often) of evidence-based tobacco treatment before and after engaging in the simulated scenarios.

for the use of animation was observed with the SSD scenario and the highest with the ADHD scenario. This difference may be explained in that the SSD scenario was rated primarily by adult providers, whereas the ADHD scenario was rated by mostly pediatric providers. This finding may warrant further qualitative explorations of differences in appeal of scenario delivery format (i.e., cartoon-based animation versus realistic depictions) based on the age of the populations served by the MHPs.

In addition, we found that the simulated scenario intervention resulted in immediate post-test changes in knowledge scores related to tobacco use and treatment in specific MI populations. A previous study found that tobacco treatment training increases knowledge, competency, and self-efficacy in tobacco treatment delivery by MHPs (30). Moreover, a more recent study assessing the use of virtual simulation to enhance counseling skills for alcohol dependence treatment among social work master's level students found that engagement in the simulation-based training resulted in improved self-efficacy and general clinical skills (31). In a similar fashion, our study findings provide some level of validation for the use of animated scenarios to enhance knowledge acquisition and intentions to change practice. Future studies with larger samples are needed to assess the use of these scenarios on a wider scale.

A few important limitations are necessary to properly consider the implications of our findings. First, this pilot study used a pre-post study design with only one post-test after the intervention. This design limits our ability to determine sustained changes in the knowledge acquisition or behavioral intentions observed in our study. Future studies using longitudinal assessments beyond the single post-test may better determine the prolonged impact of the intervention. Second, there was limited representation by counselors and other types of MHPs in the study sample. We had fewer than five providers from a particular specialty evaluating some scenarios. Our goal was to have at least five providers from among prescribers, counselors/ therapists, nurses, and social workers. Due to our recruitment process, the survey link for the evaluation may have been shared by participants to other non-MHPs who were not our main target (e.g., women's health providers evaluating the depression simulated scenario). Future studies should target specific provider groups with adequate samples to better evaluate the intervention effect. Also, the study sample underrepresented individuals from outpatient behavioral health and residential recovery settings. Targeting such sites can improve our knowledge of the impact of these scenarios across different settings. Third, it is important to note that few of the providers had prior training in tobacco treatment and about a fifth were tobacco users. Hence, given that providers who use tobacco are less likely to treat tobacco users (32, 33), our findings may have been affected by the tobacco use behaviors of the participants. Finally, the MHPs in our study were primarily female and were from a single geographic location. Hence, we cannot generalize the findings to other settings. Future studies may incorporate a random sampling of MHPs from different geographic areas to further determine the effectiveness of the scenarios in enhancing knowledge and practices.

In conclusion, ours was the first to evaluate the use of animated scenarios for tobacco treatment among MHPs. Given the exorbitant toll of tobacco use disorders among PMI, it is critical to determine easily accessible and innovative methods to enhance MHPs' training in tobacco treatment delivery. Using animated simulated scenarios of evidence-based treatment may be an option of quick delivery with easy access. Future studies are needed to further evaluate the use of such simulated scenarios across different MHPs and in broader settings. Such studies can yield valuable knowledge to enhance interventions to address the disproportionate tobacco use and disease burden among PMI.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Kentucky Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

CO conceived of the study, completed all data analysis, and developed the results section. JO developed the surveys, assisted with the development of the study, reviewed, and revised drafts of the manuscript. SS and BA drafted the introduction, measures section, assisted with drafting, and reviewing the discussion section. LW provided intellectual contribution throughout the manuscript, reviewed, and revised the final drafts. All authors contributed to the article and approved the submitted version.

FUNDING

Research reported in this presentation was supported, in part, by the Cabinet for Health and Family Services, Department for Public Health Tobacco Prevention and Cessation Program under Agreement titled Enhancing Tobacco Dependence Treatment in Community Mental Health Centers.

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BRIEF RESEARCH REPORT
published: 26 May 2022
doi: 10.3389/fpsyt.2022.853001

Tobacco Treatment Outcomes for Hospital Patients With and Without Mental Health Diagnoses

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OPEN ACCESS

Edited by:
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Reviewed by:
Suwa Goden Goar, University of Jos, Nigeria
Martin Zack, University of Toronto, Canada
Saeed Ahmed, Rutland Regional Medical Center, United States

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Specialty section:
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

Received: *11 January 2022*
Accepted: *27 April 2022*
Published: *26 May 2022*

Citation:
Sanford BT, Toll BA, Palmer AM, Foster MG, Cummings KM, Stansell S and Rojewski AM (2022) Tobacco Treatment Outcomes for Hospital Patients With and Without Mental Health Diagnoses. Front. Psychiatry 13:853001. doi: 10.3389/fpsyt.2022.853001

Background: The prevalence of mental health conditions is higher in cigarette smokers than nonsmokers. However, those with diagnosed mental health disorders are understudied within general inpatient hospital settings. This study seeks to evaluate how having a mental health diagnosis influences response to a brief opt-out inpatient tobacco treatment intervention.

Methods: Data included 4,153 admitted patients who completed a tobacco treatment visit. Post-discharge self-reported abstinence was obtained via response to an automated call 1-month after discharge. Mental health co-morbidities were assessed by reviewing electronic medical records. Logistic regression was used to assess associations between having a mental health diagnosis and patients' smoking history, interest in quitting smoking, and post-discharge abstinence.

Results: Overall 34.1% of patients were diagnosed with mental health disorders, most commonly depression or substance use disorders. Patients with a diagnosed mental health disorder were more likely to report a history of long-term heavy smoking and were less likely to express an interesting in remaining abstinent from smoking after hospitalization. An intent-to-treat analysis using logistic regression analysis found lower rates of self-reported smoking abstinence in those with a mental health disorder compared to those without (9 vs. 13.2%, $p < 0.001$).

Conclusions: Patients with a history of mental health diagnoses, such as depression or substance use disorders, was associated with lower rates of smoking abstinence in patients after hospitalization. Hospital based opt-out smoking cessation programs have shown to be generally effective and efficient. However, certain subpopulations may require tailored intervention in order to improve treatment outcomes. Future research is needed to develop brief, effective tobacco treatment for hospital patients with comorbid mental health diagnoses.

Keywords: smoking cessation, mental health, tobacco, inpatient, opt-out

INTRODUCTION

According to the U.S. Department of Health and Human Services, 14 out of every 100 U.S. adults smokes cigarettes (1) which equates to approximately 34.1 million Americans at the time of this writing. However, tobacco use is not evenly distributed across the population. Those with diagnosed mental health or substance use disorders are nearly three times as likely to smoke compared to those without [41%; (2, 3)]. Rates of smoking among those diagnosed with schizophrenia have been shown to be ∼62% (4, 5). While rates of smoking have been generally declining at a population level, this is not true of those with psychiatric comorbidity (6) across domains of mental health problems. Approximately 20% of US adults have a current mental health problem (7), and this group has been estimated to consume between 44 and 50% of all cigarettes in the United States (8). Unfortunately, those with mental health conditions are significantly less likely to quit smoking (9) and psychiatric patients' tobacco dependence is rarely addressed in routine clinical practice (10, 11), despite efforts focused on tobacco cessation being associated with improved mental health (12, 13). This is especially important as those with serious mental illness suffer premature mortality rates predominately caused by cardiovascular and respiratory diseases (14, 15).

One initiative to address hospital-based smoking cessation rates at a population level is that of brief opportunistic opt-out interventions where treatment is provided as standard procedure for all patients who smoke rather than by patient request (16). This type of approach address the needs of underserved populations who may not otherwise have access to tobacco treatment interventions. However, there remains a dearth of information regarding the relative effectiveness of these brief interventions with those diagnosed with mental health conditions. Aside from specialty clinical trials focused on patients with mental health conditions, those with mental health diagnoses are usually excluded from general tobacco treatment trials and represent a relatively understudied population within the field of smoking cessation (17).

The present study aims to evaluate the effectiveness of a brief tobacco treatment intervention among a large, hospitalized sample treated by the Tobacco Treatment Program (TTP) at the Medical University of South Carolina. Results from these analyses will provide data regarding the adequacy of services delivered for this population and suggest future directions for improving outcomes among priority populations.

METHODS

Tobacco Treatment Procedures

Inpatient tobacco treatment services at the hospital are provided via an opt-out system whereby counselors identify and provide services to all patients admitted to the hospital with a reported history of tobacco use. Interventions include a structured assessment interview, brief counseling, and pending smoking cessation pharmacotherapy (e.g., nicotine replacement therapy) orders for physicians to facilitate while inpatient and at discharge. Bedside counseling includes motivational interviewing and practical counseling strategies. Patients are then enrolled in an automated, interactive voice recognition telephone protocol, which calls them at 3, 14, and 30 days following discharge. Smoking status is assessed at these calls, and patients are offered a referral to outpatient counseling or the South Carolina Quitline. Visit notes are recorded in the electronic health record (Epic). This program has demonstrated clinical efficacy in improving treatment outcomes, reducing readmissions, and cutting costs (16).

Participants

All data were collected as part of routine treatment of general hospital patients within the TTP at Medical University of South Carolina (18). Patients admitted to the inpatient psychiatric hospital were excluded as routine opt-out treatment was not available for the duration of the data collection period.

Chart data were retrieved from patients who were admitted between July 2014 and December 2019. Patients who endorsed cigarette smoking, agreed to the bedside intervention, and accepted enrollment into the interactive voice recognition system were included in the present analysis. Of those identified, patient medical record numbers were used to obtain data on history of mental health conditions. Follow-up data were collected through review of patients' responses to the automated telephone system 30-days following discharge.

Measures

Medical Chart Data

Patients' age, race, and biological sex were obtained from the electronic health record note (TTP encounter) during admission. History of mental health conditions on day of admission was obtained from the electronic health record (i.e., "problem list") via an internal data request. Mental health diagnoses were then grouped into one of the following broad diagnostic categories: Depression, Anxiety, PTSD, chronic pain, childhood developmental disorder, serious mental illness, personality disorder, alcohol use disorder, or substance use disorder. Serious mental illness was defined as including the following diagnostic categories (1) schizophrenia, (2) bipolar disorder, (3) severe depression with psychotic features, (4) eating disorders.

Smoking Characteristics

TTP clinicians asked patients to report on how long they had been smoking, if they smoked daily, how many cigarettes were smoked per day, how soon they smoked after waking, if they use any other tobacco product, and if they live with another person who smokes. Patients were also asked how many times, if any, they tried to quit smoking during the past year. Importance to quit was measured by asking "How important is quitting smoking to you on a scale of 1–5, with 5 being the most important?" Confidence in quitting was measured by asking "How confident are you that you will be able to remain smoke free on a scale of 1–5, with 5 being the most confident?" Finally, patients were asked if they had requested and received a smoking cessation medication during hospitalization.

TABLE 1 | Patient demographics and smoking characteristics.

Characteristic ($N = 4,153$)	M or N	SD or %
Age	49.97	14.81
Sex		
Male	2,223	53.5%
Female	1,929	46.4%
Race/Ethnicity		
White	2,238	53.9%
Black/African American	1,283	30.9%
Hispanic	51	1.2%
American Indian/Alaska native	17	<1%
Asian	14	<1%
Mixed/ Other	9	<1%
Smoking Behavior		
Daily smoking	3,320	79.9%
Cigarettes per day	15.7	11.07
Years smoking	29.06	15.50
Time to first cigarette		
<5 min	1,900	45.8%
6–30 min	484	11.7%
31–60 min	223	5.4%
>61 min	381	9.2%

TABLE 2 | Patient mental health diagnoses.

Characteristic ($N = 4,153$)	*N*	%
All mental health	1,417	34.1%
Depression	460	11.1%
Anxiety	335	8.1%
Chronic pain	336	8.1%
PTSD	58	1.4%
Alcohol use disorder	447	10.8%
Substance use disorder	353	8.5%
Serious mental illness	173	4.2%
Personality disorder	18	<1%
Childhood developmental disorder	16	<1%

Follow-Up Data

The automated telephone system contacted patients 30-days following discharge. Patients were coded "quit" if they endorsed not smoking for the 7-days prior to the phone call.

Statistical Procedures

Logistic regressions, utilizing an intent-to-treat approach [ITT; (19)], coding non-responders as smokers, were used to evaluate the impact of mental health diagnoses on smoking behavior and abstinence at follow-up. Correlations were utilized to establish the relationship between mental health diagnoses and quit attempts, importance of quitting, and self-efficacy related to quitting.

RESULTS

Patient Characteristics

Chart review identified 4,153 patients who endorsed current cigarette smoking upon admission and completed an interview with the TTP while inpatient. Patient demographics are presented in **Table 1**. On average, participants were middle aged (m = 50.0). Slightly over half were male (53.5%), and a little under a third were Black/African American (30.9%) with approximately half identifying as White (53.9). A majority of patients endorsed daily smoking (79.9%), averaging about 11 cigarettes per day and a smoking history of approximately 29 years. With respect to dependence, 64.8% reported smoking their first cigarette withing 5 min of waking, 15.7% between 5 and 30 min, 7.2% between 31 and 60 min, and 12.3% later than 60 min.

Patient mental health diagnoses can be seen in **Table 2**. Overall, 34% of the patient sample was diagnosed with at least one mental health disorder. Within this subset of patients, the average number of diagnoses was 1.55 (SD = 0.89). The most common disorders diagnosed were Depression (11.1%), Alcohol Use Disorder (10.8%), Substance Use Disorder (8.5%), Anxiety (8.1%), and Chronic Pain (8.1%). Demographics of those with a mental health diagnosis did not differ significantly from those of the total sample. Of the 4,153 patients identified, follow-up data were available for 26% of patients (22.9% for those with mental health diagnoses, 27.7% for those without).

Mental Health and Tobacco Outcomes

Logistic regression analysis was utilized to investigate the effect of the presence of a mental health diagnosis on 7-day self-reported abstinence at 30-days post-discharge (ITT). Mental health diagnosis was found to significantly decrease the odds of abstinence at follow-up (B = 0.431, SE = 0.109, Wald = 15.69, $p < 0.01$). Those without a mental health diagnosis were significantly more likely to report abstinence at follow up (OR = 1.54; CI = 1.24–1.91) than those with a history of mental health diagnosis.

A second regression tested the effect of total number of mental health diagnoses on cigarettes per day at the time of intervention. Results of this analysis were also significant (B = 0.653, SE = 0.206, $t = 3.17$, $p < 0.01$) indicating that number of cigarettes smoked increases as the number of mental health conditions increase.

Finally, a series of Pearson correlations were conducted in order to characterize variables associated with smoking cessation with mental health problems. Results of these correlations can be seen in **Table 3**. Number of mental health diagnoses was associated with lower ratings of importance to quit ($r = -0.04$; $p < 0.01$) and lower self- efficacy with respect to quitting ($r = -0.06$; $p < 0.01$), but not associated with the number of quit attempts in the past year ($r = -0.002$; $p = 0.912$) or duration of most recent quit attempt ($r = -0.009$; $p = 0.597$). The mean reported values for importance to quit and self-efficacy to quit are reported in **Table 4**.

DISCUSSION

This study analyzes the effect of mental health diagnoses on outcomes of a brief, opt-out tobacco treatment intervention

TABLE 3 | Mental health diagnosis and quit attempt variables.

Variable	*n*	*M*	*SD*	1	2	3	4	5
1. Total mental health diagnoses	4,153	0.53	0.90	—				
2. Number of quit attempts in the past year	3,923	1.44	2.96	−0.002	—			
3. Importance to quit	4,128	3.84	1.33	−0.04**	0.15**	—		
4. Self-efficacy to quit	4,128	3.56	1.29	−0.06**	0.13**	0.75**	—	
5. Last quit duration	3,608	93.71	172.53	−0.009	0.22**	0.17**	0.21**	—

**Indicates $p < 0.01$.

TABLE 4 | Importance to quit and self-efficacy to quit by mental health diagnosis category.

Diagnostic category	*N*	Mean self-efficacy (Std. Dev.)	Mean importance to quit (Std. Dev.)
Those without mental health diagnoses	2,736	3.58 (1.31)	3.85 (1.28)
Chronic pain	336	3.44 (1.35)	3.74 (1.38)
Anxiety	335	3.36 (1.33)	3.70 (1.37)
Alcohol use disorder	447	3.36 (1.31)	3.59 (1.42)
PTSD	58	3.32 (1.35)	3.62 (1.41)
Childhood dev. disorder	16	3.32 (1.29)	3.45 (1.41)
Depression	460	3.30 (1.33)	3.63 (1.40)
Substance use disorder	353	3.20 (1.32)	3.45 (1.40)
SMI	173	3.06 (1.36)	3.30 (1.50)
Personality disorder	18	2.80 (1.29)	3.17 (1.43)

among a general hospitalized population. This study has several strengths: (1) the results reflect data on a relatively large number of patients treated within the opt-out program, (2) data reflect the effectiveness of an established and practical intervention, (3) data reflect an important population in need of additional research. Rates of mental health conditions, such as depression and substance use disorders, were consistent with general inpatient hospital mental health diagnosis prevalence (20). Results of the present analysis indicate that mental health diagnoses are associated with increases in cigarettes per day. Additionally, patients with one or more mental health diagnoses are less likely to report abstinence from smoking following a brief inpatient tobacco cessation intervention than those without such a diagnosis. There are several well-documented barriers to smoking cessation for those with mental health conditions. Tobacco may represent an individual's attempt to cope with stress or negative emotion (21). Smoking has also been associated with neurobiological mediators impacting mental illness (22). Mental health conditions may also impact self-efficacy for behavior change, which is consistent with our results that showed lower self-efficacy and importance for quitting among patients with mental health diagnoses. These findings highlight an increased importance to engage in more tailored or intensive treatment. For example, incorporating opt-out referrals for follow-up and emphasizing elements of treatment shown to impact on co-morbid psychopathology (23, 24). However, mental health conditions were not associated with differences in quit attempts over the past year, indicating that these individuals are equally motivated to quit. Hospital-based opt-out interventions represent an important venue and opportunity to engage this population. Indeed, hospitals appear to be a venue in which a relatively large number of people who smoke and have mental health conditions appear, and as such we should be investigating tobacco treatment interventions with this population in hospitals.

Limitations

There are several limitations of the present analysis that should be taken into consideration. No non-treatment control group was used for reference, which limits interpretations of tobacco cessation behavior in those with psychopathology with respect to baseline trends. Additionally, the large amount of missing data from follow-up may indicate responder bias.

Public Health Implications

While brief hospital-based opt-out interventions have been shown to be effective and capable of reaching a large proportion of hospital patients, it is important to identify subgroups for whom more tailored treatment would be beneficial. Those with mental health conditions represent a large subset of general hospital patients, report heavier daily smoking, and are less likely to report abstinence following standard intervention. Tobacco treatment programs should work to develop and test treatments which better identify, characterize, and serve these patients.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary materials, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by IRB-II - Medical University of South Carolina; ID - Pro00105610. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

BS contributed conceptualization, methodology, data analysis writing–original draft, and writing–review and

editing. AR and KC contributed methodology and writing–review and editing. AP, MF, and SS contributed to writing–review and editing. BT: conceptualization, methodology, and writing-review and editing. All authors contributed to the article and approved the submitted version.

FUNDING

AR, BS, and BT report funding from the following NCI grants: R01 CA235697, R01 CA261232, R01 CA207229, and K07CA214839. AP is funded though NIH Institutional Postdoctoral Training Grant NIH-T32-HL144470.

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Conflict of Interest: BT and KC have both served as paid expert witnesses in litigation against cigarette manufacturers. BT also has received payment from Pfizer Inc., to serve on an Advisory Board exploring the role of e-cigarettes on smoking behavior.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Psychiatry

ORIGINAL RESEARCH
published: 26 May 2022
doi: 10.3389/fpsyt.2022.869169

Adapting Peer Researcher Facilitated Strategies to Recruit People Receiving Mental Health Services to a Tobacco Treatment Trial

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Edited by:
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Specialty section:
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

Received: 04 February 2022
Accepted: 26 April 2022
Published: 26 May 2022

Citation:
Baker AL, McCarter K, Brophy L, Castle D, Kelly PJ, Cocks N, McKinlay ML, Brasier C, Borland R, Bonevski B, Segan C, Baird DE, Turner A, Williams JM, Forbes E, Hayes L, Attia J, Lambkin D, Barker D and Sweeney R (2022) Adapting Peer Researcher Facilitated Strategies to Recruit People Receiving Mental Health Services to a Tobacco Treatment Trial. Front. Psychiatry 13:869169. doi: 10.3389/fpsyt.2022.869169

Introduction: One of the most challenging aspects of conducting intervention trials among people who experience severe mental illness (SMI) and who smoke tobacco, is recruitment. In our parent "QuitLink" randomized controlled trial (RCT), slower than expected peer researcher facilitated recruitment, along with the impact of COVID-19 pandemic restrictions, necessitated an adaptive recruitment response. The objectives of the present study were to: (i) describe adaptive peer researcher facilitated recruitment strategies; (ii) explore the effectiveness of these strategies; (iii) investigate whether recruitment strategies reached different subgroups of participants; and (iv) examine the costs and resources required for implementing these strategies. Finally, we offer experience-based lessons in a Peer Researcher Commentary.

Methods: People were included in the RCT if they smoked at least 10 cigarettes a day and were accessing mental health support from the project's two partnering mental health organizations in Victoria, Australia. The majority of people accessing these services will have been diagnosed with SMI. Recruitment occurred over 2 years. We began with peer facilitated recruitment strategies delivered face-to-face, then replaced this with direct mail postcards followed by telephone contact. In the final 4 months of the study, we began online recruitment, broadening it to people who smoked and were accessing support or treatment (including from general practitioners) for mental health and/or alcohol or

other drug problems, anywhere in the state of Victoria. Differences between recruitment strategies on key participant variables were assessed. We calculated the average cost per enrolee of the different recruitment approaches.

Results: Only 109 people were recruited from a target of 382: 29 via face-to-face (March 2019 to April 2020), 66 from postcards (May 2020 to November 2020), and 14 from online (November to December 2020 and January to March 2021) strategies. Reflecting our initial focus on recruiting from supported independent living accommodation facilities, participants recruited face-to-face were significantly more likely to be living in partially or fully supported independent living ($n = 29$, <0.001), but the samples were otherwise similar. After the initial investment in training and equipping peer researchers, the average cost of recruitment was AU$1,182 per participant—∼US$850. Face-to-face recruitment was the most expensive approach and postcard recruitment the least (AU$1,648 and AU$928 per participant).

Discussion: Peer researcher facilitated recruitment into a tobacco treatment trial was difficult and expensive. Widely dispersed services and COVID-19 restrictions necessitated non-face-to-face recruitment strategies, such as direct mail postcards, which improved recruitment and may be worthy of further research.

Clinical Trial Registration: The trial is registered with ANZCTR (www.anzctr.org.au): ACTRN12619000244101 prior to the accrual of the first participant and updated regularly as per registry guidelines. The trial sponsor was the University of Newcastle, NSW, Australia.

Keywords: tobacco treatment, smoking cessation, quitline, peer worker, mental illness, recruitment, cost analysis, severe mental illness (SMI)

INTRODUCTION

Smoking rates are much higher among people who experience severe mental illness (SMI) compared to the general population (1). Consequently, people with SMI experience poorer quality of life related to smoking (2) and die prematurely from smoking related diseases (3). There is strong evidence that tobacco treatment consisting of cognitive behavior therapy (CBT) and pharmacotherapy (such as nicotine replacement therapy (NRT) and varenicline) are associated with reductions in smoking and cardiovascular disease risk among people with SMI (4) and that such interventions can be delivered effectively by telephone (5). However, use of quitlines tends to be low relative to their potential reach (6) and research regarding scalable, low-cost efforts to increase quitline reach is critically needed to reduce tobacco related health disparities (7).

Peer workers are individuals who provide services in mental health and/or substance use treatment settings informed by their own experience of recovery from mental illness and/or substance use and skills obtained from formal peer worker training (8, 9). We have previously reported on the successful delivery of a peer worker delivered smoking cessation and healthy lifestyle intervention among people who experience SMI (10). In that feasibility study, we received 104 referrals from one community mental health organization, with 43 people being included in the study over a 1-year period (10). Dickerson et al. (11) reported a pilot trial which recruited 30 people with SMI into a peer delivered smoking intervention over a 6-month period (11). Given the positive but modest reach of peer delivered smoking cessation interventions and the potential for higher reach of quitlines, peer workers may be able to enhance reach of quitlines to people with SMI, by identifying smokers within mental health services and facilitating referral to quitlines. As such, we conducted a randomized controlled trial (RCT, the "Quitlink Project") evaluating the effectiveness and cost-effectiveness of a peer worker facilitated intervention for smoking among people accessing support for SMI (12, 13).

One of the most challenging aspects of conducting intervention trials among people who experience SMI is recruitment (14, 15). Challenges include: the necessity for extensive collaborations between researchers, consumers, health staff and institutions, each with their own expectations and concerns; clinicians' concerns about consumers' vulnerability and reduced decision-making ability; and consumer doubts about potential benefits in the face of lengthy research procedures (16). High caseloads and clinical staff feeling they do not have the necessary knowledge of research to feel comfortable discussing this with service users have also been identified as barriers to recruitment (17). In their systematic review of recruitment strategies in mental health trials, Liu et al. (16) found only two RCTs cited among people who experience SMI that formally assessed the effectiveness of different strategies to improve

recruitment (18, 19). Neither multi-media consent procedures nor co-designed participant invitation leaflets were associated with improved recruitment. Clearly, in the face of numerous challenges, recruitment into a study needs to be appealing to staff and consumers and not represent a burden for staff.

There are additional challenges recruiting for studies of interventions for substance use, like smoking, due to high levels of ambivalence among potential participants. People experiencing SMI who smoke report being interested in quitting but may not feel ready to do so in the short-term (20). Recruitment processes need to be sufficiently attractive to people who do and do not want to quit smoking in the near future.

Globally, individuals receiving treatment for mental illness and/or substance use have faced unprecedented challenges during the coronavirus (COVID-19) pandemic. They are at elevated risk of vulnerability to COVID-19 associated with co-occurring health conditions and mental health sequelae arising from isolation and socioeconomic instability (21). During the pandemic, there was a significant divergence from routine care in Australia, with increased use of telehealth. Given our interest in potentially linking people with SMI who smoke to quitline, the characteristics of those who enrolled in our study are of interest and may help inform further uptake of the use of quitlines, post-pandemic.

Peer workers are strong role models for clients, and are particularly successful in developing hope, promoting self-esteem and empowering consumers (22). These unique skills are likely to be extremely valuable in helping to promote engagement of people with SMI within quitline services (23). In our Quitlink Project, peer workers were engaged as peer researchers, recruiting participants, collecting baseline data and delivering brief advice. We initially developed a peer delivered (face-to-face) recruitment strategy. Slower than expected recruitment and social distancing requirements and other restrictions of the COVID-19 pandemic necessitated an adaptive recruitment response, involving progressively less intensive peer facilitation. As described further below, peer facilitation was adapted from face-to-face contact with participants, to direct mail postcards with telephone contact, and then online peer researcher video presentations. Inclusion criteria were also modified to broaden the reach of the project beyond the original two mental health partner organizations involved and baseline assessment was abbreviated to allow administration via telephone and online.

There is a marked lack of evidence on the costs and recruitment effectiveness for tobacco treatment trials targeting people who experience mental illness (15, 16). Potential insights may be drawn from smoking recruitment studies amongst general populations (24) and Liu et al's. (16) systematic review of recruitment studies for mental health trials (i.e., not tobacco treatment studies). Buller et al. (24) found online advertisements could be a relatively effective and inexpensive recruitment approach (US$43.35 per enrollee, $N = 1{,}426$) compared with recruiting via quitline screening (US$133.61, $N = 149$). Liu et al. (16) found web-based advertisements could be an inexpensive way to recruit people to mental health RCTs compared with generating referrals from specialized care or primary care (UK£13.41 vs. UK£183.24 vs. UK£407.65 per patient enrolled, respectively). We anticipated recruiting to our study would be relatively more resource intensive than these studies, given we aimed to target people who experience both mental illness and tobacco dependence. Here we report on three different peer facilitated recruitment strategies, and the associated costs. The peer researchers employed on the project also report on their experiences of recruitment in a Peer Researcher Commentary.

AIMS

The objectives of the present study were to: (i) describe adaptive peer researcher facilitated recruitment strategies; (ii) explore the effectiveness of recruitment strategies in terms of recruitment number and rate of accrual; (iii) investigate whether recruitment strategies reached participants with different demographic, smoking and clinical characteristics; and (iv) examine the costs and resources required for implementing these strategies. Finally, we offer experience-based lessons from peer researchers for recruiting people who experience SMI into a tobacco treatment trial.

METHODS

Participants

As described in our protocol paper (12), to be eligible, participants smoked at least 10 cigarettes a day and were accessing treatment or support from participating mental health agencies. The majority of people accessing these services will have been diagnosed with SMI, such as schizophrenia, schizoaffective disorder, bipolar disorder, delusional disorder and depressive disorders. Exclusion criteria were: current engagement in Quitline Victoria's callback service; no ready access to a telephone; inability to complete informed consent and/or the screening survey; acute suicidality; contraindications to nicotine replacement therapy (NRT); and pregnancy. When online recruitment commenced (as described below) inclusion criteria were expanded to include people accessing support or treatment, including from their general practitioner, for a mental health and/or alcohol or other drug use condition. The target sample was 382 randomized to Quitline and NRT support or generic support.

Partnerships With Mental Health Organizations

Recruitment began by partnering with two mental health organizations in Victoria, Australia. Two chief investigators (DC and LB) were employed or funded by these organizations at the beginning of the project and they worked with the two peer researchers to promote research participation within the services. The Ethics Committee at one of these sites was the primary Ethics Committee for the study (St Vincent's Hospital, Melbourne, HREC Reference Number: HREC/18/SVHM/154). Ethics approval was also obtained from the University of Newcastle HREC (HREC Reference Number: H-2018-0192)

and the Cancer Council Victoria, HREC (HREC Reference Number: 1807).

Peer researchers were supervised by ALB (a clinical psychologist) weekly in group or individual teleconferences or videoconferences, depending on overlapping days of work. When ALB was unavailable, another clinical psychologist investigator (PJK) led supervision. The Research and Evaluation Manager (LH) at one of the participating mental health organizations attended monthly team investigator meetings and some peer research supervision sessions. As described below, each mental health organization provided current consumer names and contact details to peer researchers for recruitment.

Recruitment Procedure

Recruitment occurred over 2 years (from March 2019 to April 2021), and strategies were adapted in response to slow face-to-face recruitment (pre-COVID 19) and to social distancing and lockdowns prohibiting face-to-face access during the COVID-19 pandemic (from March 2020). The state of Victoria experienced 11 lockdowns during the recruitment period, precluding further face-to-face recruitment.

Recruitment Strategies

Recruitment strategies were adapted over the course of the trial as described below.

1) Face-to-face via peer researchers (March 2019 to April 2020)

The initial (pre-COVID-19) recruitment method employed peer researchers as described previously (12). Two peer researchers (NC and MMc) were each employed 2 days per week, with one increasing to 3 days per week during the last 6 months of recruitment. A third peer researcher (CB) assisted with administrative aspects of recruitment half a day a week as recruitment progressed. Peer workers assisted with a parallel qualitative study when they had spare time. Their work was guided by a peer manual co-designed by NC; it contains introductory scripts and detailed descriptions of study procedures. Both peer researchers received two and a half days face-to-face training on recruitment procedures by chief investigators (ALB and PJK) and one peer researcher received an additional 3 days training (by EF) on using an iPad for data entry etc. Peer researchers were observed visiting initial sites, conducting baseline assessments and delivering brief advice. Two peer researchers had formerly smoked and the other had never smoked.

Peer researchers visited various sites of the two partnering mental health organizations presenting information to staff and potential participants about the study and leaving postcards about the study and consent-to-contact forms. Supported independent living accommodation facilities were targeted, and some community services were also visited. Service staff were asked to refer potential participants using the consent-to-contact forms. This stage of recruitment also included advertising (e.g., flyers in residential and community services and online service newsletters). Peer researchers used iPads to guide potential participants through eligibility and consent procedures and to gather baseline data via REDCap (a secure web-based application designed to support data capture for research studies). Baseline data collection took around 1.5 h per participant.

2) Direct mail postcard (May 2020 to November 2020)

The second recruitment method involved two staggered direct mail postcard campaigns to all people registered with the project's two partnering mental health organizations (smoking status is not recorded on organization registers). Postcards were developed in conjunction with peer researchers (see **Supplementary Material**). The first postcard contained the project logo and brief information about the project and contact details of the peer researchers. The second postcard was the same except for a new background photo of two people in conversation. Postcards invited people registered with either participating mental health organization who smoked at least 10 cigarettes per day to telephone peer researchers to find out more about the study. Peer researchers obtained verbal consent via telephone to participate in the study and conducted an abbreviated baseline assessment. A shorter baseline assessment was necessary due to the assessment interview being conducted over the phone, to reduce participant burden, and took about 30–45 min. Both of the postcard mail outs were staggered over 3 months (May to July 2020 and September to November 2020) in order to accommodate availability of peer researchers to respond to potential participants. A postage service used by one of the mental health organizations was paid to send the postcards.

3) Online (November to December 2020 and January to March 2021)

With our recruitment rate improved by direct mail postcards (as described below) but still lower than anticipated, we broadened recruitment beyond the initial two mental health organizations. Ethics permission was granted to extend recruitment to people who smoked and were accessing support or treatment (including from general practitioners) for mental health and/or alcohol or other drug problems, anywhere in the state of Victoria. A study website was developed and the study was advertised via paid advertisements on Facebook, newsletters of community organizations and professionals and a register of substance use studies. Social media posts are attached in **Supplementary Material**. Online recruitment involved investigator and peer researcher videos explaining the study and consent procedures, asking interested people to either telephone peer researchers or complete online screening, consent and baseline assessments.

Assessment Measures

After completing consent procedures, participants completed a number of measures as part of baseline assessment, with selected measures including demographic characteristics (gender, age, relationship status, employment status, and accommodation status), smoking, mental health, alcohol use and quality of life. Psychometric properties of the measures employed have been described previously (12). Measures selected for the present study are summarized below.

Smoking

Self-reported data regarding cigarettes smoked per day (for daily smokers) or cigarettes per week (for non-daily smokers) were collected. The two item Heaviness of Smoking Index (HSI) assessed nicotine dependence (25, 26). It uses a six-point scale calculated from the number of cigarettes smoked per day (1–10, 11–20, 21–30, 31+) and the time to first cigarette after waking (≤5, 6–30, 31–60, and 61+ minutes). Nicotine dependence is then categorized into a three-category variable: low (0–1); medium (2–4); and high (5–6).

Mental Health

The 10-item Kessler Psychological Distress Scale [Kessler-10; (27)] measures non-specific psychological distress. Low scores (10–15) indicate little or no psychological distress and higher scores indicate increasing levels of distress (moderate, 16–21; high, 22–29; and very high, 30–50).

The Mini International Neuropsychiatric Interview [MINI; (28)] was administered to obtain lifetime mental health diagnosis; this was administered at the 2-month follow-up to reduce assessment burden at baseline. The McLean Screening Instrument for Borderline Personality Disorder (29) was administered to four people to verify their self-reported main diagnosis of borderline personality disorder. Of these, two were negative (on the MINI and McLean), one had a psychotic disorder according to the MINI, and the remaining person screened positive for borderline personality disorder. Diagnoses were grouped into "psychotic" and "non-psychotic" disorders. Psychotic disorders were bipolar 1 disorder, bipolar 1 disorder with psychotic features, any psychotic disorder (includes schizophrenia), and major depressive disorder with psychotic features. Non-psychotic disorders were major depressive disorder, agoraphobia, obsessive-compulsive disorder, posttraumatic stress disorder, generalized anxiety disorder and borderline personality disorder.

Alcohol Use

The Alcohol Use Disorders Identification Test – Brief [AUDIT-C; (30)], a three item screening tool, was used to identify hazardous alcohol use or active alcohol use disorder. It is scored on a 0-12 scale with a cut off of 3 (women) or 4 (men), indicative of hazardous drinking or alcohol use disorder.

Quality of Life

Health related quality of life (HRQL) scores [utilities, (31)] were elicited using the 35-item Assessment of Quality of Life-8 Dimension (AQoL-8D) (32, 33) for participants who were recruited face-to-face. To address concerns about the length of the assessment, when we transitioned to recruitment via postcard and online, we transitioned to elicit HRQL utilities using the EQ-5D-5L (34) plus four AQOL-8D question bolt-ons. These can be used in combination to calculate HRQL utilities and has been shown to be comparable to the AQOL-8D (35). Utilities are anchored by 1=perfect HRQOL and 0=death.

Costing Analysis

Following the costing principles set out in the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), we describe the resources and associated costs used to recruit participants effectively up to the point of completing baseline assessment (36). Taking the perspective of the research project, we present a breakdown of costs over four phases as they occurred in the study: (i) training and equipping peer researchers; (ii) face-to-face recruitment; (iii) postcard recruitment; and (iv) online recruitment. We then calculate the average cost per participant recruited via our package of three strategies and also the average cost per participant recruited via each strategy independently. Our investment in training and equipping peer researchers will have wider use beyond this trial and are thus excluded from average cost per participant calculations—akin to research groups engaging peer researchers already trained in RCT recruitment and implementation (24). Costs include personnel time (investigators, peer researchers, administrative support staff), iPad and mobile phone costs, travel costs associated with training, supervision, and peer researcher site visits, costs of designing and printing advertising materials, postcard design and mail-out costs, website design and hosting costs plus on-line recruitment advertising costs, and the costs of giftcard vouchers given to participants after completing baseline assessment. We exclude the costs of investigator time in completing ethics amendments to adapt recruitment methods, and constructing the baseline survey, which will have future use. All costs are presented in 2021 Australian dollars (AU$). See **Supplementary Material** for more detail of included costs and data sources.

Statistical Analyses

Descriptive statistics are presented as counts (%) and means (standard deviation; SD). An alpha level of 0.05 was specified for all tests and confidence intervals. The data were analyzed in SAS v9.4.

Differences in demographic, smoking and clinical characteristics of participants between recruitment methods were assessed using one-way ANOVA for continuous variables and Fisher's exact test for categorical variables. A Bonferoni correction was used to adjust for multiple comparisons, resulting in an adjusted alpha level of 0.005 for significance. Post-hoc tests were carried out on any significant results. Pairwise comparisons of categorical variables were assessed using Fisher's exact test, with effect sizes shown as odds-ratios (95% CI). Pairwise comparisons of continuous variables were assessed using Welch's t-test, with mean differences (95% CI).

RESULTS

A total of 110 of our projected sample of 382 participants completed consent procedures and baseline assessments and were randomized. One person subsequently withdrew, leaving a total sample of 109 people. Our recruitment target had been 16 people per month. See **Figure 1** for a summary of recruitment figures.

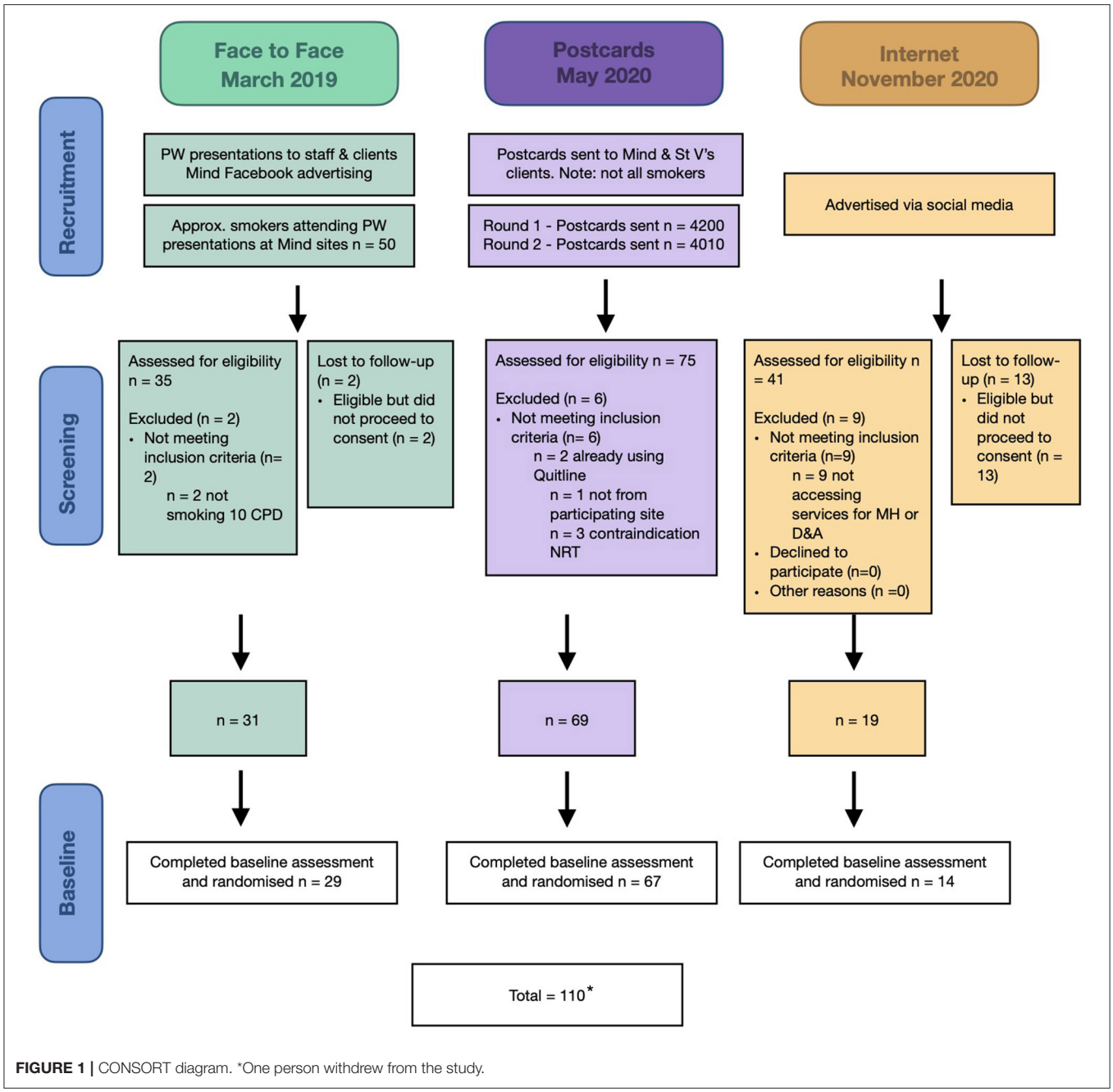

FIGURE 1 | CONSORT diagram. *One person withdrew from the study.

Figure 2 shows recruitment per month according to recruitment strategy.

In the first, face-to-face, recruitment period between March 2019 and April 2020 (13 months) ∼50 people (based on estimates by peer researchers) who smoked attended peer researcher presentations within the participating mental health organizations. Of these, 35 were assessed for eligibility. Two were excluded (not smoking 10 cigarettes per day) and two were unable to be contacted to complete consent, yielding 31 eligible people of whom 29 completed baseline assessments and were randomized. At the first mental health organization, this phase of recruitment focused on visiting six supported independent living services (from which 14 people were recruited; range 1–5), six community centers for mental health and well-being with two of these via video as they were in rural locations (none recruited), five residential rehabilitation facilities for youth (four recruited from two services; range 1–3); an accommodation support service (two recruited); and an adult outreach service (none recruited). At the second mental health organization, posters were placed in an inpatient ward (no recruits), two outpatient clinics (none recruited), and a short-stay sub-acute residential facility (three recruited). In total,

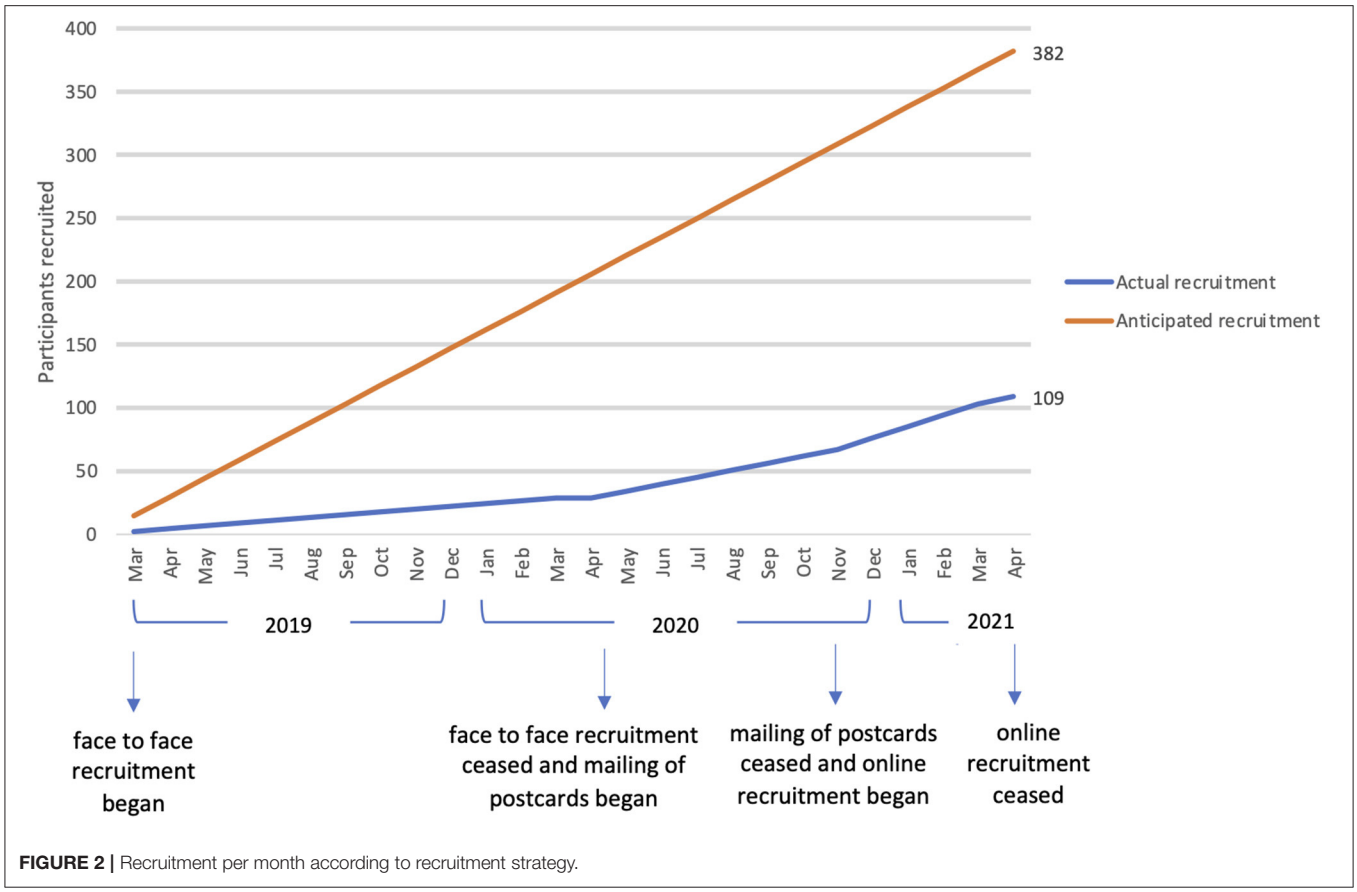

FIGURE 2 | Recruitment per month according to recruitment strategy.

23 of 29 people recruited during this face-to-face phase were recruited from residential services; the monthly recruitment rate was 2.2.

In the direct mail postcard recruitment phase, a total of 4,200 postcards were mailed between 1 May and 30 July 2020 to all people registered with the two mental health organizations participating in the study. A second postcard was sent (minus 'return to sender' addresses and those who requested no further postcards after the first mail out) to 4010 people between 17 September and 5 November 2020. Interested people responded to postcards over the 6 months that direct mail occurred but were welcome to respond until April 2021, when recruitment closed (12 months). A total of 75 people were assessed for eligibility. Six people were excluded (two were already using quitline, one was not from a participating site and three reported contraindications to NRT). A further two people did not complete baseline assessment, leaving a total of 67 participants recruited via direct postcard mail out. As mentioned above, one person subsequently withdrew their data from the study, leaving 66 people recruited via postcard. Recruitment was higher in the second mailout. During the first mailout we received the following number: June 2020 (5); July 2020 (4); August 2020 (12). During the second mail out we received: September 2020 (3); October 2020 (19); November 2020 (8); December 2020 (4); January 2021 (2); February 2021 (3); March 2021 (4); April 2021 (3). The recruitment rate per month was 5.5 people per month over the 12 month response period, still lower than the target needed to fill the sample, even if used over the entire recruitment period.

Online recruitment commenced 12 November 2020, temporarily closed between 21 December 2020 and 10 January 2021 due to Christmas vacation and recommenced on 11 January 2021, continuing until 31 March 2021 (total of four months). Facebook advertisements generated a total of 476,727 impressions (defined as an advertisement appearing on a user's page), reaching 121,467 unique individuals, with 5009 link clicks. A total of 41 people were assessed online for eligibility, with nine ineligible (not currently accessing any services or support for mental health and/or AOD problems), 13 not proceeding to consent, and five not completing baseline, leaving a total of 14 recruited into the study. The recruitment rate per month was 3.5. All people recruited chose to complete the baseline assessment online (rather than request assistance from a peer researcher).

Characteristics of the Participant Group

Demographic, smoking, mental health, and health related quality of life (HRQL) data are presented below. As seen in **Table 1**, the sample was evenly divided between men and women, aged in their mid-forties, most were unemployed, and most were not married or cohabiting. Not shown in **Table 1**, 50 (45.9%) had no further education after leaving school and 67 (61%) were

receiving a disability pension. Most (n = 99; 91%) endorsed English as the main language spoken at home. Only three people (2.8%) identified as Aboriginal or Torres Strait Islander.

Smoking

Participants began smoking regularly at a mean age of 16.7 years (SD 5.8). The mean number of cigarettes smoked per day at baseline assessment being 20.8 (SD 9.7), and the majority (n = 102; 93%) smoked their first cigarette within 30 min of waking. Most people smoked manufactured cigarettes (n = 83; 76%), around half smoked pouch tobacco (n = 54; 49.5%) and 27 (24.8%) smoked bulk tobacco. Over one-fifth (n = 25; 22.9%) smoked tobacco from butts that others left behind, with 9 of these doing so at least weekly.

Psychosocial Functioning

Levels of psychological distress (K-10) were generally elevated, with 42/91 (46.2%) reporting very high, 31/91 (34.1%) high, 17/91 (18.7%) and moderate levels of distress. The mean score was 29.1 (SD 7.7). The MINI was delivered to 91 people; of whom four did not meet diagnostic criteria on any of the delivered modules (classified as "non-psychotic" for this analysis); as such 87 received a MINI diagnosis (see **Table 1**). Of the 18 not receiving the MINI, one had a self-reported primary diagnosis of borderline personality disorder and completed the McLean Screening Instrument for Borderline Personality Disorder (29). Only one person (recruited online) reported an alcohol problem without any co-existing mental health concern. Of those for whom MINI data were missing, eight did not complete any follow-up assessments (as such the MINI could not be administered); seven attended one assessment but the MINI was not administered due to time and/or rapport constraints; one requested to cease the questions; and one was unable to complete due to medical issues.

The sample mean HRQL utility score was 0.52, indicating relatively poor HRQL. For context, Engel et al. (37) recently assessed AQOL-8D utilities using data from Australia, Canada, Germany, Norway, UK and USA, and found a mean utilities score of 0.42 amongst adults with depression (N = 917) compared with 0.83 for healthy controls (N = 1,760). We found no significant difference in HRQOL utilities between recruitment strategies (face-to-face=0.57; postcard=0.50; online=0.50). It is important to note that lockdowns in response to COVID-19 and associated economic downturns may have impacted HRQL utilities amongst participants recruited via the postcard and online recruitment strategies.

Profile of Study Participants According to Recruitment Method

Table 1 presents selected demographic, smoking and clinical characteristics of participants according to recruitment strategies. Reflecting our initial focus on recruiting from supported independent living accommodation facilities, participants recruited face-to-face were significantly more likely to be living in either partially or fully supported accommodation than those recruited online (OR = 11.40, 95% CI [2.12, 61.25], p = 0.003) or by postcard (OR = 13.78, 95% CI [4.75, 39.93], p = <0.001). As seen in **Table 1**, they also tended to be younger and more likely to be unemployed.

Costing Analysis

The cost of training and equipping peer researchers was AU$27,253, and the total cost of recruiting, including peer researcher support and supervision was AU$128,878 at an average cost of AU$1,182 per participant recruited (**Table 2**). Personnel costs made up about 80% of recruitment phase costs, though only about 60% for online recruitment (see **Supplementary Material** Costing Tables for more detailed costing). Face-to-face recruitment was the most expensive at AU$1,648 per participant compared with the least expensive postcard recruitment costing an average AU$928 per participant recruited. However, face-to-face was relatively effective in reaching people currently living in supported accommodation, indicating that any trial that focused solely on such participants would be especially resource intensive in recruitment. Online recruitment was less resource intensive in terms of peer researcher and investigator time but yielded the fewest participants, though this was presumably at least partially a result of the online advertising budget constraints.

DISCUSSION

Peer researcher facilitated recruitment into this tobacco treatment trial among people experiencing SMI was difficult and relatively expensive compared to recruitment to other smoking or mental health trials (16, 24). Even if all three recruitment strategies (face-to-face, direct mail postcards and online) had been able to occur simultaneously and assuming observed recruitment rates held constant over a longer recruitment period, it would have taken almost 3 years to achieve the target sample. Similarly, if we were able to identify and access new recipient population mail lists and just employed our most effective approach, direct mail postcards with telephone contact with peer researchers, without more peer researchers to field calls, it would take around 6 years. However, our *a priori* expectations were that recruitment of this socially marginalized population group to a smoking cessation study would require greater resources than other smoking and mental health studies (15), and important lessons have been learnt about peer researcher involvement, and the potential for direct mail postcards that may inform future research and clinical practice.

In the context of our RCT during the COVID-19 pandemic and with a limited timeline, recruitment was well below our original target. Unexpectedly, recruitment by peer researchers face-to-face before COVID-19 was slow, despite existing CI partnerships with participating mental health organizations. In contrast, the SCIMITAR+ Trial in the UK (38) recruited 526 participants into their tobacco treatment trial among people experiencing SMI (those with current drug or alcohol abuse were excluded) in just over a year. Successful recruitment was associated with use of NHS targets such as supporting access to research projects to encourage team engagement and establishing close working relationships between researchers and clinicians. Recruitment was via general practitioners, community

TABLE 1 | Participant characteristics by recruitment strategies.

Variable	Face-to-face	Postcard	Online	Total	*p*
	(*n* = 29)	(*n* = 66)	(*n* = 14)	(*N* = 109)	
Gender (% female)	13 (44.8%)	35 (53.0%)	8 (57.1%)	56 (51.4%)	0.257
Age (Mean, SD)	40.0 (11.9)	46.9 (13.0)	49.9 (12.3)	45.5 (13.0)	0.021
Married / defacto (%)	3 (10.3%)	9 (13.6%)	4 (28.6%)	16 (14.7%)	0.331
Not working (%)	22 (75.9%)	38 (57.6%)	4 (36%)	65 (59.6%)	0.014
Partially or fully supported accommodation (%)	19 (65.5%)	8 (12.1%)	2 (14.3%)	29 (26.6%)	<0.001
HSI (Mean, SD)	3.6 (1.5)	3.7 (1.2)	3.5 (1.4)	3.7 (1.3)	0.794
K10 (Mean, SD)	27.5 (7.4)	29.6 (7.8)	30.1 (8.2)	29.3 (7.8)	0.505
MINI diagnosis (% psychotic disorder)#	18/22 (82%)	34/58 (58.6%)	7/12 (58.3%)	59/92 (64.1%)	0.297
AUDIT C (% excessive alcohol consumption)	16 (55.2%)	27/65 (41.5%)	7 (50.0%)	50/108 (46.3%)	0.448
HRQL* (Mean, SD)	0.567 (0.21)	0.503 (0.19)	0.502 (0.19)	0.520 (0.20)	0.352

#Includes one person who received a diagnosis of borderline personality disorder on the McLean Screening Instrument for Borderline Personality Disorder.
**Health related quality of life (HRQL) utilities were elicited using AQOL-8D for face-to-face recruitments and the comparable EQ-5D plus four AQOL-8D bolt-on questions for postcard and online recruitments (35).*

TABLE 2 | Summary of study recruitment costs (AU$).

Research project's cost breakdown	Training and equipping Peer Researchers	Recruiting costs			
		Face-to-Face	Postcard	Online	Total recruiting costs
Research project personnel	$20,316	$41,768	$51,197	$11,987	$102,739
Equipment (incl. phone/tablet plans)	$4,411	$674	$240	$0*	$914
Travel (training, supervision & site visits)	$2,526	$3,007	$0	$0	$3,007
Advertising materials (paper-based)	$0	$1,139	$6,050	$0	$7,190
Advertising material (on-line, incl. website costs)	$0	$0	$0	$7,063	$7,063
Participant remuneration (vouchers + postage)	$0	$1,214	$3,768	$770	$5,752
Total costs	**$27,253**	**$47,803**	**$61,256**	**$19,820**	**$128,878**
Participants recruited	29	66	14	109	
Average cost per participant recruited**		**$1,648.38**	**$928.12**	**$1,415.70**	**$1,182.37**

**IT equipment for designing website etc. included in salary on-costs and advertising material costs as part of invoices.*
***Excludes the costs of training and equipping peer researchers.*

mental health teams or psychiatrists, service user groups, poster advertisements and a lifestyle survey, all with suitability for participation established by a clinician. SCIMITAR researchers screened caseloads for eligible participants and attended the next meeting with the potential participant in order to discuss the study.

Shortly prior to our study commencing, there was a major shift in service delivery in Australia, with the introduction of Australia's National Disability Insurance Scheme (NDIS). This severely impacted our study. One of the participating mental health organizations decided not to engage with the study due to the restructuring process. The residential services which we did recruit from shifted focus from residential rehabilitation to supported independent living, with eligible residents' capacity to live independently being impacted by long-term mental ill-health and having levels of psychosocial disability that required assistance with activities for daily living. All residents of the supported accommodation facilities were eligible for NDIS support that requires evidence of permanent and significant disability that affects the individual's ability to take part in everyday activities. Thus, residents were people who may have faced significant challenges in participating in this trial without considerable support. This face-to-face recruitment was also relatively resource intensive. Prior to pivoting to postcard recruitment our average cost per enrollee via face-to-face was about $1,648 per participant. However, regardless of expense, different recruitment strategies and settings will provide different sub-samples, enhancing representativeness of the data.

It is possible that more frequent visits to residential settings by peer workers, working locally within teams, may have had better success. One report (39) of recruitment of people with schizophrenia into a coronary heart disease prevention intervention required an average 10.3 home occupational therapy visits to recruit a participant. The number of required visits were influenced by potential participants forgetting appointments, having difficulty assimilating study information, and also perceiving the generally welcomed research occupational therapist visits might terminate once consent was provided. Such frequent visits would not be possible in our study, with one of our participating organizations being widely dispersed

throughout Victoria with multiple sites and different points of service delivery in urban areas and regional towns across long distances. Also, with the introduction of the NDIS and the shift to a more individualized funding approach, there was less group and center-based activities that would have enabled direct contact with potential participants.

We were unsuccessful in attracting mental health inpatients into our trial, although that had been successful in other studies (40). A potential explanation is that service delivery has become increasingly acute and pressured in recent years in Victoria, as detailed by the Royal Commission into Victoria's Mental Health Service System which was being conducted during the recruitment period (41), and together with COVID-19 restrictions, the inpatient setting was unlikely to become a source of recruitment during the study. Thus, although we had partnerships with the recruiting organizations, our peer researchers were not as strongly embedded within services as they were in the SCIMITAR+trial (39) and we were unable to make as many visits to sites as others have done due to statewide and dispersed service delivery (39). Peer researchers were facing services that had competing priorities and significant organizational disruption.

In future, establishing organizational targets for delivery of smoking interventions and possibly pairing peer workers with clinician champions in further studies or in clinical contexts may help build closer working relationships and better uptake of interventions in residential and inpatient contexts. Although challenging, it is important people within these settings receive opportunities for tobacco treatment and for representativeness in research. It is possible that financial incentives for service providers to refer could be effective because of the time constraints and overwhelming administrative work that compete with research and represent important barriers (42). In addition, although peer researchers may be able to connect effectively with consumers, there appears to be a need for alternative strategies and different messaging to engage staff and managers and explain the benefits of a trial such as this. RCTs can be an even harder "sell" when staff know only half of participants will receive an active intervention. In the current trial, we limited disclosure about intervention arm contents, but staff sometimes asked whether participants would all receive NRT. Future research needs to align with service organization goals and strategy at all levels—executive, managerial, and for practitioners. In the case of the present study, service organization goals and strategies may have been shifting quickly with the advent of the NDIS. With so many pressures, organizations are likely to prioritize activities with a clear pay off for clients and the organization.

As recruitment from community residential facilities was comparatively low and unsuccessful from acute inpatient units in this study, additional ways to link mental health consumers in those settings to quitline is worthy of further investigation. For example, in a randomized trial with 224 individuals recruited from a locked acute psychiatry unit with a smoking ban, verified smoking 7-day point prevalence abstinence over 18-months follow-up was significantly higher for those who received a computer-assisted tobacco intervention with posthospitalization NRT (20.0%) vs. usual care (7.7%) (43). Such computer delivered interventions could also provide referrals to quitline, with quitline staff potentially beginning communication with people who smoke via text or telephone, with follow-up after discharge.

Recruitment via direct mail postcards, inviting people registered with mental health organizations who smoked to telephone peer researchers to find out more about the study, was relatively successful. We began sending out postcards a year after face-to-face recruitment commenced, hoping to improve the rate of recruitment through reaching more people and to recruit in a COVID-safe manner. As described above, peer researchers obtained verbal consent via telephone from participants and a shorter baseline assessment was implemented. People recruited via postcard did not differ from other recruitment strategies, apart from residential status. Our recruitment rate (1.6%; 66 participants from postcards to approximately 4200 people over two occasions) is similar to that of other health intervention studies recruiting by postcard. For example, in a study recruiting young people for a randomized trial of weight gain prevention interventions, Crane et al. (44) mailed postcards once to 30,000 people, with 30 being randomized into the study (1.3% response rate), costing US $7,422; $247.40 per participant. They found little difference in reach between postcards and brochures (sent to a separate sample). Waltman et al. (45) mailed postcards to 72,469 women and resent them 6 months later, with 47 participants enrolling in a RCT of different interventions on bone health (0.07% response rate). The total cost of postcard recruitment was US $43,567.49; $926.96 per participant (the cost of researchers' time in implementing recruitment strategies was not considered in the calculation), which is comparable to our average cost of postcard recruitment of AU$928 per participant (including researcher time), suggesting recruitment to trials requiring difficult behavior change can be expensive. In Waltman et al. (45), postcards were the second most successful recruitment strategy after health care provider letters (n = 58) and similar to Facebook posts (n = 44); lower numbers were obtained from referral by family and friends (n = 11), newspaper or television advertisements (n = 5) and digital advertisements (n = 2). Waltman et al. regarded health care provider letters and postcards as successful in helping to reach their overall target of 275 participants. In hindsight, we could have had postcard recruitment running alongside face-to-face recruitment and may have been able to attract about 66 people annually, this would likely have introduced some efficiencies in peer researcher and investigator supervision time. In the present study, the mental health organizations involved did not have a record of smoking status so we had to send postcards to all people registered by the organizations. It would obviously be cheaper to send postcards if registries kept smoking status and other risk factor information for targeted health marketing. However, sending postcards to everyone has the advantage of capturing new and unrecorded smokers. Response to postcards was stronger following the second mail out. Peer researchers reported that respondents often commented that the second postcard prompted them to call. Even though we did not reach our recruitment target for the study, direct mail postcards every 6 months to people registered with mental health services, with the option of phoning a peer worker or quitline directly, may be a relatively effective way of increasing contact with quitlines.

Our online recruitment strategy was the least costly in total (AU$19,820) but was only implemented for the 4 months before trial closure, resulting in 14 participants ($1,416 per participant). Qualitative research with participants is currently underway to develop a more in-depth understanding of participant experiences. However, we do not have any information about why several thousand views online led to so few enrolments. It is possible the lengthy information and consent forms mandated by ethics committees did not engage people sufficiently online. Interestingly, a recent study of recruitment into an online intervention among people with SMI aimed for a sample size of 148 over 2 years and recruited only 98 (46). Had we started online recruitment at the commencement of our study, and assuming a similar rate over our 2-year recruitment period, we would have recruited about 84 participants by that method.

There is a paucity of directly comparable cost analyses for recruitment to smoking cessation studies. Buller et al. (24) recruited participants at a much lower cost per participant, but they did not target people who experience SMI. Whilst hindsight reveals some potential sources of efficiencies for our project, recruiting to such studies is resource intensive. However, it is important to put this in the context of the potential cost offsets to be gained from facilitating the prevention of smoking related illness. For example, Golsbury et al. estimate the average additional health costs for an Australian diagnosed with lung cancer between 45 and 60 years old is AU$67,689 (47). In addition, a qualitative study among the participants of the present trial reported that the peer researcher and quitline interventions in the Quitlink study have been highly valued as compassionate approaches that have the potential to assist people on a journey to quitting (McCarter et al., submitted[1]).

Training of peer researchers for this study, preparation of a detailed peer researcher manual and ongoing supervision was necessary as the peer researchers had not assisted on an RCT before and the baseline assessments were initially quite long and were administered on an iPad linked to REDcap. One solution may have been to have experienced research assistants work alongside the peer researchers. However, once such peer researchers are trained, they form an important element of the peer researcher workforce to be engaged with future studies and also help to train and support others. In Australia, the peer research workforce is limited and needs support and resourcing for future development. Lived experience is increasingly seen as a discipline, with potential of forming a recognized profession (48). This also enhances the potential for co-design of strategies to improve research activities, including recruitment. Alongside the need for this level of peer researcher training and expertise, efficiencies in postcard recruitment, involving telephone contact with peer researchers and a briefer assessment conducted over the phone (in the context of a RCT), could be a useful model for peer telehealth interventions in the age of COVID-19 but also more broadly with widely dispersed services. Nevertheless, structural impediments to postcard effectiveness, such as unstable housing and people not receiving postcards mean that face-to-face advice regarding tobacco treatment should remain an important staple of usual care.

[1]McCarter K, McKinlay M, Cocks N, Brasier C, Hayes L, Baker A, et al. (submitted). The Value of Compassionate Support to Address Smoking: A Qualitative Study With PeopleWho Experience Severe Mental Illness.

Peer Researcher Commentary

The Process of Research

Generally speaking, past research has been critiqued for "othering" mental health participants. This means that it may omit or misunderstand details which are important to the people whom we are trying to support. This might also impact the degree to which research can define or address the problem. Future studies are encouraged to utilize co-design and co-production, which is the practice of including people with lived experience in the design and conduct of the study. This is potentially a challenging process for researchers as it subverts the traditional power dynamic but also allows for new opportunities to connect with participants, which may lead to better recruitment and richer data.

Conducting the Research

Many randomized controlled trials are designed to elicit as much information from participants as possible but may not take into account how this impacts the participant (e.g., difficulty due to literacy, length of surveys, intrusive questions and their mental health). For example, around half the participants in this study had not completed further education after high school; this is when peer researchers can support participants to feel that the project is accessible and that they understand their rights, including their right to not participate or withdraw.

The Challenges With Mental Health Services

Peer researchers were responsible for managing multiple complex referral pathways across the state and between partner organizations. At times, the peer researchers felt that recruitment was impacted by poor staff engagement and gatekeeping. This, however, was not an issue during the postcards recruitment as they were delivered directly to the potential participants who were able to choose if and when to contact the peer researcher who was supporting recruitment. Overall, the peer researchers felt like valued members of the research team and helped the team to understand future opportunities for consumer involvement through working and learning together.

Understanding the Experience of Quitting Smoking

Many consumers consider smoking to be an important part of their lives. Smoking has connotations of social exclusion which can further marginalize the participants of this study. This study is important because the baseline assessment questions inquired into sources of smoking that are deeply stigmatized, such as discarded cigarette butts. In this way, it is understood that smoking is broader than just a health issue and it has deep social and economic consequences.

The Shared Experience of Quitting Smoking

Importantly, some of the peer researchers also had the lived experience of being a smoker and quitting smoking. Having experienced many common challenges (e.g., peer pressure to keep smoking, boredom, difficulty accessing or using NRT)

often increased mutuality and connection between the peer researchers and the participants. The peer researchers felt that their experience, or knowledge of other people's quitting journey, helped lessen stigma and created a non-judgmental and understanding space to explore the topic. The importance of access to NRT was highlighted in these discussions.

Support for Peer Researchers

Also, the personal impact of hearing people's personal stories was acknowledged by the peer researchers as discussion about quitting also involved sharing heart felt or challenging experiences. Peer researchers found that setting a limit of two interviews a day was manageable in terms of self-care and administrative burden. Upon reflection, the peer researchers recommend developing debriefing, more opportunities for peer-to-peer support and access to peer supervision from a more experienced peer researcher, and other potential support for the peer researchers as a part of the study design for future studies. Future studies are encouraged to include lived experience investigators, this can help anchor the lived experience perspective and increase the ease with which the study can provide support to its peer workforce.

LIMITATIONS

One of the main limitations of the present study is that we failed to recruit the intended sample of 382 people. However, this experience allowed us to adapt our recruitment strategies, and compare them. Nevertheless, it should be noted that the three strategies did not occur concurrently and were active for varying lengths of time. Further, the proportion of people included in the trial via each recruitment strategy may not be truly representative of all those invited or offered recruitment in the trial. Another limitation is that we did not compare peer researcher recruitment with alternative non-peer strategies of recruitment. Alternative approaches, such as computer delivered information about the study, accompanied by a brief intervention with a link to quitline in residential settings or use of "opt out" rather than "opt in" strategies when people who smoke newly present to mental health services may have yielded different results. There remains an opportunity to co-design these strategies with people with lived experience including peer researchers. COVID-19 may have confounded some of the measures in the study, with smoking and other substance use potentially rising and quality of life declining during the pandemic.

Changes in investigators may have influenced recruitment, with CI Brophy departing one of the main organizations from which we recruited early in the study and CI Castle leaving the other main site later in the study, potentially lessening active commitment from organizations involved. Our peer researcher lead, who had been very active in developing the study, retired just as the study began. In hindsight, a replacement for a peer researcher lead may have addressed peer researcher needs for supervision in addition to that provided by the CI.

The main organizations in the study were comprised of widely dispersed services, necessitating travel over long distances. As peer researchers were embedded at head offices of the organizations, developing an ongoing recruitment routine was difficult. Future studies may more fruitfully employ peer researchers already attached to local services to establish recruitment protocols into practice. Victoria's clinical services have become more oriented to crisis care and are characterized by supporting large numbers of people considered to have SMI with complex needs and many are on compulsory orders (41). This challenging service delivery environment may have lowered expectations of staff and contributed to lower recruitment.

In terms of methodology, we did not audio record peer researchers' interactions with participants to monitor fidelity to the recruitment procedures. Peer researchers thought recording interactions may have been declined by most people. However, some measure of fidelity, perhaps a checklist, may have given a better sense of fidelity to the peer recruitment manual. On the other hand, at commencement on the project, CIs shadowed peer researchers in delivering the recruitment information and recruitment process, observing baseline assessment, randomization and feedback to participants. Finally, some participants did not complete the MINI, so diagnosis is only available on 91 people.

CONCLUSIONS

Recruitment of a broad range of people experiencing SMI (i.e., including those with alcohol and other drug issues and those living in supported accommodation) into our smoking intervention study was difficult and expensive. The recruitment rate we achieved was far lower than targeted and required us to adapt and develop a range of recruitment strategies. Face-to-face, direct mail postcard followed by telephone contact and online recruitment required different degrees of peer researcher involvement. These recruitment strategies could run in parallel to help attract people experiencing SMI into smoking interventions in clinical settings. This study relied on the commitment of partner organizations that are often operating in the context of competing priorities. Maintaining engagement from when a research project is formulated through to its implementation requires consistent and thoughtful planning that considers changes in leadership and other disruptions. Acknowledging that staff have an important role to play in enabling recruitment requires ensuring they are supported to understand the value of tobacco treatment. A proactive longer-term view of continually recruiting into tobacco treatment is needed in community mental health organizations, alongside preventive approaches to discourage uptake of smoking. Early and continued physical health intervention from first mental health presentation is vital (5) and tobacco treatment should be part of this approach.

DATA AVAILABILITY STATEMENT

Data is available upon request subject to approval.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC Reference Number:

HREC/18/SVHM/154), the University of Newcastle Human Research Ethics Committee (HREC Reference Number: H-2018-0192) and the Cancer Council Victoria Human Research Ethics Committee (HREC Reference Number: 1807). The patients/participants provided their written, verbal (audiotaped), or digital consent to participate in this study.

AUTHOR CONTRIBUTIONS

The first draft of the paper was written by ALB with significant input from KM, RS, LB, NC, CB, and MLM followed by the remaining authors. Statistical analyses were conducted by JA, DL, and DEB. All authors contributed to the design and write up of the study.

FUNDING

This project was funded by the National Health and Medical Research Council (APP1139125). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. ALB holds a NHMRC Fellowship (APP1135901) and Faculty of Health and Medicine, University of Newcastle, Gladys M. Brawn Fellowship. KM holds a University of Newcastle Postdoctoral Scholarship. DEB was funded by a University of Newcastle Ph.D. scholarship.

ACKNOWLEDGMENTS

Many thanks to the people who participated in the study and the staff of organizations involved. Thanks to Mind Australia Research Manager, Dr. Elise Davies for assistance with the study. Thanks also to Ms. Andrea Windley for design of the website and assistance with administrative aspects of the study and cost analysis.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.869169/full#supplementary-material

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Conflict of Interest: NC and LH were employed by MIND Australia. MIND Australia is a not for profit, non-government organisation that receives public funding and private donations.

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ORIGINAL RESEARCH
published: 06 July 2022
doi: 10.3389/fpsyt.2022.866779

Developing a Smoking Cessation Intervention for People With Severe Mental Illness Treated by Flexible Assertive Community Treatment Teams in the Netherlands: A Delphi Study

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OPEN ACCESS

Edited by:
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Reviewed by:
Kristina Schnitzer, Massachusetts General Hospital and Harvard Medical School, United States
Dilek Karadoğan, Recep Tayyip Erdoğan University, Turkey

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Specialty section:
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

Received: *31 January 2022*
Accepted: *16 June 2022*
Published: *06 July 2022*

Citation:
Küçükaksu MH, Hoekstra T, Jansen L, Vermeulen J, Adriaanse MC and van Meijel B (2022) Developing a Smoking Cessation Intervention for People With Severe Mental Illness Treated by Flexible Assertive Community Treatment Teams in the Netherlands: A Delphi Study. Front. Psychiatry 13:866779. doi: 10.3389/fpsyt.2022.866779

Background: There is still limited evidence on the effectiveness and implementation of smoking cessation interventions for people with severe mental illness (SMI) in Dutch outpatient psychiatric settings. The present study aimed to establish expert consensus on the core components and strategies to optimise practical implementation of a smoking cessation intervention for people treated by Flexible Assertive Community Treatment (FACT) teams in the Netherlands.

Design: A modified Delphi method was applied to reach consensus on three core components (behavioural counselling, pharmacological treatment and peer support) of the intervention. The Delphi panel comprised five experts with different professional backgrounds. We proposed a first intervention concept. The panel critically examined the evolving concept in three iterative rounds of 90 min each. Responses were recorded, transcribed verbatim and thematically analysed.

Results: Overall, results yielded that behavioural counselling should focus on preparation for smoking cessation, guidance, relapse prevention and normalisation. Pharmacological treatment consisting of nicotine replacement therapy (NRT), Varenicline or Bupropion, under supervision of a psychiatrist, was recommended. The panel agreed on integrating peer support as a regular part of the intervention, thus fostering emotional and practical support among patients. Treatment of a co-morbid cannabis use disorder needs to be integrated into the intervention if indicated. Regarding implementation, staff's motivation to support smoking cessation was considered essential. For each ambulatory team, two mental health care professionals will have a central role in delivering the intervention.

Conclusions: This study provides insight into expert consensus on the core components of a smoking cessation intervention for people with SMI. The results of this study were used for the development of a comprehensive smoking cessation program.

Keywords: tobacco addiction, outpatient psychiatric care, behavioural counselling, psychotic disorders, schizophrenia, bipolar disorder, pharmacotherapy for smoking cessation

INTRODUCTION

Smoking is the leading factor associated with cardiovascular diseases, cancers and diseases of the respiratory system, causing nearly eight million deaths worldwide each year (1). People with severe mental illness (SMI), such as psychosis, bipolar disorder or severe depression, are affected more often by tobacco addiction, with the proportion of smokers among these patients being 2–3 times higher compared to the general population (2–4). They also have more difficulties with overcoming addiction, manifested in more quit attempts and relapses, thus widening health inequalities between the general and psychiatric population (5, 6). Additionally, the proportion of smokers in the general population showed an evident decline over the past decade, while this proportion among people with SMI did not show a decrease, but rather a stagnation (4).

There are several possible explanations underlying the high prevalence of smoking in SMI, which can be interconnected and include models of shared genetic, psychological, social and environmental risk factors. Research on the relationship between nicotine addiction and psychosis, for instance, showed some shared genetic liability (7, 8). In individuals with a pre-existing vulnerability for psychosis, cigarette smoking may lead to an earlier onset of psychosis compared to non-smokers (9). Another study showed a significant positive association between smoking and the frequency by which positive, negative and depressive symptoms are experienced, as well as an increase in positive symptoms in patients who started to smoke (10). These results suggest a potential bidirectional relationship between psychosis and smoking and further push forward the need for smoking interventions in this patient group. Shared social and environmental risk factors involve, amongst others, a lower socioeconomic status (SES). Low SES has been associated with higher smoking prevalence and social acceptance of smoking. At the same time, a low SES early in life increases the risk for psychiatric disorders, possibly due to a correlation with structural disadvantage, parental mental illness and childhood adversity (11). Taken together, these different notions are possible explanations for the very prevalent co-occurrence of smoking and SMI and describe mechanisms that cause and maintain tobacco addiction.

Another emerging concept is emotion dysregulation—a transdiagnostic factor in psychopathology, particularly for personality disorders and mood disorders—that is also associated with heavier smoking and more difficulties with quitting (12, 13). The idea of emotion dysregulation adds to the belief that cigarette smoking may have the potential to attenuate symptoms, such as depressive symptoms or cognitive problems (e.g., concentration and attention problems), and to counterbalance side effects of antipsychotic medication (e.g., increased appetite) (14). Although there is no clear evidence to support this self-medication hypothesis (10), its underlying beliefs have contributed to the social acceptance of smoking within mental health care (15). A couple of notions may have impeded the collective process of critically evaluating the association between smoking on the one hand, and psychiatric symptoms, somatic health and quality of life on the other hand: health care professionals' view that smoking may be helpful for people with SMI and therapeutic pessimism regarding both general treatment outcomes and opportunities for successfully quitting smoking.

In recent years, the Netherlands, among other countries, has introduced new policy measures to raise awareness regarding the negative impact of tobacco use, and a smoking ban in public areas, including mental health care institutions. As a result of these developments, there is a need for more evidence-based interventions for smoking cessation in mental health care settings (16, 17).

There is compelling evidence on the effectiveness of behavioural support and pharmacological treatment for smoking cessation among people with SMI. For behavioural support, the two most commonly used and researched therapeutic approaches to treat addiction are cognitive-behavioural therapy (CBT) and motivational interviewing (MI) (18). CBT for smoking cessation is comparably effective for people with and without SMI (19, 20). Moreover, studies comparing the effectiveness of CBT alone to CBT combined with pharmacotherapy showed that a combination of both is the most effective for smoking cessation (20–22). Regarding pharmacotherapy, a series of trials that examined the safety and effectiveness of Varenicline, Bupropion and nicotine replacement therapy (NRT) for people with SMI, showed overall positive results in favour of the use of these medications (23, 24). In addition to these therapeutic and medical interventions, peer support can add a source for social support and improve a person's social network—a decisive factor for smoking cessation (25). Peer support appears to be particularly relevant in the present population, in which persons often have small social networks.

A previous clinical trial on the treatment of tobacco addiction in psychiatric patients, showed that using a combination of these components was superior to care as usual (26, 27). Despite basic knowledge of the core components of a smoking cessation intervention for patients with SMI, there is a need for additional insights into the specific content of these components (following the most recent practical and scientific knowledge), on how to better tailor these to the needs of this population, and how to effectively implement them in Dutch mental health care.

Prior to a planned randomised controlled trial (RCT), which will evaluate the implementation and effectiveness of a smoking cessation program in ambulatory mental health care, we carried out a Delphi study to reach consensus on the specific content of such a program. Additional aims were to incorporate country- and time-specific characteristics of the mental health care settings (e.g., institutional restructuring following a new insurance policy and local measurements to prevent the spread of COVID-19) in which the program will be implemented (28). To the best of our knowledge, this is the first study that aims to identify and reach consensus about the structure and content of a smoking cessation intervention offered to people with severe mental illness in an outpatient clinical setting in the Netherlands.

METHODS

Study Design

We conducted a modified three-round Delphi study with five experts on smoking cessation, with different expertise and backgrounds (29). In light of the ongoing COVID-19 pandemic, all rounds were held online *via* videoconferencing software Zoom.us between December 2020 and February 2021. Using Zoom for qualitative research is well-accepted and perceived as convenient by researchers and participants (30).

Selection of Participants

We selected five experts aged between 31 and 64. Number of years of experience with treating tobacco addiction in people with SMI ranged from 3 to 10 years. Participants were recruited through the researchers' professional networks. Considering that mental health care nurses working in ambulatory mental health teams will be delivering the intervention, we included two clinical nurse specialists with ample clinical experience with smoking cessation among SMI patients. To ensure the incorporation of clients' perspectives we included an expert-by-experience. We also included a practising physician/researcher, with comprehensive clinical and research experience on smoking cessation and early psychosis. Finally, a senior project leader and consultant of tobacco regulation in mental health care in the Netherlands was included.

Data Collection

The overall aim during all three rounds was to reach consensus about the composition of the three central components of the smoking cessation intervention, and strategies to optimise implementation in clinical practise. Participants were invited and informed through an electronic invitation letter. All rounds, with a duration of 90 min, were semi-structured and recorded for analysis. MK prepared the Delphi procedures and processed all responses. To compensate for two participants' absence during the group interviews on two occasions, individual interviews were conducted with three of the researchers (TH, MA and MK). BvM moderated the panel sessions while MA moderated the two individual sessions. Two weeks before the first round, participants received three documents for preparation:

1. An overview of the procedures of the Delphi study, as well as a description of what participation in the panel entails.
2. The smoking cessation intervention concept describing propositional components and elements of the intervention, including their rationale, theoretical background and context (31).
3. Nine open-ended questions to stimulate general feedback on the first concept version (see **Supplementary Material** *Interview Guide*).

Responses to the open-ended questions were received through e-mail from each participant before the first panel session. In summary, the structure of the three rounds was as follows (see also **Figure 1**):

Round 1: Each question ($n = 9$) and participants' responses were reviewed and discussed. The experts' contributions of the first round were then thematically summarised. The focus during this round was on the general structure of the intervention program.

Round 2: Participants received 14 new questions based on preliminary outcomes from round 1. Participants also received a new draught of the intervention concept based on the first round. Responses to the 14 open-ended questions were deliberated during round 2. The specific focus during this second round was on the use of e-cigarettes, strategies for relapse (prevention), and the involvement of peers and family members.

Round 3: Participants received an overview with preliminary conclusions drawn from the first two rounds and 12 final open questions. In this round, the discussion focused, among other things, on the ratio of individual and group behavioural support, concrete guidelines for pharmacological treatment and how to deal with comorbid cannabis use disorder.

Differences in opinions were regarded as opportunities to explore these discrepancies and find compromise for the intervention design and its implementation. After each round, the research team debriefed, and points of disagreement were the starting point for the next round. After the final round, the panel received a definitive version of the intervention. The panel reached eventual consensus through negotiation, taking into consideration the expected effectiveness of the component, the needs of clients, treatment possibilities of clinical staff and practical conditions for implementation in psychiatric institutions.

Ethical Considerations

We obtained consent for video and audio recordings beforehand from all participants. The transcripts were pseudonymised. Monetary compensation of 1,100 euros for preparation and participation in all three rounds was offered, which participants received after the last round.

Analysis

Thematic analysis was applied (32). Two authors (MK and LJ) transcribed all audio recordings verbatim. The authors familiarised themselves with the data by listening to the interviews. Subsequently, the transcripts were coded using MAXQDA. As there was already a predefined

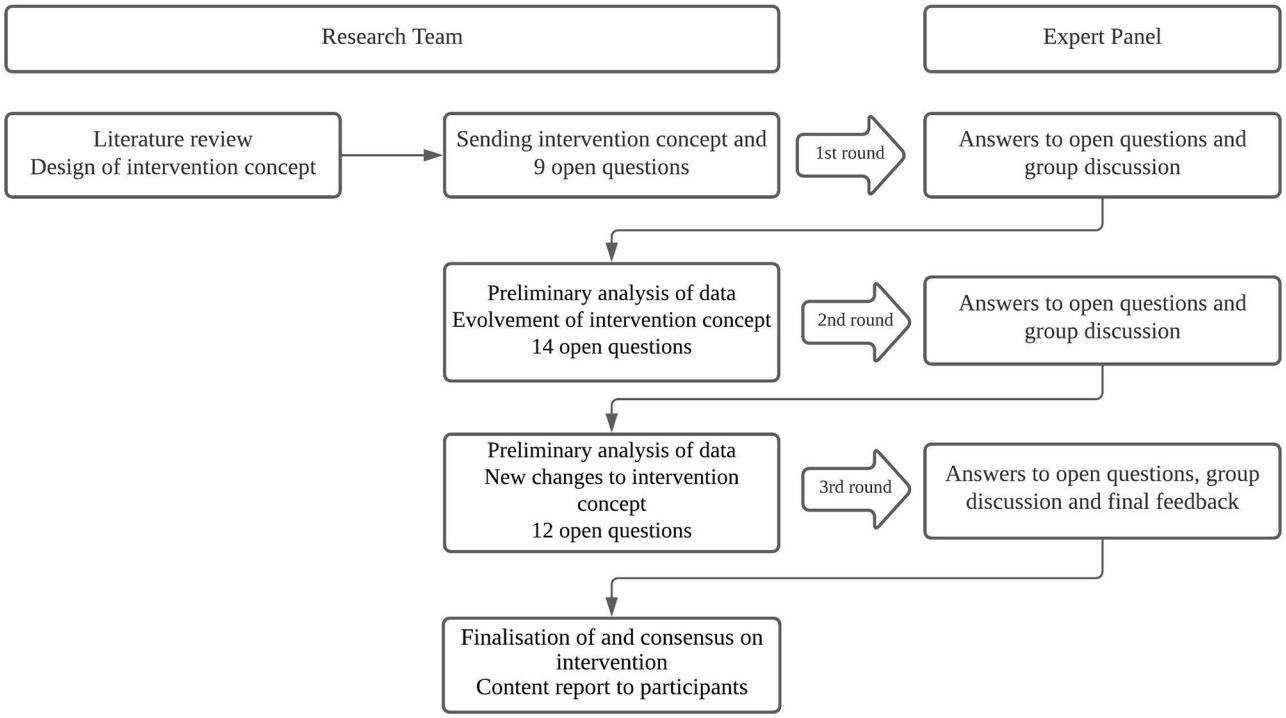

FIGURE 1 | Flowchart of the three-round Delphi procedure.

intervention concept, the three intervention components (1. Behavioural counselling based on CBT and MI techniques; 2. Pharmacological treatment; 3. Peer support) and aspects of practical implementation were defined as an initial framework before coding. Based on this framework, code words and themes were generated. New code words and themes, that emerged from the data, were added. Next, the research team reviewed the generated themes and discussed discrepancies if needed.

RESULTS

Intervention Components

Behavioural Counselling

The initial phase of behavioural counselling prepares the patient for the actual quitting moment through psycho-education, assessment of motivation to quit and identification of individual support needs. Although individual counselling was regarded as therapeutically effective and should be actively suggested to patients, there was consensus among the experts to offer group sessions per default once a week. For reasons of limited staff capacity within clinical teams, individual consults are available upon demand. The panel also noted that group sessions could strengthen patients' social connectedness and that motivation to quit smoking was enhanced by mutual contacts within the group of patients. This aspect can be additionally reinforced by peer support meetings. At the same time, constraints of group sessions, such as cognitive overstimulation and concentration problems, should be taken into consideration by introducing sufficient breaks and facilitating new content with, for instance, visual material.

Further, all participants agreed to emphasise relapse prevention and normalisation of relapse as well as the differentiation between relapse and "slips." While "slips" refer to a momentary give-in to craving (e.g., smoking one cigarette), relapse entails returning to a regular smoking pattern similar or identical to before quitting. Relapse and "slips" need to be addressed explicitly as common parts in overcoming addiction and therefore un-labelling them as a failure. This may be particularly important to reduce feelings of shame, prevent a decrease or total loss of motivation to quit and promote a more flexible approach to smoking cessation in both patients and clinical staff. Experts agreed and recommended a relapse prevention plan for each patient, addressing personal challenges and risk factors for "slips" and relapse. External and internal triggers such as friends/relatives smoking, alcohol consumption, stress and exacerbation of psychiatric symptoms, can be risk factors for relapse. These should be discussed with the patient and used as a starting point to formulate "emergency measures," i.e., (preventive) actions to be undertaken in case of confrontation with these triggers. Finding new ways to deal with stress and replacing smoking with other stress-relieving activities is especially relevant in the light of emotion dysregulation, depression and potentially decreased tolerance to stress associated with severe mental illness.

TABLE 1 | Final smoking cessation intervention concept.

Component	Core elements	Frequency/duration/ dose	Responsible mental health care professional
Behavioural Counselling	Group meetings by default, with additional individual counselling if needed. • Motivational preparation for smoking cessation • Psycho-education on: 1. Basic mechanisms of nicotine addiction 2. Physical/mental/emotional effects of smoking cessation in the context of mental health problems 3. Effects of smoking cessation medication • Normalisation of relapse • Personalised relapse prevention plan • Critical assessment of risks and subjective benefits of smoking • Challenging core beliefs and thoughts that maintain tobacco use (including cannabis use if applicable) through CBT techniques such as behavioural experiments • Improving emotion regulation, e.g., dealing with stress • Dealing with withdrawal symptoms and craving	• Month 1–3: weekly • Month 4–12: monthly	Mental health care specialist nurse psychologist
Pharmacological treatment (options)*	(1) Nicotine replacement therapy (chewing gum, patches, pastilles)	Total duration: up to 6 weeks	Mental health care specialist nurse psychiatrist/physician
	(2) Varenicline	Total duration: 12 weeks quit date between week 1 and week 2 of treatment cycle	
	(3) Bupropion	Total duration: 9 weeks	
Peer support	• Regular group meetings with non-therapeutic approach • Connecting participants and creating group cohesion • Creating a safe environment in which participants can share experience • Participants can gain hope from positive attitude and deep understanding of expert-by-experience Group meetings do not have fixed content. Participants decide on discussion topics or activities together.	Month 1–3: weekly Month 4–7: bi-weekly Month 8–12: monthly	Expert-by-experience

**Building up and tapering off doses are determined through shared decision making between patient and mental health care professional following national guidelines.*

Pharmacological Treatment

Participants agreed that medication should be proactively offered to patients in the initial phase to increase chances for successful quitting. Current international guidelines for pharmacological treatment for smoking cessation recommend nicotine replacement therapy (NRT), Varenicline and Bupropion (31). In line with these guidelines, all participants preferred Varenicline and NRT related to their higher effectiveness and fewer side effects. Regarding NRT, there was agreement about not including mouth spray and inhalators for administering nicotine fast through the mucous membranes and hence potential dependency. Participants did not recommend Bupropion as a first-choice medication because of more side effects and interactions with certain anti-depressants and anti-psychotic medication (e.g., Clozapine, Aripiprazole, Risperidone).

Nevertheless, Bupropion could be an alternative in case patients present intolerance or contra-indications for the use of Varenicline (i.e., severe kidney disease or dysfunction) and when patients suffer from attention-deficit/hyperactivity disorder. To the best of the panel's knowledge and clinical experience there is no clear evidence that Varenicline substantially exacerbates present or induces new psychiatric symptoms. One participant referred to a series of trials that examined the safety and effectiveness of these medications for people with SMI (23, 24, 33).

A psychiatrist with comprehensive knowledge of psychopharmaca and smoking cessation medication needs to supervise medication use. The panel also emphasised the importance of recognising that smoking interferes with the metabolism of some antipsychotic medication by enzymes in liver cells. Through this interference, smokers need higher doses of antipsychotic medication. Hence, after smoking cessation, plasma levels need to be determined and medication dose should be adjusted accordingly to avoid strong side effects or unnecessary high levels of antipsychotic medication. The prospect to potentially reduce medication doses was regarded as an important motivating factor for patients. Lastly, there was consensus about the importance of psycho-education about

supportive medication so as to build up trust and willingness to use medication. According to the experts, there seems to be some reluctance towards medication for smoking cessation because of expected side effects.

Peer Support

There was consensus about the relevance of peer support groups, taking place at least once a week. Most importantly, it offers a safe space to exchange experiences. The participants pointed out the motivational role that a peer group can have when quitting to smoke. The panel considered it essential that the expert-by-experience supporting these group meetings had personal experience with mental illness and addiction in the past and should take a facilitating rather than a leading role. The expert-by-experience has the ability to share their own storey with some emotional distance and make room for patients' experiences with an accepting and hopeful attitude. Topics during these meetings should be determined by the patients themselves, based on their actual experiences while participating in the smoking cessation program.

The involvement of family members was proposed as an optional form of support. Central points for attention are the establishment of rules about smoking in the proximity of the patient and the reduction of other triggers, such as smoking equipment at home (e.g., rolling paper, ashtray). Systemic support by family and/or friends can aid to mitigate these environmental triggers. Similarly, including family members or friends when making the relapse prevention plan can increase chances of quitting success by, for instance, appointing a person who can be contacted in challenging moments of craving. **Table 1** outlines the finalized intervention concept with core elements, frequency and duration of the treatment components.

Compensatory Behaviours, Co-addictions and Harm Reduction

E-Cigarettes

According to the panel, e-cigarettes have increasingly become an alternative way of nicotine intake. Advantages of e-cigarette use are their potential to reduce harm of combustible cigarettes, and the possibility of easily lowering nicotine dosages. However, e-cigarette use maintains the habit of smoking and oral fixation, which were described as serious threats to permanent quitting success. Additionally, e-cigarette use can lead to possible long-term negative health effects. Therefore, the panel reached consensus on the fact that e-cigarettes should not be actively promoted. E-cigarettes were, however, proposed as a last resort for patients unresponsive to any treatment offered (i.e., 7–8 unsuccessful quit attempts).

Cannabis and Other Substance Use

Cannabis use and the prevalence of cannabis use disorder is high among people with severe mental illness. It can both relieve and trigger psychiatric symptoms, for instance, psychosis. There was agreement that cannabis use has to be treated simultaneously within this intervention since it is often consumed together with tobacco. Therefore, smoking cannabis has the potential to maintain tobacco dependence at the same time. More importantly, cannabis use is discouraged in consideration of its main compound tetrahydrocannabinol (THC), which has a strong psychoactive effect. Positive symptoms such as paranoid ideations, hallucinations and cognitive tendencies contributing to delusions and anxiety can be reinforced by THC. The panel acknowledged a potential subjective beneficial effect of cannabis (e.g., with sleeping problems, low mood or pain relief). If cannabis is indispensable for the patient, the aim will be to find alternative ways of consumption, such as eating or vaporising, rather than quitting its use. Attention needs to be paid to the possibility that, as a compensatory behaviour, the use of other substances may exacerbate or, through disinhibition, contribute to relapse in smoking.

Implementation

Smoking Culture in Mental Health Care and Professionals' Attitude

Firstly, mental health care professionals' perception of and attitude towards smoking is decisive to the intervention's success. Participants reported treatment pessimism among clinical staff regarding the opportunities for smoking cessation of their patients. The panel supposed that pessimistic attitudes of staff about treatment success are related to increased relapse in this specific population. Such a pessimistic attitude can potentially be transferred—implicitly through negligence and lack of support and explicitly through verbal expression of frustration or discouragement—to the patient. Additionally, tobacco addiction is often not included in the primary diagnosis by mental health care professionals. Such diagnostic omission can be an obstacle to offering a structured therapeutic trajectory for smoking cessation and hinder reimbursement for treatment costs from health insurances. Furthermore, mental health care professionals' smoking behaviour is crucial for their motivation to address tobacco addiction with their patients and is also conditional for being a positive role model. Consequently, the panel agreed to select clinical teams for the RCT based on their mind-set and determination about smoking cessation. Two clinical staff members should be appointed based on their motivation, and trained to be responsible for recruiting patients and delivering the smoking cessation intervention. While striving to tailor the intervention as much as possible to the patient's individual needs and personal circumstances, feasibility of its integration into daily clinical routine for clinical staff has to be considered carefully.

DISCUSSION

The present Delphi study aimed to establish expert consensus on the development and implementation of a smoking cessation intervention for people with severe mental illness, treated in outpatient clinical settings in the Netherlands. To achieve this, we conducted a three-phase Delphi study in which five experts critically reviewed the progressing intervention concept and responded to a number of critical open-ended questions. The panel reached consensus on the intervention's core components [behavioural counselling, pharmacological treatment (NRT, Varenicline, Bupropion) and peer support], their specific content, structure and strategies for optimal implementation. This

outcome is in line with recent scientific research findings that showed the safety and effectiveness of these components compared to usual care in reducing smoking and nicotine dependence (27). Studies examining the risk for neuropsychiatric adverse events of smoking cessation medications have not found a significantly increased risk for depression, anxiety, suicidal ideation or suicidal behaviour in people with psychotic and mood disorders (23, 33, 34). These studies also suggest a superior effect of Varenicline compared to Bupropion, NRT and no medication. Psychiatric contra-indications for Bupropion include a diagnoses of bipolar disorder or eating disorders as Bupropion may increase symptoms of depression and/or anxiety and reduce appetite (23, 35), which is in line with the panel's recommendations.

The results of this study help to further specify the contents and structure of these components as well as their contextualisation into current Dutch mental health care. In addition, peer support will make up a fixed part, which has not been standardised in any other study on smoking cessation for people with SMI so far. Mixed-methods studies on peer support groups for people with schizophrenia or psychotic disorders show beneficial effects by improving patients' social networks (36, 37). Therefore, introducing peer support on a regular basis could aid to empower patients during smoking cessation.

Additionally, compensatory behaviours, co-addictions, harm reduction and considerations for optimal implementation were addressed. Despite differences in opinion, the panel reached agreement about the role of e-cigarettes, i.e., being a "last resort" for treatment-resistant patients regarding their smoking behaviour. Two of the experts proposed e-cigarettes a "last resort" to reduce harm of combustible cigarette smoking, while the other three experts did not support the use within clinical practise at all because of habit maintenance and negative health consequences. These discrepancies resonate with current national guidelines on the one hand, that clearly advise against e-cigarette use because of lacking evidence for their safety and the argument that their use could deter long-term cessation and normalise smoking (38, 39). On the other hand, there is research that shows that e-cigarettes are associated with recent quit attempts in people with SMI indicating an interest and potentiality to use e-cigarettes as a quitting aid in this population by reducing smoking of combustible cigarettes (40). One could also argue that through the use of e-cigarettes antipsychotic medication doses can be lowered, as it is the non-nicotinic ingredients of combustible cigarettes that impact enzyme levels and lead to a higher required medication dose (41). In practise, it is a joint process of clinician and patient to negotiate among treatment goals, options and priorities.

Different opinions also arose about whether or not to propose alternative ways of cannabis use. There was, however, clear discouragement of cannabis use in this patient group due to its psychoactive effect and therefore its potential to exacerbate psychotic symptoms. Recent research suggests that cannabis use is associated with a lower likelihood for tobacco abstinence, including those who use cannabis for medical reasons (e.g., pain, insomnia) (42). Hence, these results favour an integrative treatment addressing co-addictions in case of dual use. The research team agreed that patients with alcohol use disorder (AUD) will not be considered for inclusion as AUD could negatively interfere with participation and commitment to the present smoking cessation intervention. Binge drinking and heavy drinking during smoking cessation treatment are associated with a greater risk of smoking lapse (43, 44). An impaired response inhibition, and hence a lower threshold to give in to craving, resulting from alcohol use might account for this greater risk (45, 46). Additionally, alcohol use can increase levels of cigarette craving (47), and cigarette craving is a predictor of smoking relapse (48). Another challenge during the treatment of individuals with AUD is the high rate of treatment dropout (49–51). In conclusion, the treatment of tobacco dependence in individuals with AUD comes with specific challenges that are outside the scope of this intervention and should be tackled in a specially designed treatment.

All aspects considered, consensus on many aspects of the development and implementation of a smoking cessation program in people with SMI treated in outpatients clinical setting was reached. Yet, implementation in realistic clinical settings might still hold unexpected challenges, which will be assessed in a planned RCT subsequent to this study.

Our study has several strengths. Firstly, participants were highly experienced and specialised in treating mental disorders and comorbid addiction or smoking. Secondly, the semi-structured online sessions gave sufficient direction to gather the knowledge needed for the design of the intervention while also allowing new content to emerge. Thirdly, the results portray the complex interplay of physical, psychological, social and environmental factors. Through this, they can endorse a holistic approach to treatment within mental health care institutions and improve the quality of personalised care.

There are limitations to our study. Firstly, our sample size ($n = 5$) is relatively small, which could potentially lower the generalisability of the outcomes. However, for the purpose of our study we selected a small but highly specialised group of experts that we considered sufficient based on relevant knowledge. Despite the small sample size, we do have a broad representation of people with diverse expertise and experiences. Guidelines on the Delphi methodology in scientific research emphasise the selection criteria of having specialised expertise on the subject at hand, rather than suggesting researchers to include a specific number (29, 52). Additionally, there is already existing general consensus on the effective treatment components for smoking cessation. For specifying the contents of these components, an in-depth qualitative study with a smaller number of experts may be more suitable to yield data that can be translated into an intervention protocol. Secondly, even though we included an expert-by-experience to integrate the perspectives from a former patient, we did not include a person who is currently in psychological treatment and is also a current smoker. The inclusion of the broad range of patients' perspectives, which could have added unique content to the design and implementation of the intervention, may therefore be insufficient. To compensate for this to some extent, we encouraged participants to integrate their knowledge and theory of mind about patients' perspectives into their responses.

Furthermore, a higher degree of heterogeneity regarding the cultural background of the participants could have increased the intervention's sensitivity for cultural differences in the present patient group.

Overall, this study provides insight into expert opinions on the most relevant elements of the core components and implementation of a smoking cessation intervention for people with SMI treated by FACT teams in the Netherlands. Future research applying the Delphi method for the design of therapeutic interventions should ensure the inclusion of patients in the panel.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

MK drafted the intervention concept, prepared the Delphi procedure, and drafted the manuscript. TH, JV, MA, and BM revised it. MK and LJ processed all received responses, transcribed the audio recordings, and independently conducted the analysis. BM moderated the panel sessions while. MA moderated two individual sessions. JV contributed intellectually to the final design of the intervention. All authors have read and approved the final manuscript.

FUNDING

This work was supported by *Stichting tot Steun VCVGZ* and the Dutch *Ministry of Health, Welfare and Sport*s (Grant Number 258): KISMET—a smoking cessation intervention for people with severe mental illness.

ACKNOWLEDGMENTS

We thank all participants for their time and efforts.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.866779/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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ORIGINAL RESEARCH
published: 14 July 2022
doi: 10.3389/fpsyt.2022.869158

Effectiveness of Mental Health Warnings on Tobacco Packaging in People With and Without Common Mental Health Conditions: An Online Randomised Experiment

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OPEN ACCESS

Edited by:
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Reviewed by:
Sonu Goel, Post Graduate Institute of Medical Education and Research (PGIMER), India
Venkata Lakshmi Narasimha, All India Institute of Medical Sciences, Deoghar (AIIMS Deoghar), India

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Specialty section:
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

Received: *03 February 2022*
Accepted: *03 June 2022*
Published: *14 July 2022*

Citation:
Sawyer K, Burke C, Ng RLY, Freeman TP, Adams S and Taylor G (2022) Effectiveness of Mental Health Warnings on Tobacco Packaging in People With and Without Common Mental Health Conditions: An Online Randomised Experiment. Front. Psychiatry 13:869158. doi: 10.3389/fpsyt.2022.869158

Background: Health warning labels on tobacco packaging are a cost-effective means of health risk communication. However, while an extensive range of physical health risks are well-portrayed *via* current tobacco health warnings in the UK, there are none that currently portray the negative impact of smoking on mental health.

Aims: (i) develop novel mental health warning labels for tobacco packaging and (ii) test perceptions of these warnings in smokers and non-smokers, with and without mental health problems.

Methods: Six mental health warning labels were developed with a consultancy focus group. These warning labels were tested in an online randomised experiment, where respondents ($N = 687$) rated six Mental Health Warning Labels (MHWLs) and six Physical Health Warning Labels (PHWLs) on measures of perceived effectiveness, believability, arousal, valence, acceptability, reactance and novelty of information.

Results: MHWLs were perceived as low to moderately effective (mean = 4.02, SD = 2.40), but less effective than PHWLs (mean = 5.78, SD = 2.55, $p < 0.001$, $\eta_p^2 = 0.63$). MHWLs were perceived as less believable, arousing, unpleasant, and acceptable than PHWLs. MHWLs evoked more reactance and were rated as more novel. Perceptions of MHWLs did not differ in people with and without mental health problems except for reactance and acceptability, but consistent with the PHWL literature, perceptions of MHWLs differed between non-smokers and smokers.

Conclusion: MHWLs could be an effective means to communicate novel information about the effects of smoking on mental health. MHWLs are perceived as less effective, believable, arousing, unpleasant, and acceptable than PHWLs, but MHWLs evoke more reactance and are rated as more novel.

Keywords: tobacco warning labels, tobacco control, mental health, smoking, survey

INTRODUCTION

Smoking is the leading cause of preventable death and illness in the UK (1), with 77,800 deaths per year estimated to be attributable to smoking (2). In high income countries, smoking rates have declined among the general population (3, 4). However, people with common mental health conditions such as anxiety and depression, are twice as likely to smoke than the general population (5, 6). Smokers with mental health conditions encounter substantial barriers to cessation, such as heavier smoking and greater nicotine dependence and withdrawal symptoms (7–10). People with mental health conditions die 10–20 years younger than the general population, and smoking is a primary reason for this (11, 12). Smoking represents a major driver of health inequalities and there have been calls from governments and healthcare agencies for bespoke and targeted interventions for people with mental health conditions (4, 13).

It is well established that smoking damages physical health, and warning labels on tobacco packaging are a cost-effective method of communicating these health risks (14). In 2017, the UK implemented plain tobacco packaging with pictorial warnings (15). There is an extensive range of physical health risks portrayed on tobacco health warning labels in the UK and internationally (16), which are demonstrated to be effective in promoting smoking cessation, and reducing smoking uptake (14, 17, 18). However, it is less well known amongst the general public and healthcare professionals that smoking can negatively affect mental health (19–21). A large body of evidence suggests that tobacco use increases the risk of developing depression, schizophrenia and bipolar disorder (22–25), and that smoking cessation can reduce symptoms of depression, anxiety, and stress, and lead to improved wellbeing and positive feelings (26). Qualitative research suggests that people who smoke and have mental health conditions "buy in" to the idea that tobacco can worsen mental health, they understand that smoking can make their depression and anxiety worse, and that quitting could improve their mental health (27). Hence, mental health warnings on tobacco packaging represent a key strategy to promote smoking cessation and prevent uptake, by, for example, increasing understanding and believability of the link between smoking and mental health, or increasing arousal when viewing tobacco warning labels.

The World Health Organisation (WHO) recommends that warnings on tobacco packaging should expand to include the risks of smoking for mental health (28), however, only one country has adopted this recommendation, and there is only one study testing the effectiveness of one MHWL. Columbia introduced one mental health warning in 2018 describing the effects of smoking on anxiety, and found larger warnings decrease positive pack perceptions and have the potential to reduce the demand for tobacco products (29). Other than this one study, no other countries have adopted this recommendation, and there are no other research testing the effectiveness of such warning labels. Notably, limited empirical research suggests that pictorial mental health warnings for cannabis products are perceived as moderately effective and believable (30). Some evidence suggests that smokers with mental health conditions might respond differently than other populations to tobacco warning messages (31, 32). Smokers with mental health conditions are more likely to perceive physical health warnings as more effective (31), and exhibit greater attention and cognitive responses to health warning labels (32). However, people with mental health conditions are also more likely to avoid looking at the health warning label (32).

Therefore, this study aims to develop novel mental health warning labels for tobacco packaging and to address the following exploratory research questions:

1. Are Mental Health Warning Labels (MHWLs) rated differently to Physical Health Warning Labels (PHWLs) on measures of perceived effectiveness, believability, arousal, valence, acceptability, reactance, novelty of information, and potential effectiveness?
2. Do ratings of warning labels differ according to smoking status or mental health status?
3. Does the difference in ratings between PHWLs and MHWLs vary according to smoking status or mental health status?

MATERIALS AND METHODS

The protocol was pre-registered on the Open Science Framework (OSF) (DOI 10.17605/OSF.IO/37×56). Ethical approval was obtained from the Psychology Research Ethics Committee (PREC) at the University of Bath on 27/April/2020 (PREC ID 20-028). Consultation with service users and members of the public has shaped the methodology proposed. Additional information on study methods is provided in **Supplementary Material 1**.

Study Design and Setting

This study was an online, randomised experiment with a $2 \times 2 \times 2$ design. Mental health status (people with common mental health disorders vs. people without common mental health disorders) and smoking status (smokers vs. non-smokers) were between subjects' variables, and type of tobacco health warning (MHWLs vs. PHWLs) was a within subjects' factor. Warnings were presented in a randomised order, randomised in blocks (with PHWLs and MHWLs constituting each one block) and the order of specific warnings within each block also randomised.

Participants and Recruitment

Participants were recruited *via* email lists, third-sector services, public engagement events, social media, and PROLIFIC.[1] Participants were aged 18 years or greater, UK residents, able to read English. We also targeted males when we realised that we had a disproportionate number of females. Our sample is comparable to large scale studies of smokers in the UK in terms of sex, age, and tobacco dependency (33). Smokers were those self-reported to smoke at least 100 cigarettes during their lifetime, and at the time of participating in the survey smoking at least once per week (34). Non-smokers were those self-reported to have

[1]https://prolific.co/

smoked at least 100 cigarettes during their lifetime, and at the time of participating in the survey not currently smoking. Having a common mental health condition was defined as scoring above clinical cut-off scores on the GAD-7 (35) and the PHQ-9 (36) [score of ≥ 8 on the GAD-7 (35, 37, 38) and/or ≥ 10 on the PHQ-9 (36)], currently receiving treatment for a mental health problem was not used as grouping criteria.

Power Calculation

A priori power was calculated using G*Power. To achieve 95% power at 5% alpha level to determine a small effect size of f = 0.1 on our primary outcome (effectiveness), we needed 608 participants. A study by Maynard et al. (39) used to guide some measures in this study, examining the difference in perceived effectiveness of tobacco warning labels between smokers and non-smokers, reported a η2 of 0.04, which corresponds to an effect size of f = 0.2 (40). Given that mental health warnings are not established and are untested in this population, we implemented a more conservative effect size for this power calculation (f = 0.1).

Stimuli

Warning labels were presented as pictorial and text warning together in a stacked format, as in accordance with EU guidance, with a size of 300 by 300 pixels (16).

The final set of MHWLs to be implemented in the online experiment was guided by a patient and public consultancy group. The MHWLs were informed by causal evidence of the effect of smoking on mental health (22–25). The MHWLs were approved by three members of the public with lived experience of smoking and/or mental health in a consultancy focus group, which involved deep discussions around both the text and pictures to be selected for the current study. For more information on development please see the preregistered protocol (DOI 10.17605/OSF.IO/37X56). The MHWLs presented were: "Smoking increases the risk of schizophrenia," "Smoking harms your mental health," "Smoking increases the risk of depression," "Smoking increases anxiety and tension," "Smoking increases the risk of bipolar disorder" and "Smoking makes stress worse," due to copyright, stimuli are available on request from the primary author.

PHWLs were selected from set 2 of the European Union pictorial warnings (16). Images from set 2 were chosen due to rotation date occurring at the start of recruitment (May 2020). The following warning labels were selected: "Smoking causes 9 out of 10 lung cancers," "Smoking increases the risk of blindness," "Smoking damages your teeth and gums," "Smoking causes heart attacks," "Smoking causes stroke and disability," "Smoking clogs your arteries," due to copyright, stimuli are available on request from the primary author.

Primary Outcome Measures

Effectiveness

Potential effectiveness of tobacco health warning labels was assessed by a measure adapted from Pechey et al. (41): "Does this affect how much you want to have a cigarette right now?," answered on a visual 1–7 Likert scale, with 1 labelled as "not at all" and 7 labelled as "very much." This question was only presented to smokers.

Perceived effectiveness of tobacco health warning labels was assessed by a measure adapted from Maynard et al. (39): "Overall, on a scale of 1–10, how effective is this health warning? (e.g., in encouraging smokers to quit, increasing concerns about smoking, and discouraging youth from starting to smoke)", with 1 as not at all and 10 as extremely.

Secondary Outcome Measures

Believability

Believability was assessed by asking "Overall, on a scale of 1–10, how believable is this health warning?" The questions was answered on a visual 1–10 Likert scale, with 1 labelled as "not at all" and 10 labelled as "extremely" (39).

Valence and Arousal

Emotional response to the health warning labels was assessed using the valence and arousal items of the Self-Assessment Manakin (SAM) (31, 42). Respondents rated their affective states on 9-point visual analogue scales for valence, ranging from 1 "unpleasant" to 9 "pleasant," and arousal, ranging from 1 "calm" to 9 "agitated," with 5 as neutral. Note that "agitated" replaced "excited" as this was deemed more appropriate in this study context.

Acceptability

Acceptability of tobacco health warning labels was assessed by asking "Do you support or oppose putting this label on tobacco products?" on a visual 1–7 Likert scale, with 1 labelled as "strongly oppose" and 7 labelled as "strongly support." Adapted from previous research assessing alcohol health warning labels (41). Participants were also asked to provide a response in a free-text box to the question "Why do you support/oppose putting the label on tobacco products?"

Reactance

Reactance to health warning labels was assessed using the Brief Measure of Reactance to Health Warnings Scale (RHWS) (43). Respondents were asked "Please state how much you agree or disagree with each statement about the health warning presented above" in response to "The health effect on this warning is overblown," "This warning is trying to manipulate me" and "This warning annoys me" on a visual 1–5 Likert scale, with 1 labelled as "strongly disagree" and 5 labelled as "strongly agree." Scores were summed to give an overall total reactance score.

Novelty of Information

To assess novelty of information participants were asked: "Have you learned something new from this packaging about the effects of smoking cigarettes on health and wellbeing?" on a visual Likert scale of 1–10 with 1 labelled as "not at all" and 10 labelled as "extremely." Respondents were then asked to "Please briefly describe your response in the box below."

Qualitative Data

Adapted from Pechey et al. (41), after each block of warning label type participants were presented with an open-text comment box

and asked, "Do you have any further thoughts or comments that you would like to add about the last 6 health warnings you viewed?"

Additional Measures

We collected data about age, gender, level of education, ethnicity, and country of residence. Smoking status was screened by asking respondents "Have you smoked at least 100 cigarettes in your lifetime?" (Yes/No), and "How often do you smoke cigarettes?" (every day, every week, less than every week or not at all) (34). Fagerström Test of Nicotine Dependence (FTND) was used to assess nicotine dependence of smokers only (44); smokers were asked the type of cigarette smoked (45), and smokers motivation to stop smoking were assessed by the Motivation To Stop Scale (MTSS) (46, 47).

The GAD-7 and PHQ-9 were used to assess having depression or anxiety. For demographic information only participants were also asked if they were receiving treatment for a mental health condition: "Are you currently undergoing treatment (psychological or medical) for a mental health condition?" This question was used to describe the sample characteristics and not for inclusion or grouping criteria.

Procedure

The complete experiment, including screening, consent, and randomisation, was implemented online using Qualtrics.[2] Following consent, participants completed screening questions and quota items. Participants were asked to rate a series of 12 tobacco health warning labels, 6 of each warning label type (see **Figure 1**). Participants were debriefed and informed about how be contacted about study findings and/or enter the study prize draw for the chance to win a £50 Amazon Voucher (538 people entered).

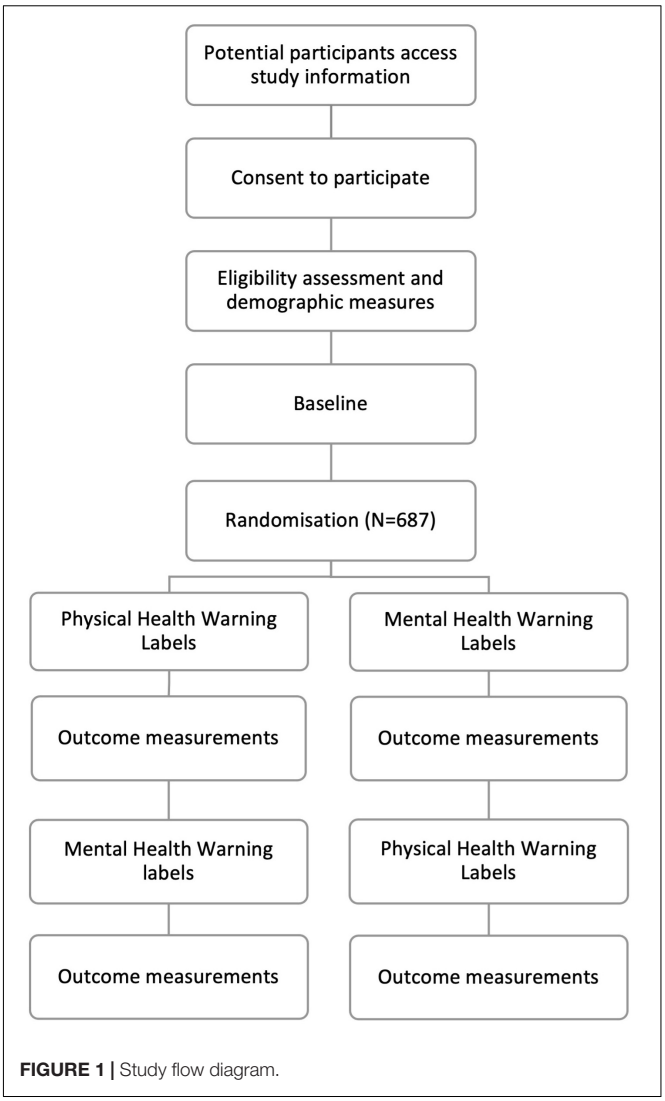

FIGURE 1 | Study flow diagram.

Randomisation

Random Allocation and Sequence Generation

Participants were randomly assigned to view either the MHWLs first and then the PHWLs or the PHWLs then the MHWLs with a 1:1 allocation. The order of 6 warnings within each block was also randomised. The random sequence was generated using Qualtrics computer software embedded simple randomisation functions.

Allocation Concealment Mechanism

Participants were randomised using Qualtrics, allocation was concealed as the randomised sequence was not recorded and so was unavailable to the research team. The research team were blind to the randomisation order of both blocks and individual warnings within each block.

Implementation

Randomisation was implemented using Qualtrics randomisation function, Qualtrics generated the allocation sequence, assigned participants to each order after participants completed consent questions on Qualtrics. Randomisation only occurred after participant identifier, eligibility and consent had been recorded to ensure that implementation was not influenced by the research team or the participants.

Statistical Analysis

Data were analysed using Stata IC, do-files will be made available on OSF. Dummy variables were generated to indicate participants' smoking and mental health status. Prior to analyses, composite measures for MHWLs and PHWLs were generated to assess the warning label types, these were created using mean ratings across each health outcome in each label group, for each measure. $2 \times 2 \times 2$ mixed ANOVAs were performed, with mental health condition and smoking status as between-groups factors and health warning label type as a within-groups factor. Label type, mental health status and smoking status were independent variables and perceived effectiveness, believability, arousal, valence, acceptability, reactance, novelty of information were dependent variables.

[2] www.qualtrics.com

TABLE 1 | Participant characteristics.

Participant characteristic	Mean (SD) or *n* (%) *n* = 687
Age in years	41.78 (15.48)
Gender	
Female	539 (78.46)
Male	139 (20.23)
Gender neutral	1 (0.15)
Genderqueer	1 (0.15)
Non-binary	4 (0.58)
Prefer not to say	3 (0.44)
Education	
GCSE or equivalent	113 (16.45)
A-Level or equivalent	162 (23.58)
Undergraduate degree or equivalent	206 (29.99)
Postgraduate degree or equivalent	181 (26.35)
No formal qualifications	20 (2.91)
Prefer not to say	5 (0.73)
Ethnicity	
African	5 (0.73)
Any other Asian	11 (1.60)
Any other mixed/multiple ethnic	6 (0.87)
Any other white	53 (7.71)
Any other ethnic	4 (0.58)
Arab	1 (0.15)
Bangladeshi	2 (0.29)
Caribbean	3 (0.44)
Chinese	24 (3.49)
English/Welsh/Scottish/Northern Irish/British	531 (77.29)
Gypsy or Irish traveller	1 (0.15)
Indian	15 (2.18)
Irish	3 (0.44)
Pakistani	4 (0.58)
Prefer not to say	7 (1.02)
White and Asian	8 (1.16)
White and black caribbean	9 (1.31)

TABLE 2 | Participant mental health and smoking information.

Participant mental health and smoking information	*Mean* (SD) or *n* (%)
Receiving psychological treatment for:	*n* = 681
Depression	91 (13.36)
Generalised anxiety disorder (GAD)	42 (6.17)
Not receiving treatment	481 (70.63)
Obsessive-compulsive disorder (OCD)	5 (0.73)
Other	36 (5.29)
Panic disorder	7 (1.03)
Phobia	3 (0.44)
Post-traumatic stress disorder (PTSD)	16 (2.35)
Mental health scores	
GAD-7	6.87 (5.45)
PHQ-9	8.20 (6.38)
	n = 316
Nicotine dependence (mean FTND score)	4.37 (2.73)
Type of tobacco used	
Factory made and roll your own	81 (25.63)
Only factory made	116 (36.71)
Only roll your own	119 (37.66)
Motivation to stop (MTSS)	
MTSS score	7.04 (1.53)
I don't want to stop smoking	34 (10.76)
I think i should stop smoking but don't really want to	129 (40.82)
I want to stop smoking but haven't thought about when	35 (11.08)
I really want to stop smoking but I don't know when I will	57 (18.04)
I want to stop smoking and hope to soon	36 (11.39)
I really want to stop smoking and intend to in the next 3 months	18 (5.70)
I really want to stop smoking and intend to in the next month	7 (2.22)

Free-text questions were manually coded by two authors using content analysis with verbatim responses coded into a small set of meaningful categories. The results of this analysis are reported elsewhere.

Missing Data

Forced responses on all primary and secondary measures were implemented *via* Qualtrics to limit missing data. The qualitative, free-text questions were optional responses.

Protocol Deviations

Midway through the active survey the measure of Potential effectiveness was identified as being without direction and coded incorrectly, therefore was excluded from the analysis. Although we aimed to have balanced groups an error in the Qualtrics survey quota requirements led to unbalanced group sizes.

RESULTS

Characteristics of Participants

A total of 687 participants took part in the study, 371 were non-smokers, 316 were smokers, 372 did not have a mental health problem, 315 did have a mental health problem. Across combined groups 219 were non-smokers without mental health problems, 152 were non-smokers with a mental health problem, 153 were smokers without a mental health problem, 163 were smokers with a mental health problem. The mean age was 41.78 (SD = 15.48), and 78.46% (n = 539) were females, details of participant characteristics are displayed in **Tables 1**, **2**. Results are presented in **Table 3**.

Perceived Effectiveness

There was no significant three-way interaction of label type × mental health status × smoking status for perceived effectiveness. There was no significant interaction of label type with mental health status, or label type with smoking status.

There was a significant main effect of label type on perceived effectiveness with a large effect size ($p < 0.001$, $\eta_p^2 = 0.46$) with PHWLs perceived as being more effective (mean = 5.78, SD = 2.55) than MHWLs (mean = 4.02, SD = 2.40) across the sample (**Figure 2**).

There was no significant main effect of mental health status on perceived effectiveness, people without mental health problems (mean = 5.11, SD = 2.61) did not differ from people with mental health problems (mean = 4.65, SD = 2.61) in their perceptions of effectiveness of the tobacco warning labels. There was a significant effect of smoking status on perceived effectiveness with a large effect size ($p < 0.001$, $\eta_p^2 = 0.28$), with non-smokers perceiving labels as more effective (mean = 6.01,

TABLE 3 | Results of mixed ANOVAs for each outcome.

Outcome		*F*(1, 683)	*p*	η_p^2	95% CI
Perceived effectiveness					
	Label type × mental health status × smoking status	0.75	0.39	0.00	0.00, 0.01
	Label type × mental health status	0.11	0.74	0.00	0.00, 0.01
	Label type × smoking status	0.84	0.36	0.00	0.00, 0.01
	Label type	577.64	<0.001**	0.46	0.41, 0.50
	Mental health status	2.09	0.15	0.00	0.00, 0.02
	Smoking status	259.54	<0.001**	0.28	0.22, 0.33
Believability					
	Label type × mental health status × smoking status	0.15	0.70	0.00	0.00, 0.01
	Label type × mental health status	1.82	0.18	0.00	0.00, 0.02
	Label type × smoking status	18.37	<0.001**	0.03	0.01, 0.05
	Label type	779.25	<0.001**	0.53	0.49, 0.57
	Mental health status	0.71	0.40	0.00	0.00, 0.01
	Smoking status	144.77	<0.001**	0.17	0.13, 0.22
Valence					
	Label type × mental health status × smoking status	0.15	0.70	0.00	0.00, 0.01
	Label type × mental health status	0.50	0.48	0.00	0.00, 0.01
	Label type × smoking status	1.13	0.29	0.00	0.00, 0.13
	Label type	302.59	<0.001**	0.31	0.25, 0.36
	Mental health status	0.15	0.70	0.00	0.00, 0.01
	Smoking status	21.86	<0.001**	0.03	0.01, 0.06
Arousal					
	Label type × mental health status × smoking status	0.44	0.51	0.00	0.00, 0.01
	Label type × mental health status	0.17	0.68	0.00	0.00, 0.01
	Label type × smoking status	1.20	0.27	0.00	0.00, 0.01
	Label type	82.34	<0.001**	0.11	0.07, 0.15
	Mental health status	3.12	0.08	0.00	0.00, 0.02
	Smoking status	51.28	<0.001**	0.07	0.04, 0.11
Acceptability					
	Label type × mental health status × smoking status	0.00	0.94	0.00	0.00, 1.00
	Label type × mental health status	1.64	0.20	0.00	0.00, 0.02
	Label type × smoking status	0.30	0.58	0.00	0.00, 0.01
	Label type	312.94	<0.001**	0.31	0.26, 0.37
	Mental health status	7.87	0.01*	0.01	0.00, 0.03
	Smoking status	99.31	<0.001**	0.13	0.08, 0.17
Reactance					
	Label type × mental health status × smoking status	0.67	0.42	0.00	0.00, 0.01
	Label type × mental health status	1.15	0.28	0.00	0.00, 0.01
	Label type × smoking status	13.53	<0.001**	0.02	0.00, 0.04
	Label type	195.38	<0.001**	0.22	0.17, 0.27
	Mental health status	4.84	0.03*	0.01	0.00, 0.02
	Smoking status	81.22	<0.001**	0.11	0.07, 0.15
Novelty					
	Label type × mental health status × smoking status	0.08	0.77	0.00	0.00, 0.01
	Label type × mental health status	0.05	0.82	0.00	0.00, 0.01
	Label type × smoking status	5.86	0.02*	0.01	0.00, 0.03
	Label type	65.27	<0.001**	0.09	0.05, 0.13
	Mental health status	1.16	0.28	0.00	0.00, 0.01
	Smoking status	145.78	<0.001**	0.18	0.13, 0.23

*$p < 0.05$; **$p < 0.001$.

SD = 2.32) than smokers (mean = 3.60, SD = 2.34) (see **Supplementary Figure 1**).

Believability

There was no significant three-way interaction of label type × mental health status × smoking status for believability. There was no significant interaction of label type with mental health status. There was a significant interaction of label type and smoking status with a small to moderate effect size ($p < 0.001$, $\eta_p^2 = 0.03$). Bonferroni corrected *post-hoc t*-tests, indicate that smokers rated MHWLs as less believable than PHWLs (−2.61, SE = 0.17, $p < 0.001$, 95% CI [−3.07, −2.16]) to a greater

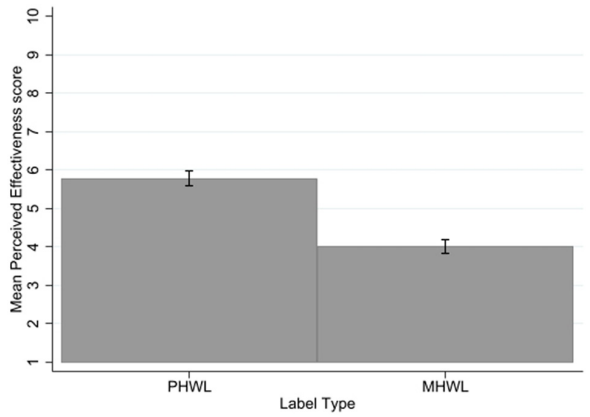

FIGURE 2 | Perceived effectiveness by label type. Error bars represent 95% confidence intervals.

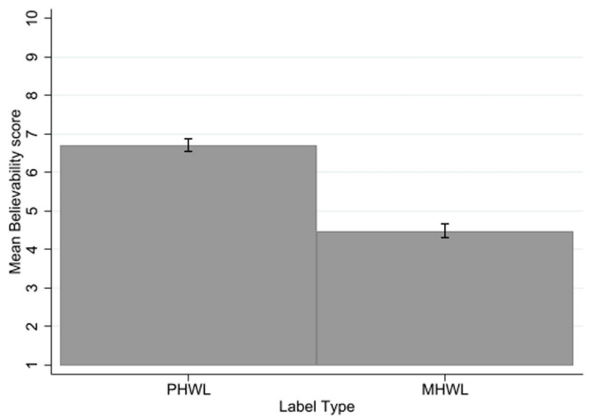

FIGURE 3 | Believability by label type. Error bars represent 95% confidence intervals.

extent than non-smokers (−1.98, SE = 0.16, $p < 0.001$, 95% CI [−2.31, −1.47]).

There was a significant main effect of label type on believability with a large effect size ($p < 0.001$, $\eta_p^2 = 0.53$) with PHWLs rated as more believable (mean = 6.70, SD = 2.25) than MHWLs (mean = 4.48, SD = 2.44) across the sample (**Figure 3**).

There was no significant main effect of mental health status on believability, people without mental health problems (mean = 5.73, SD = 2.58) did not differ from people with mental health problems (mean = 5.43, SD = 2.61). There was a significant main effect of smoking status on believability with a large effect size ($p < 0.001$, $\eta_p^2 = 0.17$), with non-smokers rating labels as more believable (mean = 6.40, SD = 2.24) than smokers (mean = 4.61, SD = 2.67) (see **Supplementary Figure 2**).

Valence

There was no significant three-way interaction of label type × mental health status × smoking status for valence. There was no significant interaction of label type with mental health status, or label type with smoking status.

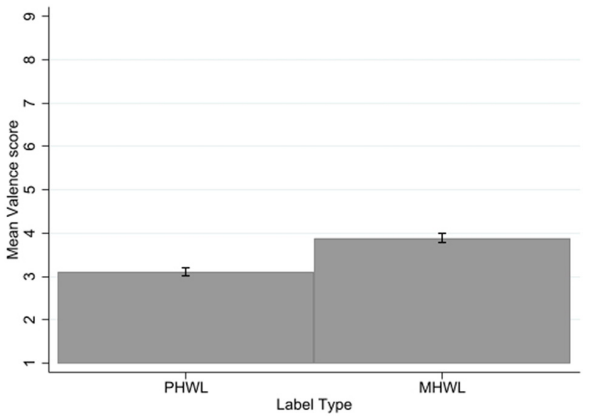

FIGURE 4 | Valence by label type. Error bars represent 95% confidence intervals.

There was a significant main effect of label type on valence, with a large effect size ($p < 0.001$, $\eta_p^{2.} = 0.31$) with PHWLs rated as more unpleasant (mean = 3.11, SD = 1.26) than MHWLs (mean = 3.89, SD = 1.30) across the sample (**Figure 4**).

There was no significant main effect of mental health status on valence, people without mental health problems (mean = 3.49, SD = 1.35) did not differ from people with mental health problems (mean = 3.50, SD = 1.33). There was a significant main effect of smoking status on valence, with a small to moderate effect size ($p < 0.001$, $\eta_p^2 = 0.03$), with non-smokers rating labels as more unpleasant (mean = 3.31, SD = 1.28), than smokers (mean = 3.72, SD = 1.38) (see **Supplementary Figure 3**).

Arousal

There was no significant three-way interaction of label type × mental health status × smoking status for arousal. There was no significant interaction of label type with mental health status or label type with smoking status.

There was a significant main effect of label type on arousal with a medium to large effect size ($p < 0.001$, $\eta_p^2 = 0.11$), with PHWLs were rated as more arousing (mean = 4.45, SD = 1.97) than MHWLs (mean = 3.94, SD = 1.87) across the sample (**Figure 5**).

There was no significant main effect of mental health status on arousal, people without mental health problems (mean = 4.13, SD = 1.97), did not differ from people with mental health problems (mean = 4.27, SD = 1.90). There was a significant main effect of smoking status on arousal, with a medium effect size ($p < 0.001$, $\eta_p^2 = 0.07$), with non-smokers rating labels as more arousing (mean = 4.62, SD = 1.86) than smokers (mean = 3.69, SD = 1.91) (see **Supplementary Figure 4**).

Acceptability

There was no significant three-way interaction of label type × mental health status × smoking status for acceptability. There was no significant interaction of label type with mental health status or label type with smoking status.

There was a significant main effect of label type on acceptability with a large effect size ($p < 0.001$, $\eta_p^2 = 0.31$) with

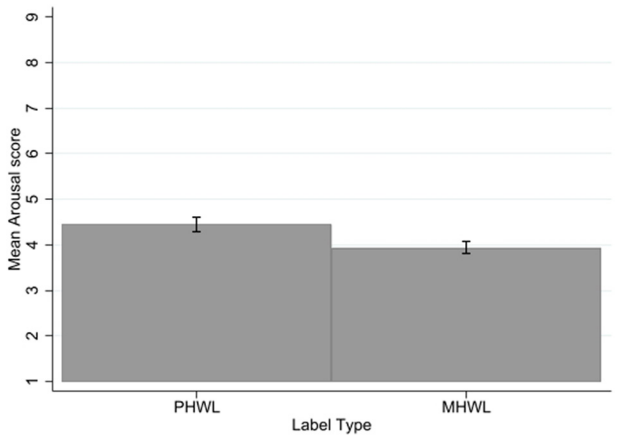

FIGURE 5 | Arousal by label type. Error bars represent 95% confidence intervals.

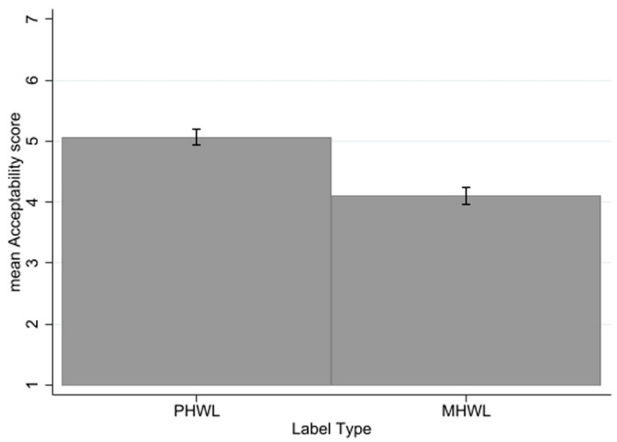

FIGURE 6 | Acceptability by label type. Error bars represent 95% confidence intervals.

PHWLs rated as more acceptable (mean = 5.07, SD = 1.68) than MHWLs (mean = 4.10, SD = 1.80) across the sample (**Figure 6**).

There was a significant main effect of mental health status on acceptability (p = 0.01, η_p^2 = 0.01). People without mental health problems (mean = 4.79, SD = 1.76) rated labels as more acceptable than people with mental health problems (mean = 4.35, SD = 1.83). There was a significant main effect of smoking status on acceptability with a large effect size ($p < 0.001$, η_p^2 = 0.13). Non-smokers rated labels are more acceptable (mean = 5.12, SD = 1.53) than smokers (mean = 3.96, SD = 1.90) (see **Supplementary Figure 5**).

Reactance

There was no significant three-way interaction of label type × mental health status × smoking status for reactance. There was no significant interaction of label type with mental health status. There was a significant interaction of label type with smoking status ($p < 0.001$, η_p^2 = 0.02). Bonferroni corrected *post-hoc* *t*-tests, indicate that smokers rated MHWLs as evoking more reactance than PHWLs (1.62, SE = 0.24, $p < 0.001$, 95% CI [0.98, 2.26]) to a greater extent than non-smokers (0.91, SE = 0.22, $p < 0.001$, 95% CI [0.32, 1.50]).

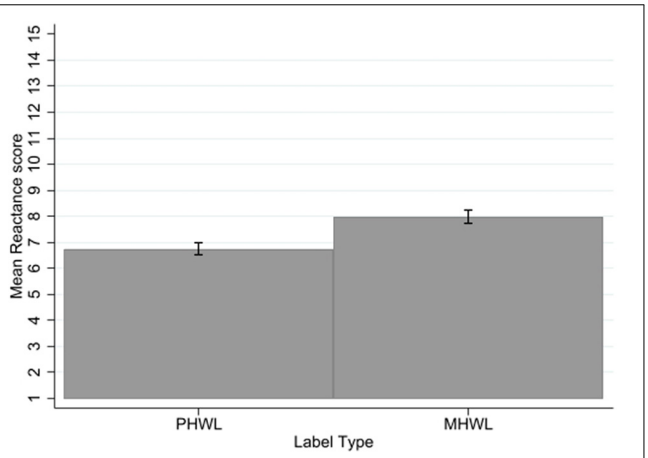

FIGURE 7 | Reactance by label type. Error bars represent 95% confidence intervals.

There was a significant main effect of label type on reactance with a large effect size ($p < 0.001$, η_p^2 = 0.22) with PHWLs evoking less reactance (mean = 6.75, SD = 2.97) than MHWLs (mean = 7.98, SD = 3.41) across the sample (**Figure 7**).

There was a significant main effect of mental health status on reactance with a small effect size (p = 0.03, η_p^2 = 0.01), with greater reactance in people with mental health problems (mean = 7.73, SD = 3.33) compared to those without mental health problems (mean = 7.05, SD = 3.16). There was a significant main effect of smoking status on reactance with a medium to large effect size ($p < 0.001$, η_p^2 = 0.11), non-smokers reported lower reactance (mean = 6.45, SD = 2.86) than smokers (mean = 8.44, SD = 3.36). (see **Supplementary Figure 6**).

Novelty

There was no significant three-way interaction of label type × mental health status × smoking status for novelty. There was no significant interaction of label type with mental health status. There was a significant interaction of label type with smoking status (p = 0.02, η_p^2 = 0.01). Bonferroni corrected *post-hoc* *t*-tests, indicate that smokers rated MHWLs similarly in novelty to PHWLs (0.43, SE = 0.17, p = 0.08, 95% CI [−0.03, 0.88]), whereas non-smokers rated MHWLs as more novel than PHWLs (0.79, SE = 0.16, $p < 0.001$, 95% CI [0.37, 1.21]).

There was a significant main effect of label type on novelty of information with a medium to large effect size ($p < 0.001$, η_p^2 = 0.09), with PHWLs rated as less novel (mean = 3.21, SD = 2.22) than MHWLs (mean = 3.83, SD = 2.50) (**Figure 8**).

There was no significant main effect of mental health status on novelty, people without mental health problems (mean = 3.69, SD = 2.49) did not differ in ratings of novelty to people with mental health problems (mean = 3.32, SD = 2.25). There was a significant main effect of smoking status on novelty with a large

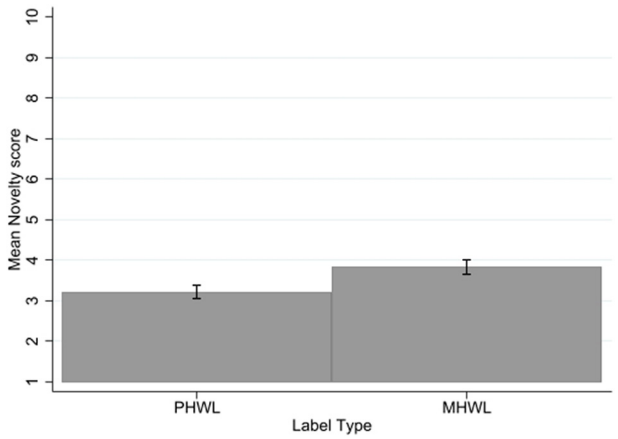

FIGURE 8 | Novelty by label type. Error bars represent 95% confidence intervals.

effect size ($p < 0.001$, $\eta_p^2 = 0.18$), with non-smokers rating the labels as more novel (mean = 4.37, SD = 2.34) than smokers (mean = 2.53, SD = 2.03) (see **Supplementary Figure 7**).

Qualitative Responses

The qualitative responses are summarised in depth in another paper. Briefly, respondents displayed mixed support for the mental health warning labels, some respondents supported the mental health warning labels to inform the public about the risks of smoking to mental health and deter smoking, others found the warnings manipulative or thought tobacco warning labels in general were ineffective at preventing smoking. There were also conflicting responses regarding the images used on the warning labels, some described the images depicting mental health as vague, inaccurate, or inappropriate, others described them as accurately representing the mental health condition and being well suited to the text component of the warning. Another key finding was the potential for the mental health warning labels to create stigma for people with mental health conditions. People's previous understanding or beliefs about smoking were important in their responses, those who believed smoking reduced stress or anxiety seemed to be less supportive of the mental health warning labels.

DISCUSSION

Summary of Findings

To our knowledge, this is the first study to design and investigate the effectiveness of a series of mental health tobacco warning labels. We found that MHWLs are perceived as less effective, believable, arousing, unpleasant, and acceptable than PHWLs, but MHWLs evoke more reactance and are rated as more novel. Perceptions of MHWLs did not differ in people with and without mental health problems, except for reactance and acceptability, with greater reactance in people with mental health problems compared to those without mental health problems and people without mental health problems rated labels as more acceptable than people with mental health problems. Perceptions of warning labels differed between non-smokers and smokers. Smokers perceived labels as less effective, believable, arousing, acceptable, novel, more pleasant and had higher reactance. The difference in ratings between PHWLs and MHWLs did not vary according to mental health status. The difference in ratings between PHWLs and MHWLs varied according to smoking status for believability, reactance, and novelty. For believability, differences between MHWLs and PHWLs were greater for smokers than non-smokers, smokers rated MHWLs as much less believable than PHWLs. For reactance, differences between MHWLs and PHWLs were greater for smokers than non-smokers, smokers rated MHWLs as evoking much more reactance than PHWLs. For novelty, smokers rated MHWLs similarly in novelty to PHWLs, whereas non-smokers rated MHWLs are more novel than PHWLs.

Strengths and Limitations

Strengths of our study include the large sample size, inclusion of both smokers and non-smokers, and people with and without mental health problems. Another strength is the use of patient and public involvement (PPI) throughout the study design, including development of the warnings and survey measures. Limitations include the use of self-report measures, Tamayo et al. (48) suggest that explicit reactions could be different to implicit reactions to warning labels, thus self-report measures may not accurately reflect people's true perception of the warning labels (48). The use of self-report measures also means it is unclear whether MHWLs influence actual effectiveness or smoking behaviour, although a meta-analysis found that perceived effectiveness does predict quit intentions and cessation (49). The study also includes only those with common mental health conditions, depression and anxiety, in the mental health group, and not people with more severe and complex psychotic spectrum disorders, this limits the generalisability of the findings to a wider population of people with more severe mental health problems. Also, not including this population in our sample could have affected our findings as people with more severe psychotic spectrum disorders could have different perceptions of the MHWLs compared to people with more common mental health conditions (31). The study is also limited by its sample which is not representative of the wider population. Our sample was made up of mostly white females; research suggests that both gender and ethnicity can influence ratings of health warning labels, with females rating labels as more effective, and people of white ethnicity rating labels as less effective (50, 51). Future research should aim to increase the representativeness of the sample and investigate potential moderating effects of gender, and ethnicity on responses to mental health warning labels.

Interpretation and Comparison to Other Studies

MHWLs could be perceived as less effective due to the causal language used. PHWLs used the phrase "smoking causes" whereas MHWLs used "smoking increases the risk of." Our PPI

focus group advised us to use the phrase "increases risk of" as "causes" was viewed as reductionist and potentially stigmatising. However, evidence suggests that warnings with strong causal language are perceived as most effective at discouraging people to smoke, thus the lack of causal language in the MHWLs could have limited their effectiveness (17, 52). Future research needs to investigate how to balance the need for MHWLs to be effective and the potential for mental health stigma.

How graphic the images were could explain the differences between the warning labels, as PHWLs had more graphic images than the MHWLs. Research suggests that graphic images increase perceived harms of smoking, quit intentions, prevention of smoking and are more effective (17, 53–59). By their nature, the mental health images were less graphic than those included in the PHWL condition (e.g., surgical scars, tooth decay). It is possible that this influenced the rating of MHWLs as more pleasant and less arousing. This is supported by some qualitative feedback such as "*Think there are better images to convey poor mental health. Feel quite calm about this image, even though have struggles with my mental health this image and message doesn't really affect me.*" However, capturing mental health problems as a single image, particularly a graphic image, is very challenging. Not only is it difficult to represent mental health problems in a picture but doing so raises ethical issues. Negative media images of mental health problems can elicit mental health stigma and can impair the self-esteem and recovery of people with mental health problems (60). Thus, ethically representing mental health images graphically is a challenge. Arguably, text-only warnings could be used to address this challenge, however text-only warnings are not demonstrated to be as effective as pictorial warnings in the existing literature (30). Pictorial warnings have also been found to be important for communicating the effects of smoking in low and middle income countries with low literacy rates (45, 61). Future research should include people with mental health problems to further develop the images on mental health warning labels.

The "misattribution hypothesis" could also explain some of the differences seen between MHWLs and PHWLs. There is a common misperception that smoking can alleviate stress and help people to cope in challenging situations (19, 27). Many people also describe using smoking as a method to "self-medicate" mental health symptoms, such as depression or anxiety (19, 27, 62). This view is persistent among many populations, including health professionals (20, 21). Therefore, the MHWLs contradict peoples' current understanding of the effects of smoking, and the effects of smoking on mental health are not well understood. This contrasts to PHWLs, which are well understood and communicated from government tobacco control policies, including tobacco warning labels (63). Considering the misattribution hypothesis, the MHWLs are at odds with smokers own experience of smoking, compared to non-smokers who do not experience the effects of smoking, which could explain why smokers rated the MHWLs as less believable and evoking more reactance than PHWLs, to a greater extent than non-smokers (19, 27, 62).

There could also be more defensive reactions to the MHWLs compared to PHWLs as MHWLs challenge and threat people's current beliefs about smoking and mental health (19, 27, 62). This is supported by initial feedback from our qualitative data, such as: *"I think for a lot of people smoking actually helps with anxiety and tension. This seems like a lie."; "I don't believe this is true."* Another issue which could explain this is the threat of stigma. Qualitative data collected from this study suggests that participants found the MHWLs to be reductive and placing blame upon the individual for their mental health problem: *"This sounds odd and feels a bit unpleasant (mental health is serious and doesn't need more stigma! if I was depressed the last thing I would want to hear it's that I am depressed because I smoke)"*; *"It seems more likely to increase the risk of depression. But again, there's the risk of people blaming depressed people for being depressed just because they smoke"; "Mental health already is stigmatised against, without these blaming statements."* Thus the MHWLs cause a threat, which could explain the higher reactance and less acceptance, particularly in people with mental health problems (64–66). Future research should further investigate how to balance the potential stigma of MHWLs against using them as an effective tool for health risk communication.

Consistent with the physical health warning literature we found that ratings differed according to smoking status. In line with the literature, smokers perceived labels as less effective, believable (14, 39, 67), arousing (48, 68), acceptable and novel (69). Smokers rated HWLs as more pleasant (higher valence) (48), and had higher reactance to the HWLs (70, 71). These differences could be explained by perceived susceptibility to the warning labels, as previous research has found the higher the perceived susceptibility to the HWL, the higher the ratings of effectiveness and believability (17, 32). Smokers are known to judge the risk of health effects of smoking as lower than non-smokers, potentially because they minimise the risk to themselves and so rate the labels as less effective and believable (72). Perceived susceptibility is also important in determining fear responses to HWLs, this could explain why smokers exhibited less arousal, and rated warnings as more pleasant (65, 73). Higher exposure to tobacco health warnings and information on the health effects of smoking could explain why smokers rated all warning labels as less novel (63, 74). Smokers' rating of HWLs as less acceptable and having higher reactance could be explained by cognitive dissonance experienced when viewing the labels. Smokers are aware of the health risks of smoking but continue to smoke, which is aversive, so to minimise this smokers avoid, ignore or reject HWLs, evoking higher reactance and lower ratings of acceptability (34, 70, 71, 75, 76).

We found that ratings of warning labels did not differ according to mental health status except for reactance and acceptability, with greater reactance in people with mental health problems compared to those without mental health problems and people without mental health problems rated labels as more acceptable than people with mental health problems. Research on differences in responses to tobacco warning labels in people with and without mental health problems is limited and conflicting. Our findings contrast with some previous findings, Coletti et al. (31) assessed views of young people with recent onset psychosis (ROP) of physical health warning labels and found that people with ROP were more likely to rate the warning labels as effective

than healthy controls. However, our findings are similar to Osman et al. (32) who found that although at first introduction of PHWLs people with and without mental health problems differed in their responses, over time responses increased in people with low depression symptoms and the difference between mental health groups disappeared. Osman et al. (32) assessed depression using the Epidemiological Studies Depression scale (CES-D-7), which is similar to our assessment of depression. One explanation for the difference in findings between studies is that Coletti et al. (31) used clinical assessments of psychotic disorders whereas our study looked at symptoms of depression and anxiety reaching the threshold for caseness. It could be that severity of mental health symptoms, or differences in mental health disorders and measurement tools influenced responses to warning labels. Another explanation could be age, Coletti et al. assessed responses in young people (mid-20s) whereas this study and Osman assessed responses in adults (40s). It could be that age is important in predicting differences in responses in people with and without mental health status, which is a topic for future research.

Implications for Policy and Practice

To our knowledge, this is the first study to design and test the perceptions of a series of MHWLs for tobacco. MHWLs were identified as low to moderately effective method for the communication of health risks of smoking on mental health, however, refinement of the MHWLs is necessary. Future research should further refine the MHWLs to provide novel information to inform the public about an underappreciated health risk of smoking, whilst balancing the risk of stigmatising mental health problems. Future research could also investigate whether communicating the benefits of smoking cessation for mental health *via* tobacco warning labels is effective, such gain-framed appeals are suggested to be effective for smoking abstinence (26, 77). It appears that the same underlying mechanisms are present for MHWLs as PHWLs, in terms of differences in perceptions for smokers and non-smokers, future research should investigate whether susceptibility to the mental health risks of smoking influences responses. However, much of the health warning label literature is conducted in developed and high-income countries, although more work is being done in developing countries the evidence is more limited and implementation of warnings more challenging (78), this has implications for the design and potential implementation of MHWLs, thus future research should investigate MHWLs in developing countries. When designing this study we found large variation in the outcomes measured and measurement tools in warning label research, and so we recommend that a Core Outcome Set be developed for warning label research (79).

CONCLUSION

Mental health warnings labels could be an effective means to communicate the effects of smoking on mental health. MHWLs are perceived as less effective, believable, arousing, unpleasant, and acceptable than PHWLs, but MHWLs evoke more reactance and are rated as more novel. Perceptions of MHWLs did not differ in people with and without mental health problems except for reactance and acceptability, but consistent with the PHWL literature, perceptions of MHWLs differed between non-smokers and smokers.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because anonymised data can be accessed from University of Bath's Research Data Archive. All data will be anonymised using unique identifiers, and data access will be restricted. Data will be made available to approved bona-fide researchers: after they have signed a data access agreement, the person will be granted access to the University of Bath's Data Archive. Requests to access the datasets should be directed to https://library.bath.ac.uk/research-data/archiving-and-sharing/home.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Psychology Research Ethics Committee (PREC) at the University of Bath. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KS and GT involved in study conception. KS, CB, and RN involved in acquisition, analysis, and interpretation of the data. KS led the project and drafted the manuscript. All authors were involved in the design and revising the manuscript.

FUNDING

GT was funded by the Cancer Research UK Population Researcher Postdoctoral Fellowship award (reference: C56067/A21330) and Cancer Research UK project award (reference: PPRCPJT\100023).

ACKNOWLEDGMENTS

We would like to thank our PPI group for helping us design the warning labels, their feedback was invaluable. We would also like to thank everyone who took part in the survey.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.869158/full#supplementary-material

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Conflict of Interest: GT had previously received funding from Grand (Pfizer) for work not related to this project.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers | Frontiers in Psychiatry

TYPE Original Research
PUBLISHED 19 July 2022
DOI 10.3389/fpsyt.2022.869802

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

RECEIVED 05 February 2022
ACCEPTED 27 June 2022
PUBLISHED 19 July 2022

CITATION
Hart JT, Boeckman LM and Beebe LA (2022) Unique cessation tools in the box: Quitline utilization and effectiveness trends among a large sample of tobacco users reporting mental health disorders.
Front. Psychiatry 13:869802.
doi: 10.3389/fpsyt.2022.869802

Unique cessation tools in the box: Quitline utilization and effectiveness trends among a large sample of tobacco users reporting mental health disorders

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It is estimated that the prevalence of smoking among adults with MHDs ranges between 40-60%, as compared to about 17% among those without an MHD. In addition, smokers with MHDs smoke more cigarettes, are more nicotine dependent, and experience more difficulty quitting, compared to other smokers. The uniquely high smoking prevalence among the MHD population is a serious public health concern; unfortunately, a majority of individuals experiencing difficulty receive no treatment. The US Public Health Service guidelines, as well as the National Cancer Institute, strongly recommend quitlines as an evidence-based treatment strategy to reduce barriers to cessation treatment, especially among smokers with MHDs; however, the literature is sparse on quitline engagement trends and associated outcomes for quitline participants with MHDs. This study sought to contribute to this gap with the largest sample to-date of MHD-endorsing tobacco quitline (Oklahoma Tobacco Helpline, OTH) participants. From 2015 to 2020, ~65,000 registrants (45-50% of total registered participants) with the OTH identified as having one or more MHDs in addition to their tobacco use. This study tested for the presence of significant differences between groups with and without MHDs (as well as within the MHD-identified group) on program enrollment selections, the intensity of engagement with chosen services, NRT utilization, and quit rates. It also tested for the existence of differences and moderating effects of demographic variables associated with the comparison groups. Statistically significant differences were found between these two groups with regard to: sex, age, racial identity, education level, annual income and insurance status. Significant differences were also found with tobacco use patterns reported by individuals (e.g., timing and daily use amounts). Differences in quitline program selection were demonstrated, such that the MHD-endorsing sample were more likely

to participate and agree to the most robust service available. Significantly higher rates of service intensity (number of services engaged) were demonstrated, and MHD individuals were also significantly more likely to receive NRT as a part of their treatment. This study suggests a simplistic "more is better" quitline services approach may suffer in effectiveness because it neglects barriers common to this population. Important information is provided on these unique variables associated with MHD-endorsing individuals trying to quit their tobacco use. These results can help tobacco quitlines conceptualize the unique difficulties experienced by individuals with MHDs and then tailor their approach to respond supportively and constructively to this high need group.

KEYWORDS

quitline, tobacco cessation, mental health, smoking, stress

Introduction

There are an estimated 52.9 million adults (21.0% of the adult population) suffering from mental health disorders (MHDs) in the United States (1). Among those with mental health disorders, ∼17 million are also diagnosed with a co-occurring substance use disorder (SUD) and frequently also present with co-morbid physical health conditions (1–3). A recent review revealed that only 7.4% of these individuals receive treatment for both disorders, while 55% receive no treatment at all (4). Of the substances typically abused by Individuals with mental health disorders, tobacco is one of the most common (5). It is estimated that the prevalence of smoking among adults with MHDs ranges between 40-60%, as compared to about 17% among those without any mental health conditions (6). Furthermore, smokers with MHDs tend to smoke more cigarettes, be more nicotine dependent, and experience more difficulty quitting as compared to smokers without co-occurring MHDs (7, 8). While overall smoking rates have declined in recent years, rates among those with MHDs have remained almost the same, with about 45% of annual tobacco-related deaths estimated to be among smokers with MHDs (9, 10). The uniquely high smoking prevalence among this population should be cause for serious concern representing a significant public health disparity.

As noted above, an estimated 55% of individuals with a co-occurring mental health and substance abuse disorders (to include nicotine dependence) receive no treatment. For those who do receive treatment, it is often not for both disorders present (i.e., treatment targets mental health-related symptoms but doesn't address nicotine dependence). Barriers to treatment for this group in particular have been well-documented and include: physical access to treatment sites, healthcare, time and financial burden, etc. (e.g., lack of paid time off for medical appointments) (11). One unique treatment that overcomes several of these noted barriers and has been demonstrated to be effective with smokers (including smokers with MHDs) are state tobacco quitline services (12, 13).

The US Public Health Service guidelines, as well as the National Cancer Institute, strongly recommend quitlines as a treatment strategy to reduce barriers to cessation treatment, especially among smokers with mental health disorders. Specifically, quitlines represent an endorsed best practices approach with their provision of both cessation coaching and supporting nicotine replacement therapy typically represented in their multiple call program protocols (14, 15). Quitlines are available in all 50 states and two US territories and provide confidential, free cessation counseling by trained staff in multiple languages to ∼400,000 smokers each year. Most quitlines also provide free nicotine replacement therapy (NRT) in the forms of nicotine patches, gum, and lozenges in durations from 2 weeks of mono-NRT up to 12 weeks of combination NRT (16). It has been found that about half of the callers to state quitlines report having at least one MHD; however, this group of quitline callers tend to have lower reported rates of quitting as compared to callers without any MHDs (17, 18).

Efforts to understand and address this disparity have included examination of unique variables and quitline trends associated with quitline callers identifying with MHDs, as well as development of tailored quitline protocols (11–13, 19). Implemented enhancements included unique cessation counseling strategies and coach training, access to a greater number of counseling calls, and access to more weeks of nicotine replacement therapy (NRT) to support a quit attempt (12, 20). The literature is limited on quitline engagement trends and associated outcomes of quitline participants with MHDs. One study examining a group of three states' participants in 2012–13 found that individuals with reported mental health conditions enrolled in a multiple call program tended to complete more calls than individuals without mental health

conditions; however, they were less likely to receive NRT from the quitline (21). Another study found that participants with MHDs were more likely to choose a combination of coaching calls and NRT compared to a sample of participants without MHDs (22).

More research is needed to establish a sufficient evidence base to determine which adaptions of current quitline services actually improve quitline effectiveness with this unique population. Undoubtedly, this quest is made more difficult in part due to the fact that this population is not a homogenous group outside of their identification with experiencing an MHD (a diverse category within itself as well). Individuals within the MHD population differ on demographic variables also known to have unique correlations to smoking status such as age, race, sex, SES, geographic location, and co-morbid physical health conditions (23, 24). Also, significant differences between disorders exist, such as Schizophrenia and Attention-Deficit/Hyperactivity Disorder or Bipolar Disorder and Adjustment Disorder. For example, one study demonstrated anxiety disorders in particular can be uniquely problematic with regards to tobacco cessation success, and that individuals struggling with anxiety could benefit from an approach unique to their specific difficulty (not unlike the myriad adaptations of cognitive-behavioral therapy) (25, 26).

Although the heterogeneity within this group is significant, good argument can still be made for the importance of identifying cross-cutting common variables to help inform tailored quitline adaptations. As state quitlines seek to tailor their services to magnify their impact with priority groups, more service options are being made available and are demonstrating effectiveness (e.g., Behavioral health quitline programs, text- and web-based live interactions, as well as automated options) (12, 27, 28). Quitline use trends and associated outcomes are needed data to help state quitlines prioritize limited service delivery resources and guide targeted marketing dedicated to promotion of cessation support and programming.

Oklahoma has one of the highest prevalence rates of smoking in the country, with the most recent estimates suggesting a smoking prevalence rate among adults in the state to be 19.1%, compared to a national rate of 17.1% (14). The Oklahoma Tobacco Helpline (OTH) has been in operation since 2003 and serves ∼25,000 individuals each year; it has consistently been ranked in the top five quitlines for reach across North America (per the North American Quitline Consortium). Based on annual internal survey data, between 2015 and 2020, ∼65,000 registrants (45–50% of total registered participants) with the OTH identified as having one or more MHDs in addition to their tobacco use.

The purpose of this analysis is to examine quitline service use and engagement trends in a large, recent sample of participants with and without reported MHDs. Differences between groups (with and without MHDs) as well as within the MHD-identified group are explored to identify significant differences in program enrollment selections, the intensity of engagement with chosen services, NRT utilization, and quit rates.

Specifically, the following research questions were examined for a sample of OTH participants eligible for the multiple call program (5 calls and at least 2 weeks of combination NRT):

- Among those eligible for the multiple call program, do significant demographic differences exist between groups with and without MHD endorsement?
- Do individuals endorsing MHDs demonstrate a pattern of Helpline service selection that significantly differs from individuals not endorsing an MHD?
- What factors predict selection of the multiple call program among tobacco users reporting an MHD?
- Is there a significant difference in 7-month, self-reported quit rates between an Oklahoma sample of MHD and non-MHD tobacco users after using Helpline services?
- Among tobacco users reporting an MHD, are there significant differences in quit rates among those who receive the multiple call program compared to those who receive less intensive service?

The analysis will offer a unique, regional perspective of quitline use in a south-central, high-use, state. The data will be helpful as quitlines make decisions allocating limited resources in a worthwhile effort to maximize their reach and effectiveness with complex, high-risk groups.

Methods

OTH programming

The Oklahoma Tobacco Helpline is a free tobacco cessation service available to all residents of Oklahoma and is a program of the Oklahoma Tobacco Settlement Endowment Trust (TSET). Funding for the OTH is primarily provided by TSET, with additional funding provided by the Oklahoma State Department of Health. Residents of Oklahoma can register for OTH services *via* telephone or web, or they can be referred by a health care provider. All registrants are eligible for at least one cessation coaching call and 2 weeks of mono-NRT (either patch, gum, or lozenge) at no cost to the individual. Uninsured, Medicare-, and Medicaid-insured individuals are eligible for a multiple call program of up to five counseling calls and 2–8 weeks of NRT. Prescription medication (e.g., Varenicline, Bupropion) is not available for fulfillment through OTH. Registrants can also enroll into web-, text-, and email-based cessation support services and opt to receive a quit guide mailed to them with written cessation support information.

Study design and setting

This cohort study was embedded in the overall evaluation of the Oklahoma Tobacco Helpline, and included a retrospective analysis of two cohorts of tobacco users registering for OTH services: those with and without an MHD. Unique OTH registrants from July 2015 to April 2020 were included, as this time period corresponds to the launch of expanded individual services including text, email, web and a two-week NRT starter kit with no required coaching calls. Registrations after April 2020 are not included because of the launch of the expanded behavioral health intervention for tobacco users who report having one or more mental health or substance abuse disorder. The evaluation study includes a 7-month follow-up, with tracking of Helpline services received since baseline registration and an outcome survey of a randomly selected sample of registrants.

Participant sample

Because we were interested in factors related to engagement and quit rates, participants in this analysis were limited to those eligible for the multiple call program. This included registrants who reported being uninsured, or having Medicaid or Medicare. We retrospectively identified the two groups for comparison. The MHD group was defined as those who reported an MHD by responding affirmatively to a question at registration about diagnosis or treatment for a list of behavioral health and substance abuse conditions. The non-MHD group did not self-identify as having an MHD.

Data sources

Registration and service utilization data were accessed for those meeting eligibility criteria for this analysis. These data are provided monthly by the quitline provider. Outcome data were obtained from a follow-up survey of a random sample of all OTH registrants. To be eligible for the follow-up evaluation, registrants had to complete at least one intervention call or receive at least 2-weeks of NRT from the OTH. This study includes 7-month follow-up data collected from February 2016 through November 2020, and is limited to randomly selected tobacco users meeting our definitions for the MHD and non-MHD cohorts. Registration and service utilization data are available for 48,770 tobacco users with an MHD and 43,148 tobacco users without an MHD. The follow-up survey sample included 5625 tobacco users with an MHD and 4866 tobacco users without. Response rates for the 7-month follow-up survey were 49.1% for those with an MHD and 50.0% for those without. This study and the overall evaluation of the OTH were reviewed and approved by the University of Oklahoma Health Sciences Center IRB (IRB No. 2616).

Variables

The following demographic data were collected at registration and used in this analysis: gender (female, male), age (<18, 18–24, 25–44, 45–64, 65+ years), race (White, Black, American Indian, Other), income (<$10,000, $10,000–$19,999, $20,000–$34,999,≥ $35,000), health insurance status (Medicaid, Medicare, and uninsured) and mental health and substance abuse disorder (MHSAD) (none, and 1 or more).

Tobacco use patterns at baseline registration included number of cigarettes per day (none, <20, 20+), frequency of cigarette smoking (daily, non-daily) and time after waking to first cigarette (5, 6–30, 31–60, >60 min). E-cigarette use in the past 30-days at the time of registration was also examined. Mode of quitline registration included phone, online or referral from a health care provider. Type and amount of intervention services received were used to define engagement. They included program (single call program, multiple call program, individual services and WebCoach, an online cessation support platform), number of calls completed (zero, one, two, three or more), and amount of NRT sent by the OTH (no NRT, 2, 4–6, 8+ weeks). An intensity of services (four levels) variable was derived using a combination of the number of calls completed and the amount of NRT shipped to the participants. Supplementary Table 1 displays the combinations of calls and NRT used for each of the four intensity of services levels. All of the levels of intensity of services could also include web and/or text, and/or e-mail.

Quit outcomes were defined using the 7-month follow-up data. We calculated respondent quit rates (30-day point prevalence abstinence) by dividing the number of respondents who reported not smoking in the past 30 days at 7-month follow-up by the total number of respondents to the follow-up survey. Participants in the 7-month follow-up survey were asked if they had at least one quit attempt lasting at least 24-h any time between enrollment and follow-up, regardless of smoking status at the time of the follow-up survey. This was used as a measure of intermediate quit success.

Statistical methods

We examined and compared the enrollment, engagement and tobacco cessation outcomes among quitline users with one or more MHD to those without an MHD. Descriptive statistics were used to obtain percentages and Pearson chi-square tests were used to test for significant differences between groups. For outcome data gathered through the follow-up survey, we calculated and reported percentages and 95% CIs for each group. We used logistic regression to calculate the odds of selecting

the multiple call program among those with an MHD. We used backward selection to identify an adjusted model controlling for confounders. Covariates remained in the adjusted model based on a significance level of 0.1 during model selection. A significance level of 0.05 was used for all final comparisons, and all analyses were conducted using SAS, version 9.4 (SAS Institute Inc., Cary NC).

Results

The MHD sample was significantly more likely to be female ($p < 0.0001$) and between the ages of 25-44 ($p < 0.0001$, Table 1). They were significantly more likely to report a racial identity of American Indian or Other, and less likely to report identification of Black or White ($p < 0.0001$). Annual income was also significantly lower for MHD-endorsing individuals compared to the non-MHD sample ($p < 0.0001$). Over 80% of those reporting an MHD reported an annual income of <$20,000 (with almost 50% reporting under $10,000). The non-MHD sample was significantly more likely to be uninsured (61.8 vs. 50.8%, $p < 0.0001$), whereas the MHD group was more likely to endorse Medicaid coverage (26.6 vs. 15.4%).

Tobacco use patterns reported by individuals also included some significant differences between groups. The MHD sample was significantly more likely to endorse first tobacco use within 5 min of waking up (56.4 vs. 49.2%, $p < 0.0001$), and were slightly more likely to report smoking over twenty cigarettes daily (58.1 vs. 56.7%, $p < 0.0001$). Those reporting an MHD were significantly more likely to report e-cigarette use in the last 30 days compared to those without MHD (17.9 vs. 11.8%, $p < 0.0001$).

Compared to those without an MHD, individuals endorsing an MHD were significantly more likely to enroll in the comprehensive multiple call program (52.8 vs. 44.1%) and less likely to enroll for individual services (38.5 vs. 46.0%) ($p < 0.0001$, Table 1). They were also more likely to engage with the OTH, with significantly higher rates of service intensity (number of services engaged). 16.5% of persons reporting an MHD received the most intense level of service available. Non-MHD individuals were significantly more likely to enroll in less intensive services (58.5%) such as a 2-week starter kit with no calls with a coach.

Of the 44,797 individuals who enrolled in the multiple call program, a lower proportion of the MHD participants completed no calls (17.9 vs. 21.4%, Table 2). MHD individuals were also significantly more likely to receive 2 weeks of free NRT from the Helpline (17.5 vs. 9.9%, $p < 0.0001$) and less likely to have not received any NRT (24.9 vs. 27.0%). Overall, MHD participants received higher levels of intensity of services within the multiple call program, as compared to those without an MHD.

TABLE 1 Characteristics of tobacco users registering for Oklahoma Tobacco Helpline (OTH) services and service utilization, by mental health disorder (MHD) status, July 2015-April 2020, among those eligible for the multiple call program.

Variable	No MHD $N = 43,148$ *n* (%)	1 or more MHD $N = 48,770$ *n* (%)	*p*-value
Sex			<0.0001
Female	23,417 (54.3)	32,285 (66.2)	
Male	19,720 (45.7)	16,467 (33.8)	
Missing	11	18	
Age in years			<0.0001
18–24	3,410 (7.9)	4,246 (8.7)	
25–44	16,662 (38.6)	21,246 (43.6)	
45–64	16,016 (37.1)	19,473 (39.9)	
65+	7,060 (16.4)	3,805 (7.8)	
Race			<0.0001
White	30,285 (74.2)	35,062 (73.8)	
Black/African American	4,048 (9.9)	3,750 (7.9)	
American Indian	4,175 (10.2)	5,591 (11.8)	
Other	2,300 (5.6)	3,080 (6.5)	
Missing	2,340	1,287	
Annual income			<0.0001
<$10,000	13,459 (35.0)	22,403 (49.8)	
$10,000–19,999	12,792 (33.3)	13,843 (30.8)	
$20,000–34,999	7,696 (20.0)	5,962 (13.3)	
$35,000 +	4,480 (11.7)	2,784 (6.2)	
Missing	4,721	3,778	
Health insurance			<0.0001
Medicaid	6,625 (15.4)	12,949 (26.6)	
Medicare	9,862 (22.9)	11,060 (22.7)	
Uninsured	26,661 (61.8)	24,761 (50.8)	
Cigarettes smoked per day			<0.0001
<20 per day	18,351 (43.3)	20,142 (41.9)	
20+ per day	24,074 (56.7)	27,904 (58.1)	
Missing	723	724	
Time to first tobacco			<0.0001
Within 5 min of waking	20,445 (49.2)	27,053 (56.4)	
6–30 min	14,137 (34.0)	14,512 (30.3)	
31–60 min	4,097 (9.9)	3,724 (7.8)	
>60 min	2,873 (6.9)	2,662 (5.6)	
Missing	1,596	819	
E-cigarette use in past 30 days	4,623 (11.8)	8,243 (17.9)	<0.0001
Missing	3,901	2,608	
Method of registration			<0.0001
Phone	28,025 (65.0)	33,316 (68.3)	
Web	11,821 (27.4)	8,514 (17.5)	

(Continued)

TABLE 1 Continued

Variable	No MHD $N = 43,148$ *n* (%)	1 or more MHD $N = 48,770$ *n* (%)	*p*-value
Referral	3,302 (7.7)	6,940 (14.2)	
OTH Program enrollment			<0.0001
Multiple call program	19,036 (44.1)	25,761 (52.8)	
One call program	132 (0.3)	279 (0.6)	
Individual services	19,839 (46.0)	18,756 (38.5)	
WebCoach	4,141 (9.6)	3,974 (8.1)	
Intensity of OTH Services received			<0.0001
1	25,223 (58.5%)	24,831 (51.0%)	
2	5,187 (12.0%)	7,240 (14.8%)	
3	6,659 (15.4%)	8,664 (17.8%)	
4	6,079 (14.1%)	8,035 (16.5%)	

TABLE 2 Engagement with quitline services by mental health disorder (MHD) status, July 2015-April 2020, among those who enrolled in the multiple call program.

	No MHD $N = 19,036$ *n* (%)	1 or more MHD $N = 25,761$ *n* (%)	*p*-value
Intervention calls completed			<0.0001
0	4,066 (21.4)	4,610 (17.9)	
1–2	11,596 (60.9)	16,435 (63.8)	
3 +	3,374 (17.7)	4,716 (18.3)	
NRT sent by the helpline			<0.0001
No NRT	5,137 (27.0)	6,404 (24.9)	
2 weeks	1,878 (9.9)	4,503 (17.5)	
4–6 weeks	8,277 (43.5)	10,327 (40.1)	
8+ weeks	3,744 (19.7)	4,527 (17.6)	
Intensity of OTH services received			<0.0001
1	4,892 (25.7)	5,975 (23.2)	
2	1,441 (7.6)	3,136 (12.2)	
3	6,625 (34.8)	8,615 (33.4)	
4	6,078 (31.9)	8,035 (31.2)	

Multivariable analysis identified several factors associate with the selection of the multiple call program among tobacco users with an MHD and eligible for the service (Table 3). Being female, Black/African American, American Indian, and insured by Medicaid or Medicare were associated with enrollment in the multiple call program compared to less intensive services. Those registering for services as the result of a referral from a healthcare provider or *via* the website had a lower odds of choosing the multiple call program as compared to those registering by phone. Tobacco users who believed their MHD would interfere with quitting at registration had a higher odds of choosing the multiple call program as compared to those who believed their MHD would not interfere. Less addiction, as measured by time to first cigarette at the time of registration, was inversely associated with choosing the multiple call program.

When assessing quit rates between the MHD vs. non-MHD groups eligible for the multiple call program, response rates at the 7-month follow up call for evaluation for the two groups were very similar (49.1% and 50.0%). Quit rates reported between the two groups did reveal significant differences with the MHD group demonstrating lower quit rates. Responder quit rates were 29.5% for the MHD group vs. 34.1% for the non-MHD group (Table 4). When looking within the MHD group, quit rates differed when assessing quit rates for multiple call program participants vs. less intense program engagement (31.2 and 27.5%).

Discussion

Studies have suggested that individuals with MHD may benefit from *tailored* quitline services to assist them in their attempt to quit; however, there has been limited research on establishing which aspects of current standard quitline service could be changed or augmented to increase quitline effectiveness with this unique population (12, 28). As mentioned previously, this is at least in part due to the fact that the population of individuals endorsing an MHD is not a homogenous group. Furthermore, as seen in the results of this study, significant demographic differences were evident when comparing the MHD and non-MHD groups. The difficult task this presents for researchers and public health agencies is how reasonable adaptation can and should be made in quitline service that uniquely addresses the shared experience of living with an MHD, while simultaneously acknowledging the diverse array of unique attributes represented within an MHD-endorsing group. Due to the sheer number of possible MHDs, their different symptom profiles, etiologies and impacts on functioning, and limited public health resources, effort must be made to explore areas of overlap. To this end, this study sought to not only highlight the unique variables represented in the heterogeneity within an MHD-endorsing quitline group, but to also to contribute to the identification of these cross-cutting, common variables. The goal and dilemma is how to best translate these variables into culturally-relevant, but broadly efficacious, quitline adaptations addressing these overlapping aspects of identity (27).

To our knowledge, this is the largest sample of MHD-endorsing quitline participants that has been examined in the tobacco cessation literature. Overall, it was noteworthy that participants endorsing MHDs tended to engage the more robust treatment option offered at higher rates (multiple call

TABLE 3 Predictors of multiple call program enrollment among tobacco users reporting a mental health disorder (MHD) and eligible for the multiple call program [adjusted odds ratios (aOR) and 95% confidence interval (CI)].

Covariate	aOR (95% CI)	*p*-value
Sex		
Female	1.27 (1.22–1.33)	<0.0001
Male	Ref	
Income		
<$10,000	Ref	
$10,000–19,999	1.11 (1.06–1.16)	<0.0001
$20,000–34,999	1.19 (1.12–1.27)	
$35,000 +	1.14 (1.04–1.25)	
Race		
White	Ref	
Black/African American	1.09 (1.02–1.18)	0.0112
American Indian	1.07 (1.01–1.14)	
Other	1.09 (1.00–1.18)	
Insurance status		
Uninsured	Ref	
Medicaid	1.11 (1.05–1.16)	<0.0001
Medicare	1.55 (1.46–1.63)	
Mode of registration		
Phone	Ref	
Referral	0.90 (0.85–0.95)	<0.0001
Web	0.60 (0.56–0.63)	
Belief about role of MHD		
MHD will not interfere with quitting	Ref	
MHD will interfere with quitting	1.24 (1.18–1.30)	<0.0001
Does not know	0.99 (0.94–1.05)	
Cigarettes per day		
< 20 per day	Ref	
20+ per day	0.96 (0.92–1.00)	0.0695
Time to first tobacco		
Within 5 min of waking	0.87 (0.79–0.96)	0.0002
6–30 min after waking	0.88 (0.79–0.97)	
31–60 min after waking	0.77 (0.69–0.87)	
More than 60 min after waking	Ref	
Used an e-cigarette in the last 30 days	0.98 (0.93–1.04)	0.4662

vs. individual services). They also opted to use more of the supplementary supports offered (e.g., text, email, quit guide), as well as accessing at least 2 weeks of free NRT at higher rates. This is consistent with previous findings highlighting the willingness within an MHD sample to accept help with tobacco cessation (29, 30). This is an encouraging finding that supports the use of quitline support as an acceptable option with this unique group.

One question not asked during cessation support *via* the OTH, was whether or not individuals were receiving treatment for their reported MHD or if they had received treatment in the past. Based on the fact that the participant was able to confirm the diagnosis of a specific MHD, it is reasonable to assume that in most, if not all, cases this came as a result of a past interaction with a health care professional who assessed for and determined the presence of the reported diagnosis. Undoubtedly, participants' history of treatment for an MHD prior to quitline engagement varied (i.e., some may have undergone brief or long-term counseling or psychopharmacological treatment for an MHD), but at least one potential explanation for the increased engagement trend observed may be linked to a likely previous history of treatment for MHDs. A willingness to report the presence of an MHD and its potentially complicating impact on a quit attempt also indicates a level of acceptance or acknowledgment of an issue for which the individual needs some assistance. There is internal consistency in the concept that an individual willing to acknowledge that an MHD may negatively impact their quit attempt would also be more willing accept the most supportive service the quitline could offer (as well as have an understanding of their need for additional support). Although this explanation cannot be made definitively, further understanding should be sought for why this group accepts supports offered at higher rates. One potential downside of this style of engagement is that if all available options are accepted and tried at once, it leaves less opportunity for hope (with an unsuccessful quit attempt) that other untapped options may work in the future (31).

As noted above, individuals in the MHD sample were more likely than the non-MHD group to be females in the 25–44-year-old age range, more likely to have an annual income between $10,000 and $20,000 and to be insured by Medicaid. The link between increased willingness to engage in help-seeking and being female, as well as, links between willingness to acknowledge MHDs for females and younger people has been established in previous research (32, 33). A logical connection based off the trends related to income level in this study is that the offer of free NRT (which can be expensive) as well as other free program supports could be more attractive to an individual living with a lower income and unable to pay for support elsewhere.

Consistent with other quitline studies within this group, is that in spite of this higher level of engagement, self-reported quit rates at 7-month follow-up were still significantly lower for the MHD group (21, 22). This follows a well-established trend in the literature that individuals endorsing MHDs report quitting tobacco at lower rates than those without MHDs. One explanation for this finding could be the fact that most, if not all, MHDs are inherently accompanied with (if not defined by) increased difficulties with coping and stress (8, 34). In

TABLE 4 Quit outcomes by mental health disorder (MHD) status and program enrollment.

	At the 7-month follow-up				
	Response proportion % (respondents/ sampled)	**30-day point-prevalence abstinence % (95% CI)**	***p*-value**	**24-h quit attempt % (95% CI)**	***p*-value**
Among those eligible for the multiple call program					
MHD reported	49.1% (2761/5625)	29.5% (27.8–31.2)	<0.001	86.6% (85.3–87.9)	0.864
No MHD	50.0% (2433/4866)	34.1% (32.3–36.0)		86.8% (85.4–88.1)	
Among those reporting an MHD					
Enrolled in multiple call program	52.4% (1536/2929)	31.2% (28.8–33.5)	0.035	87.4% (85.7–89.0)	0.182
Enrolled in less intense services	45.4% (1225/2696)	27.5% (25.0–30.0)		85.6% (83.7–87.6)	

addition to addressing motivation, a primary feature of many psychotherapeutic approaches is identification of destructive coping patterns and/or identification of more constructive strategies for coping with stress or other unwanted cognitive and behavioral patterns and/or symptoms (35). The process of tobacco cessation requires coping with both the obvious physical impact of nicotine withdrawal, as well as the loss of a, likely long-term habitual, behavior that was very possibly being utilized as a coping mechanism itself.

A plausible hypothesis on the reason lower quit rates persist in spite of more support is that the support is either poorly targeted or insufficient to address the role increased physical and psychological stress plays in thwarting quit attempts. Supporting this hypothesis, Supporting this hypothesis, when Carpenter and colleagues published on their design of a *tailored* quitline approach to specifically help individuals with mental health conditions, it was reported that their cessation support protocol was specifically adapted to increase assessment and attention to a participant's *stress* levels during their quit attempt (12). In-depth explanation for why this was added to the program protocol, other than that it is a typical cause of relapse, and what the stress assessment results were over the course of their pilot were not reported; however, they did report that the program yielded increases in engagement and quit rates among MHD participants in the program. While number of calls and amount of NRT provided was reportedly higher, this study's results don't support a simply "more is better" approach. The protocol design suggested that this population is in need of unique support beyond standard coaching and NRT.

With this emphasis on stress highlighted, the impact of stress on motivation to quit for this unique group should also be considered (36–39). The unique difficulty in achieving high rates of cessation success with this group may be better addressed by offering enhanced support resources and help with the primary stressors both contributing to their tobacco use and acting as a barrier to cessation (19, 40–42). This would likely need to go beyond an assessment of the presence of stress, and to an actual supportive action to connect that individual to a resource that can help them materially or psychologically respond to the stressor in a constructive way. For example, an active resource connection component (such as connection to a 2-1-1 support line or local non-profit) could be integrated into quitline services with a more thorough needs assessment for MHD-endorsing individuals. This could likely be facilitated with a technology-mediated approach in conjunction with a program using ecological momentary assessment to provide real-time options to address stress other than coping by tobacco use (43).

Helpline cessation programs that seek to actively address sources of stress in participants' lives beyond their use of tobacco products will likely incur increased costs due to increased time spent with assessment and connection of individuals to identified resources. The reality of limited funding for many quitlines will require innovative and collaborative solutions to this problem. Future studies should explore the feasibility and efficacy of pairing needs assessment and active resource connection to telephonic and electronic-based tobacco cessation programming. As agencies continue to maintain and market their quitlines as resources, the focus must continue to shift away from an emphasis on "if you build it (and tell them about it), they will come." The quitline community is encouraged to meaningfully consider why this study found that certain groups demonstrate lower quit rates even when engaging higher amounts of the quitline's services. More pilot studies should be designed examining the impact of incorporating unique support such as stress assessments and amelioration strategies into quitline practice. These studies could provide additional insight into how quitlines can not only help an individual stop a destructive habit but constructively build up new positive habits and supports in its place.

A unique strength of this study was its large sample size of users all eligible for the same OTH service. This allowed for less biased comparisons between groups regarding service

selection type and intensity trends in a way that has not before been examined within the literature on tobacco quitlines. An acknowledged limitation of the use of backwards selection for the analysis is that it could have increased the possibility of Type 1 error. This should be taken into account as the results are considered. Although unavoidable due to missing data, variables such as education level, Hispanic ethnicity and sexual orientation would have provided additional information pertinent to the examination and discussion. These variables should be included in future investigations on this topic. It should also be noted that this was a study within a treatment-seeking group of tobacco users. Future comparisons to tobacco users endorsing MHDs not seeking treatment would yield additional insight into potentially helpful strategies for offering the most relevant quitline service. The study was also limited in that MHD status was based solely on self-report. As noted earlier in the discussion, willingness to report MHDs is a study area in itself. As such, it cannot be assumed that the non-MHD comparison group was completely devoid of participants with MHDs (either undiagnosed or unready to share that information).

In conclusion, this study noted the complex reality inherent to tobacco cessation support for individuals dealing with the unique stress of living with mental health difficulties. It supported quitlines as one of the ways this support can be provided, but highlighted the need for unique tailoring, noting that standard quitline care was less effective with this unique group. While this demographically diverse group shares in common the identifier of endorsing an MHD, this is contrasted to the diverse array of symptom presentations within the category of MHDs. This should not, however dissuade the tobacco cessation community from trying to find innovative, impactful ways of attending to the common denominators across this group, to include the role of stress. It is recommended that quitlines and public health entities partner to accomplish this mission. Departments of health and mental health, associations of psychology, counseling, and addiction treatment professionals, public health funders and educational systems should all be sought out as invaluable connections to their region's tobacco quitline. These systems-level partnerships model the universal need for support and provide opportunities for impact multiplication and avoidance of siloed redundancy.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by University of Oklahoma Health Sciences Center IRB (IRB #2616). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

JH was responsible for study design, drafting of the introduction, discussion, and article submission. LMB was responsible for statistical analysis. LAB was responsible for study design, methods and results, as well as overseeing statistical analysis and content revision prior to submission. All authors contributed to the article and approved the final version for publication.

Funding

The Oklahoma Tobacco Settlement Endowment Trust (TSET) is the primary funder of the Oklahoma Tobacco Helpline and also provided funding for the researchers involved in this study.

Acknowledgments

The authors would like to acknowledge the support of TSET for funding this research, as well as the University of Oklahoma and their ongoing support of cancer research, prevention, and the public health of Oklahomans.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.869802/full#supplementary-material

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frontiers | Frontiers in Psychiatry

TYPE Original Research
PUBLISHED 22 July 2022
DOI 10.3389/fpsyt.2022.869023

OPEN ACCESS

EDITED BY
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SPECIALTY SECTION
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

RECEIVED 03 February 2022
ACCEPTED 27 June 2022
PUBLISHED 22 July 2022

CITATION
Schirmbeck F, van der Ven E, Boyette L, McGuire P, Valmaggia LR, Kempton MJ, van der Gaag M, Riecher-Rössler A, Barrantes-Vidal N, Nelson B, Krebs M, Ruhrmann S, Sachs G, Rutten BPF, Nordentoft M, Group EHRS, de Haan L and Vermeulen JM (2022) Differential trajectories of tobacco smoking in people at ultra-high risk for psychosis: Associations with clinical outcomes. *Front. Psychiatry* 13:869023. doi: 10.3389/fpsyt.2022.869023

Differential trajectories of tobacco smoking in people at ultra-high risk for psychosis: Associations with clinical outcomes

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Objective: People at ultra-high risk (UHR) for psychosis have a high prevalence of tobacco smoking, and rates are even higher among the subgroup that later develop a psychotic disorder. However, the longitudinal relationship between the course of tobacco smoking and clinical outcomes in UHR subjects is unknown.

Methods: We investigated associations between tobacco smoking and clinical outcomes in a prospective study of UHR individuals (n = 324). Latent class mixed model analyses were used to identify trajectories of smoking severity. Mixed effects models were applied to investigate associations between smoking trajectory class and the course of attenuated psychotic symptoms (APS) and affective symptoms, as assessed using the CAARMS.

Results: We identified four different classes of smoking trajectory: (i) Persistently High (n = 110), (ii) Decreasing (n = 29), (iii) Persistently Low (n = 165) and (iv) Increasing (n = 20). At two-year follow-up, there had been a greater increase in APS in the Persistently High class than for both the Persistently Low (ES = 9.77, SE = 4.87, p = 0.046) and Decreasing (ES = 18.18, SE = 7.61, p = 0.018) classes. There were no differences between smoking classes in the incidence of psychosis. There was a greater reduction in the severity of emotional disturbance and general symptoms in the Decreasing class than in the High (ES = −10.40, SE = 3.41, p = 0.003; ES = −22.36, SE = 10.07, p = 0.027), Increasing (ES = −11.35, SE = 4.55, p = 0.014; ES = −25.58, SE = 13.17, p = 0.050) and Low (ES = −11.38, SE = 3.29, p = 0.001; ES = −27.55, SE = 9.78, p = 0.005) classes, respectively.

Conclusions: These findings suggests that in UHR subjects persistent tobacco smoking is associated with an unfavorable course of psychotic symptoms, whereas decrease in the number of cigarettes smoked is associated with improvement in affective symptoms. Future research into smoking cessation interventions in the early stages of psychoses is required to shine light on the potential of modifying smoking behavior and its relation to clinical outcomes.

KEYWORDS

ultra-high risk, psychosis, tobacco, smoking, affective symptoms, trajectories

Introduction

The prevalence of tobacco smoking is much higher in patients with psychosis (61.6%) (1), and individuals at ultra-high risk for psychosis (UHR) (up to 53%) (2, 3) than in the general population (25.9%) (4). In addition to an increased risk for somatic morbidity and mortality, tobacco smoking is associated with an increased incidence of psychotic disorders (5, 6) and a higher level of symptoms in patients with a psychotic disorder (7–9). In the general population and UHR samples, some studies have found an association between tobacco smoking and severity of subclinical or attenuated psychotic symptoms (10–12), while other studies have not (2, 3). The cross-sectional nature of most studies and categorical approach on tobacco smoking leaves differences in the severity and course unrecognized. Investigating different long-term trajectories of tobacco smoking and their associations with clinical outcomes in UHR individuals may help to identify subgroups in whom the effects of tobacco smoking may be particularly detrimental and are therefore most suitable for clinical interventions aimed at reducing tobacco use. It is possible that not all tobacco users are equally at risk for psychotic symptom exacerbation but that heavy users or those who increase their use are at higher risk of poor clinical outcomes. In this line, one prospective study from the Northern Finland Birth Cohort 1986 found a greater risk for subsequent psychosis in the heaviest smoking category (13). Regarding symptomatic outcome other than psychotic symptoms, a recent prospective cohort study found specifically early onset and heavy smoking as risk factors for affective symptoms later in life (14). Accordingly, another study in UHR individuals found a larger number of cigarettes smoked per day associated with more severe general symptoms including anxiety and depression (2).

To the best of our knowledge, different prospective patterns of smoking behavior and possible differential associations with symptomatic outcome have not yet been investigated in UHR populations. Applying advanced methods to detect trajectories of tobacco smoking as a possible modifiable risk factor could contribute to the efforts of prevention. We therefore aimed to identify 2-year trajectories of tobacco smoking behavior in UHR individuals who were recruited to the multicenter European Gene-Environment Interactions (EU-GEI) study. Second, we sought to examine sociodemographic and clinical characteristics associated with identified trajectory classes. Finally, we aimed to examine associations between trajectories and the course of attenuated psychotic symptoms (APS), including the risk of transition to psychosis, as well as associations between trajectory class and the course of emotional disturbance and general symptoms as assessed with the Comprehensive Assessment of At-Risk Mental States (CAARMS). We hypothesized that more unfavorable tobacco smoking trajectories would be associated with a more negative course of symptoms and increased risk for transition to psychosis.

Methods

Study design and participants

Data were collected as part of EU-GEI study, from May 2010 to April 2015 (15). The study methodology has previously been described in detail elsewhere (16). In short, the study had a naturalistic, prospective design, consisting of a baseline and two or three follow-up assessments, depending on the outcome measure. Subjects were recruited from 11 mental healthcare institutions in London, Amsterdam, The Hague, Vienna, Basel, Cologne, Melbourne, Kortenberg, Paris, Barcelona and São Paulo. The study protocol was approved by the Medical Ethics Committees at each participating sites. EU-GEI was conducted in accordance with the Declaration of Helsinki.

Typical age of participants was 18–35 years but not restricted to due to variation between sites in the age at which persons are accepted by clinical services. Subjects were eligible for the study if they met criteria of the CAARMS (17) for the UHR state classified into one or more of the following three groups: (1) GRD: schizotypal personality disorder or having a first degree relative with a psychotic disorder and experiencing a significant decline in or chronic low psychosocial functioning, (2) APS: having positive psychotic symptoms that do not reach the threshold levels for psychosis (3) BLIPS: an experience of a recent brief psychotic episode which remitted within a week without use of antipsychotic medications. Psychometric features of the UHR state have been described elsewhere (18). Exclusion criteria were an intelligence quotient (IQ) below 60 and the prior experience of a psychotic episode of more than 1 week as assessed by the CAARMS.

Assessment

Participants were invited for face-to-face follow-up meetings at baseline, and 6 months (limited data as this assessment was introduced later in the course of the study), 12 months and 24 months after baseline. Information regarding transition to psychosis were followed up for 2 years using available clinical records, in case face-to-face meetings were not possible.

Tobacco smoking was assessed with the Composite International Diagnostic Interview (CIDI) (19). The CIDI defines smokers as people who smoked daily during at least 1 month over the past 12 months. In addition, participants were asked how many cigarettes they smoked per day in the time frame they smoked the most during the past months. Studies have confirmed good test-retest and interrater reliability of the CIDI as well as good agreement of CIDI diagnosis with routine clinical diagnosis and applied checklists (20). Sociodemographic and clinical characteristics at baseline included age, gender, ethnicity, education in years, current employment status, IQ and medication use. General functioning was assessed with the disability score of the General Assessment of Functioning Scale (GAF-d) (21). The GAF proved to be a reliable and valid measure of psychiatric disturbances (22, 23). Cannabis use was measured with the Cannabis Experience Questionnaire (CEQ) asking participants whether or not they currently use cannabis. The experience of childhood trauma was assessed with the Childhood Trauma Questionnaire (CTQ) (24) a 25-item self-report questionnaire assessing traumatic events before the age of 17 including emotional abuse, physical abuse, sexual abuse, emotional neglect, and physical neglect. Good reliability and validity of the CTQ has been reported in the general population (25), as well as in patients with psychotic disorders (26).

Attenuated psychotic and affective symptoms were assessed with the CAARMS (17), a semi-structured interview with a total of 27 items, clustered in seven subscales. For the current study the following three subscales were used: APS included items measuring unusual thought content, non-bizarre ideas, perceptual abnormalities and disorganized speech. Emotional disturbance included items measuring subjective emotional disturbance, observed blunted and observed inappropriate affect. General symptoms included symptoms of depression, anxiety, obsessive compulsive disorder, mania, suicidality and self-harm, mood swings, dissociative symptoms and impaired tolerance to normal stress.

Symptom severity was operationalized by summing intensity*frequency scores of the corresponding items (27, 28). Good reliability and prognostic validity of the CAARMS has been reported (17). The prospective course of CAARMS positive, emotional disturbance and general symptoms was assessed at baseline, 1 and 2 years follow up, in addition to the risk of transition defined as the development of psychotic disorder according to the CAARMS (29).

Covariates

A-priori selected potential confounders based on previous literature (2, 30) including age, gender, socioeconomic status as assessed with education in years and current employment status, childhood trauma, and cannabis use.

Statistical analysis

Latent class mixed model analysis (LCMM) was used to empirically identify and visualize clusters of participants with similar trajectories of tobacco smoking over time within one sample. For reporting of study design and analyses we followed state-of-the-art guidelines (GRoLTS checklist) (31).

Missing values at baseline were replaced applying multiple imputation procedure to be able to include participants with at least one assessment. With maximum likelihood (ML) estimation LCMM then makes use of all available data, regardless of intermittent missing data and/or later dropout.

Subject and time were used to infer latent class trajectories of cigarettes smoked per day. The actual individual time of measurement (days since baseline) was used to account for possible deviation around the planned assessment date. The maximum observational period was set to <1,000 days to avoid including large outlying values (>2SD).

Unconditional LCMM were used to describe the "raw" latent trajectories of smoking without imposing any conditions/predictors on the model. Starting with a one-class model, we fitted models with increasing numbers of classes until we reached the inflection point of the Akaike information criterion (AIC) and Bayesian information criterion (BIC). The AIC can be used to identify the point at which the benefits of improved model fit are outweighed by the cost of the model in terms of its complexity and thus helps to prevent overfitting of the data. In addition, we also examined the somewhat stricter Bayesian information criterion, and the log-likelihood (LL). The latter is a measure of goodness of model fit regardless of model complexity. Finally, posterior probabilities of class membership for each patient were computed using the Bayes theorem (32). According to the GRoLTS checklist the final model was selected based on both statistical (log-likelihood, AIC, BIC) and clinical (class size, distinctness of class-specific trajectories, likelihood of class membership based on posterior probabilities) considerations.

According to the standard Three-Step Method (31), unconditional trajectories were identified as described above (step 1) and class membership was saved and merged with the original data (step 2). To examine associations between baseline characteristics with most likely trajectory class membership chi-square test and analyses of variance (ANOVA) were conducted for categorical and continuous variables, respectively (step 3).

To examine associations between longitudinal outcome in APS and affective symptoms in relation to trajectories of smoking, mixed effects models were applied. The model included fixed effects for time (as categorical), most likely class membership (based on the LCMM as reported above), their two-way interaction, a random intercept and an autoregressive error covariance structure to account for within-subject correlation over time. Pre-specified contrasts were tested from the model with the low and decreasing trajectory class as reference for sequential follow-up assessments. Analyses were controlled for a priori selected covariates.

Associations between trajectory class and risk to transition to psychotic disorders within the 2-year follow-up interval was assessed using Cox proportional hazard regression analyses after assessing the proportional hazards assumption. The overall cumulative risk of psychosis onset for individuals with different trajectories was plotted with the Kaplan–Meier cumulative event function and 95% confidence intervals (CI) (33).

LCMM was conducted using the lcmm R package (34), cox proportional hazard regression analyses were analyzed using survival R package (35) and survminer R package (33) to plot Kaplan–Meier functions with R version 3.6.2. All other analyses were performed using SPSS version 26.

Results

Sample characteristics

Of the 345 CHR-P individuals participating in EU-GEI, 324 provided data on the number of cigarettes smoked per day. Of these 324 individuals, 39 (12.0%) were assessed with the CIDI and CAARMS at 6-months follow-up, 174 (53.7%) at 1 year and 127 (39.2%) at 2 years follow-up, respectively. Median follow-up period in days was 196 (range 21–272) for 6 months, 380 days (range 187–580) for 1-year, and 757 days (min = 535 and max = 993) for 2-year assessments. See flow-chart Supplementary Figure 1.

Data regarding missingness at baseline, and comparisons between dropouts and completers at 1-year are presented as Supplementary Sections 2, 3. Comparing completers and dropouts at 1-year follow-up showed no significant differences in number of cigarettes smoked per day, age, gender, current employment, GAF disability scores, experienced childhood trauma and current cannabis use at baseline. Dropouts had a lower IQ ($t = 3.380$, $p = 0.001$), less years of education ($t = 4.057$, $p < 0.001$) and were more likely to have an ethnic minority background ($X = 6.521$, $p = 0.011$).

Overall, 13 (4.0%) of the 324 participants who were included in our study completed all four assessments, 103 (31.8%) three, 95 (29.3%) two and 113 (34.9%) one assessment. Attrition within the analysis sample seemed mostly at random as the number of assessments was not associated with tobacco smoking, CAARMS outcome, trajectory class membership, gender, ethnicity, current employment, cannabis use, GAF, trauma. Participants with one or two assessments were significantly younger compared to those who completed three assessments.

Trajectories of smoking behavior

A 4-class model was selected for smoking trajectories as the associated BIC was the lowest among the tested models (see Table 1). For this 4-class model, mean class probabilities were moderate to high (0.78- 0.95), suggesting individuals had a 78–95% probability to be correctly assigned to one of the four latent classes.

After visual inspection of the identified trajectories, the smoking classes were labeled as: (i) Persistently High ($n = 110$), (ii) Decreasing ($n = 29$), (iii) Persistently Low ($n = 165$) and (iv) Increasing ($n = 20$), see Figure 1. Individuals in the Persistently High smoking trajectory class smoked on average 15.23 (SD = 8.34) cigarettes per day across time points, patients in the Low smoking trajectory class smoked no cigarettes or a

TABLE 1 Model Fit Parameters for LCMM of numbers of cigarettes smoked with One to Five Classes.

Number of classes	Number of parameters	AIC	BIC	Max log-likelihood	Posterior probability	Sample size per class
1	11	3794.156	3835.744	−1886.078		
2	14	3618.716	3671.647	−1795.358	0.98	137 / 187
3	17	3585.048	3649.321	−1775.524	0.85–0.98	43 / 173 / 108
4	**20**	**3528.232**	**3603.847**	**−1744.116**	**0.78–0.95**	**110 / 29 / 165 / 20**
5	23	3573.718	3660.675	−1763.859	0.59–0.92	43 / 0 / 11 / 173 / 97

AIC, Akaike Information Criterion; BIC, Bayesian Information Criterion; LCMM, Latent Class MixedModeling.
The bold values indicate the statistically significant results ($p \geq 0.05$).

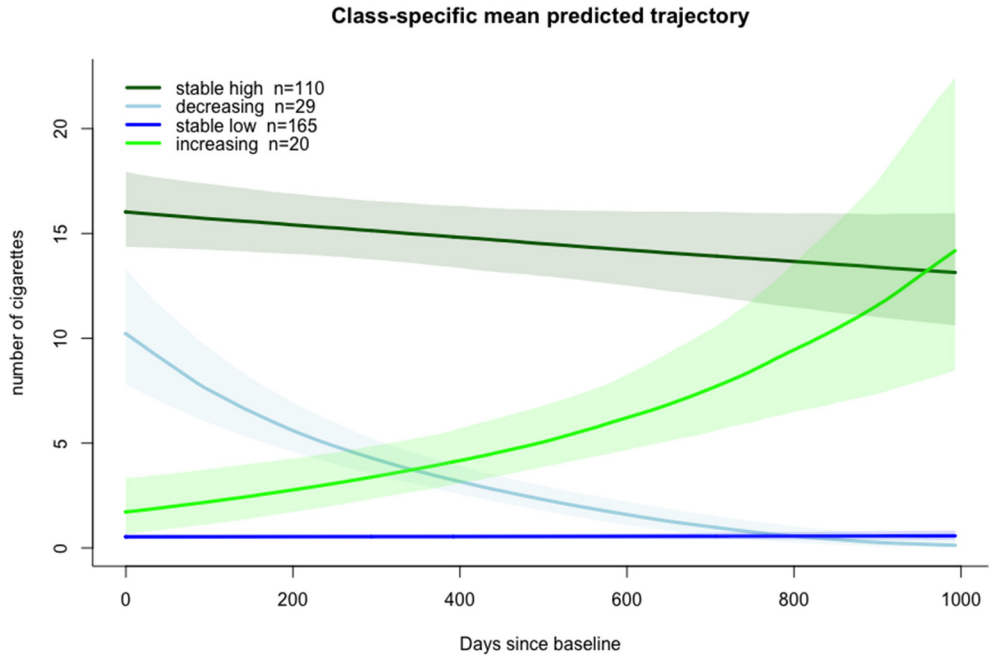

FIGURE 1
Model estimated class-specific mean predicted trajectories of tobacco smoking with 95% confidence intervals.

consistently low number (mean of 0.24 (0.84) and maximum of 5 cigarettes per day). For observed individual courses of cigarettes smoked per day by most likely trajectory membership see Supplementary Figures 2A–D.

Trajectory class membership and baseline characteristics

Comparisons between trajectory classes on baseline characteristics are presented in Table 2. Classes did not significantly differ in gender, ethnicity, years of education, GAF disability scores, IQ score or medication use. The Persistently High and Increasing class was older compared to the Persistently Low smoking class. In term of cannabis use, subjects in the Low smoking class reported less current cannabis use compared to all other trajectory classes.

Prospective outcome associated with trajectory class

As only a small subgroup of participants provided CAARMS data at 6 months follow-up (see flow-chart, Supplement Figure 1), we only included baseline, 1 and 2-years follow-up data of APS, emotional disturbance and general symptoms in the analyses on smoking trajectory and clinical outcomes.

Although the overall trajectory class by time interaction effect for APS was not significant ($F = 1.677$, $p = 0.127$), pre-specified contrasts with the Low and Decreasing trajectory

TABLE 2 Baseline information on sociodemographic and clinical variables by trajectory class.

	Class 1 (persistent high) $N = 110$	Class 2 (decreasing) $N = 29$	Class 3 (persistent low) $N = 165$	Class 4 (increasing) $N = 20$	Group comparisons	Pairwise comparisons
Age	23.17 (5.22)	22.00 (5.69)	21.74 (4.61)	24.35 (5.09)	$F = 2.964$, $\mathbf{p = 0.032}$	High > Low, Inc > Low
Gender (% male)	58.2	55.2	48.5	65.0	X = 3.731, $p = 0.292$	
Ethnicity (% white)	73.6	65.5	70.9	60.0	X = 1.94, $p = 0.585$	
Years of education	13.98 (3.19)	13.93 (2.00)	14.42 (3.18)	15.40 (2.60)	$F = 1.485$, $p = 0.219$	
Now paid work or student (% yes)	49.1	51.7	64.0	70.0	X = 7.631, $p = 0.054$	
GAF disability	53.83 (10.90)	55.07 (11.75)	57.19 (13.50)	53.90 (12.34)	$F = 1.781$, $p = 0.151$	
Cannabis use (% yes)	39.1	37.9	12.7	35.0	X = 28.308, $\mathbf{p < 0.001}$	High > Low, Inc > Low, Dec > Low
Childhood trauma	9.73 (3.09)	10.87 (3.58)	9.71 (3.11)	9.67 (3.14)	$F = 1.840$, $p = 0.146$	
IQ	95.94 (16.01)	96.22 (19.79)	100.66 (17.40)	99.89 (14.57)	$F = 2.098$, $p = 0.101$	
Medication*	26 (28.6)	5 (20.8)	43 (31.9)	6 (37.5)	X = 1.695, $p = 0.638$	
Antidepressants/ Mood stabilizers						
Anxiolytics	11 (12.1)	0	13 (9.6)	2 (12.5)	X = 3.290, $p = 0.349$	
Antipsychotics	11 (12.1)	1 (4.2)	12 (8.9)	3 (18.8)	X = 2.850, $p = 0.415$	

SD, standard deviation; Cigs/day, number of cigarettes per day; GAF, global assessment of functioning. *Information from a subsample of n = 266.
The bold values indicate the statistically significant results ($p \geq 0.05$).

classes as reference, revealed a significant increase in APS in the High trajectory class compared to the Low trajectory class (ES = 9.770, SE = 4.873, $p = 0.046$) and Decreasing trajectory class (ES = 18.182, SE = 7.612, $p = 0.018$) at 2-years follow-up, respectively (Table 3). A significant overall interaction effect was found for CAARMS emotional disturbance ($F = 2.308$ $p = 0.035$). Pre-specified contrasts showed more decrease in the Decreasing trajectory class at 2 years compared with the High (ES = −10.396, SE = 3.414, $p = 0.003$), Increasing (ES = −11.347, SE = 4.551, $p = 0.014$) and Low class (ES = −11.378, SE = 3.290, $p = 0.001$) (Table 4). No significant overall interaction effect was found for CAARMS general symptoms ($F = 1.494$ $p = 0.180$). Pre-specified contrasts showed more decrease in the Decreasing trajectory group at 2 years compared with the High (ES = −22.356, SE = 10.074, $p = 0.027$), Increasing (ES = −25.582, SE = 13.169, $p = 0.050$) and Low smoking class (ES = −27.553, SE = 9.783, $p = 0.005$) (Table 5).

Model estimated means for CAARMS APS, emotional disturbance and general symptoms by trajectory class are presented in Figures 2A–C, respectively.

Transition

Transition to psychosis data within the 1,000 days' timeframe was available in 312 participants of the current sample, who were assigned to one of the four smoking trajectory classes. Within the 2-year period, 53 (16.8%) UHR individuals transitioned to psychosis. Transition occurred in 15 (14.3%) individuals from the Persistently High smoking class, 5 (25.0%) from the Increasing, 5 (17.8%) from the Decreasing and 28 (17.6%) form the Persistently Low class. The median time to transition was 220.5 days (25th−75th percentiles 122–398). The last transition was observed at 779 days when 28 individuals were still at-risk. Cox proportional hazard regression analyses showed no increased cumulative risk to develop a psychotic disorder in the High HR = 0.84 (95%CI:0.45–1.6, $p = 0.593$), Decreasing HR = 0.75 (95%CI:0.29–1.9, $p = 0.556$) or Increasing 1.25 (95%CI:0.48–3.3, $p = 0.647$) trajectory class compared to the Low class, while again controlling a priori defined covariates. The corresponding Kaplan–Meier cumulative risk of psychosis curves are depicted in Figure 3.

Discussion

To our knowledge, this is the first study investigating differential trajectories of tobacco smoking in UHR individuals. Our findings show a clustering around four distinct trajectory classes, with the majority of participants (84%) reporting either persistently high (34%) or persistently low (51%) tobacco smoking across the 2 year assessment period. Smaller subgroups showed a longitudinal decrease (9%) or an increase (6%)

TABLE 3 Results of mixed model analyses of the effect of trajectory class membership on attenuated positive symptoms (APS).

Outcome	Fixed effects		Estimate	SE	*p*-value	95% CI	
APS	Reference low smokingclass						
		Intercept	30.574	7.541	0.000	15.735	45.412
	Trajectoryclass	High	−3.329	2.764	0.229	−8.760	2.102
		Decreasing	7.835	4.349	0.072	−0.710	16.381
		Increasing	1.157	5.215	0.824	−9.088	11.403
	Time	1 year	−12.691	2.616	0.000	−17.838	−7.542
		2 years	−17.189	3.135	0.000	−23.358	−11.019
	Class*Time	High*1 year	−0.092	3.949	0.981	−7.865	7.679
		High*2 years	9.770	4.873	**0.046**	0.179	19.360
		Decreasing*1 year	1.508	5.849	0.797	−10.004	13.021
		Decreasing*2 years	−8.412	7.328	0.252	−22.838	6.014
		Increasing*1 year	3.652	6.877	0.596	−9.887	17.191
		Increasing*2 years	10.324	8.132	0.206	−5.697	26.345
	Reference decreasingclass						
		Intercept	38.409	8.402	0.000	21.882	54.936
	Trajectoryclass	High	−11.164	4.46	0.013	−19.935	−2.393
		Low	−7.835	4.349	0.072	−16.381	0.710
		Increasing	−6.678	6.300	0.290	−19.056	5.699
	Time	1 year	−11.181	5.232	0.033	−21.481	−0.881
		2 years	−25.601	6.627	0.000	−38.650	−12.552
	Class*Time	High*1 year	−1.601	6.013	0.790	−13.437	10.234
		High*2 years	18.182	7.612	**0.018**	3.196	33.168
		Low*1year	−1.508	5.849	0.797	−13.021	10.004
		Low *2 years	8.412	7.328	0.252	−6.014	22.838
		Increasing*1 year	2.143	8.233	0.795	−14.065	18.352
		Increasing*2 years	18.736	10.012	0.062	−0.985	38.457

The bold values indicate the statistically significant results ($p \geq 0.05$).

in number of cigarettes smoked. The High and Increasing trajectory class was older and reported more cannabis use when compared to the Low trajectory class. Identified trajectory classes did not significantly differ on any other sociodemographic or clinical characteristics at baseline.

Regarding associations between trajectory class membership and the course of symptoms, a persistently high level of tobacco smoking was associated with an unfavorable course of APS severity at 2-years follow up: in contrast the Persistently Low and Decreasing trajectory classes showed a continuous decrease in APS severity over time, the Persistently High smoking class showed increasing severity at 2-years follow-up (see Figure 2A). Although no increased risk for transition was found in the Persistently High or Increasing smoking trajectory class, interpretation of this finding is limited by the small transition numbers per class. Furthermore, results show a larger decrease in emotional disturbance and general symptoms in the Decreasing trajectory class compared to all other classes (see Figures 2B,C).

Noteworthy, we can only compare our results with studies conducted in psychiatric patients or the general population, which limits comparability. In line with our finding of a larger reduction of emotional symptoms in the decreasing smoking class, a previous general population study found smoking cessation associated with a decrease in depressive symptoms and increased resilience over a two-year period (36). A recent meta-analysis showed that smoking discontinuation led to an improvement of mental health symptoms, also in psychiatric patients (37). Although our results suggest an unfavorable course of APS severity at the last assessment in the Persistently High smoking class, we did not find an increased risk for transition, as has previously been reported for the heaviest smoking category in The Northern Finland Birth Cohort 1986 study (13).

Regarding associations between baseline characteristics and smoking trajectory class membership, associations with age and cannabis use are in line with earlier research in the general population (38, 39). A prospective investigation of first episode psychosis patients found cannabis use to be associated with lower smoking cessation rates, specifically in female smokers (40). We also found higher cannabis use in the Persistently High and Increasing class,

TABLE 4 Results of mixed model analyses of the effect of trajectory class membership on emotional disturbances.

Outcome	Fixed effects	Parameter	Estimate	SE	*p*-value	95% CI	
Emotional	Reference low smoking class						
		Intercept	7,123	3,640	0.051	−0.044	14,290
	Trajectoryclass	High	1,333	1,303	0.307	−1,228	3,895
		Decreasing	7,653	2,047	0.000	3,629	11,677
		Increasing	−1,821	2,456	0.459	−6,648	3,006
	Time	1 year	−5,923	1,388	0.000	−8,660	−3,186
		2 years	−5,405	1,442	0.000	−8,254	−2,555
	Class*Time	High*1 year	1,906	2,094	0.364	−2,220	6,033
		High*2 years	−,982	2,228	0.660	−5,385	3,420
		Decreasing*1 year	−1,265	3,240	0.697	−7,653	5,123
		Decreasing*2 years	−11,378	3,290	**0.001**	−17,883	−4,873
		Increasing*1 year	0.063	3,556	0.986	−6,951	7,077
		Increasing*2 years	−,031	3,745	0.993	−7,440	7,378
	Reference decreasing class						
		Intercept	14,776	4,034	0.000	6,837	22,716
	Trajectory class	High	−6,320	2,101	0.003	−10,449	−2,191
		Low	−7,653	2,047	0.000	−11,677	−3,629
		Increasing	−9,474	2,966	0.001	−15,304	−3,645
		1 year	−7,188	2,927	0.015	−12,960	−1,416
		2 years	−16,783	2,958	0.000	−22,633	−10,932
		High*1 year	3,171	3,324	0.341	−3,382	9,725
		High*2 years	10,396	3,414	**0.003**	3,645	17,146
		Low*1year	1,265	3,240	0.697	−5,123	7,653
		Low *2 years	11,378	3,290	**0.001**	4,873	17,883
		Increasing*1 year	1,328	4,394	0.763	−7,337	9,993
		Increasing*2 years	11,347	4,550	**0.014**	2,345	20,348

The bold values indicate the statistically significant results ($p \geq 0.05$).

however not in the Decreasing class compared to the Low smoking trajectory class. Due to small samples sizes we were unable to investigate possible moderating effects of gender.

A previous study showed cannabis use to be a possible mediating factor between adolescent smoking trajectory and adult mental health (14). In another study, authors directly compared the effect of patterns of cigarette and cannabis use on subsequent psychotic experiences in a prospective cohort study and found an almost 2-fold increased risk in early-onset cigarette-only users and an almost 4-fold increased risk in early-onset cannabis users, compared with non-users (41). In contrast to a previous study, we did not find childhood trauma to be associated with an unfavorable smoking course. Yoon et al. found that adolescents with early childhood trauma were 2 to 3 times more likely to show increase in smoking behavior compared to the persistently low smoking trajectory class (42).

Different non-mutually exclusive mechanisms have been proposed to explain the link between tobacco smoking and mental health symptoms, including biological explanations such as nicotine-induced elevated dopamine release (6, 43) and shared genetic vulnerability (44). On the behavioral level, both maladaptive coping and misattribution are thought to play a key role in the relationship between smoking and symptoms. Smoking may represent a maladaptive strategy of trying to cope with the stress of experienced symptoms, potentially resulting into even higher levels of symptoms (45). Smokers may misattribute the relief of withdrawal symptoms such as irritability, anxiety, and depression after smoking to the perception that smoking has psychological benefits, which also makes them less likely to stop smoking (46). A growing body of evidence showed that smoking is not effective to alleviate symptoms but stopping smoking is associated with improvement of mental health in both the general population as clinical samples, arguing against the self-medication hypothesis (7, 37, 47). So far, most research suggests a bidirectional relation between smoking and symptoms. Experienced stress and related emotional distress may heighten the risk of smoking initiation, progression, maintenance, cessation avoidance, and relapse (48). Conversely, smoking and associated withdrawal symptoms cause stress and emotional disturbances. Lastly, those

TABLE 5 Results of mixed model analyses of the effect of trajectory class membership on general symptoms.

Outcome	Fixed effects	Parameter	Estimate	SE	*p*-value	95% CI	
General	**Reference low smoking class**						
		Intercept	25,909	10,202	,012	5,833	45,984
	Trajectoryclass	High	5,588	3,658	,127	−1,602	12,777
		Decreasing	8,787	5,749	,127	−2,510	20,085
		Increasing	5,943	6,894	,389	−7,605	19,489
	Time	1 year	−17,557	3,404	,000	−24,268	−10,866
		2 years	−14,768	4,136	,000	−22,893	−6,642
	Class*Time	High*1 year	0,219	5,094	,966	−9,810	10,248
		High*2 years	−5,197	6,304	,410	−17,584	7,189
		Decreasing*1 year	−4,602	7,767	,554	−19,896	10,690
		Decreasing*2 years	−27,553	9,784	**,005**	−46,778	−8,329
		Increasing*1 year	6,197	8,469	,465	−10,481	22,876
		Increasing*2 years	−1,971	10,575	,852	−22,753	18,810
	Reference decreasing class						
		Intercept	34,697	11,314	,002	12,440	56,953
	Trajectory class	High	−3,199	5,897	,588	−14,787	8,388
		Low	−8,787	5,749	,127	−20,085	2,510
		Increasing	−2,845	8,325	,733	−19,204	13,514
		1 year	−22,169	6,956	,002	−35,927	−8,412
		2 years	−42,321	8,869	,000	−59,748	−24,893
		High*1 year	4,821	7,952	,545	−10,837	20,479
		High*2 years	22,356	10,075	**,027**	2,560	42,152
		Low*1year	4,602	7,767	,554	−10,691	19,896
		Low *2 years	27,553	9,78	**,005**	8,32	46,778
		Increasing*1 year	10,799	10,437	,302	−9,756	31,356
		Increasing*2 years	25,582	13,169	**,050**	−,296	51,460

The bold values indicate the statistically significant results ($p \geq 0.05$).

with more severe symptoms might have difficulties in stopping smoking or decreasing the number of cigarettes smoked per day (49, 50).

Limitations

Our results should be interpreted in the light of several limitations. First, from a temporality point of view there was no information available on whether smoking initiation took place before or after the occurrence of first psychotic experiences, precluding causal interpretations. A large cohort study investigating longitudinal classes of tobacco use in minors showed that specifically early-onset tobacco use was correlated with subsequent onset of psychotic experiences (41). In order to determine causal interrelations between tobacco smoking and the course of symptoms, future studies should seek to assess tobacco smoking in the daily life of UHR individuals. This would allow the investigation of moment-to-moment associations between smoking behavior and psychotic or affective experiences. Second, the relatively small number of individuals assigned to the increasing and decreasing trajectory class, in combination with considerable loss to follow-up during the course of the study, limits the reliability of the assessed associations between identified trajectories and prospective outcome. Although sensitivity analyses (see Supplementary Section 5) resulted in comparable tobacco smoking trajectory classes, careful interpretation is warranted and there is a need for replication with prospective data of a larger sample. Third, loss to follow-up might further have influenced our findings as dropouts showed lower IQ, less years of education and were more likely to have an ethnic minority background compared to completers. These differences limit the generalizability of findings. Fourth, generalizability is also limited to help-seeking UHR individuals. Fifth, information on other potential confounders affecting the course of psychopathology such as the effect of medication use was only available in a subgroup of participants and therefore not included in the analyses. In the subgroup with known medication status, no significant differences between

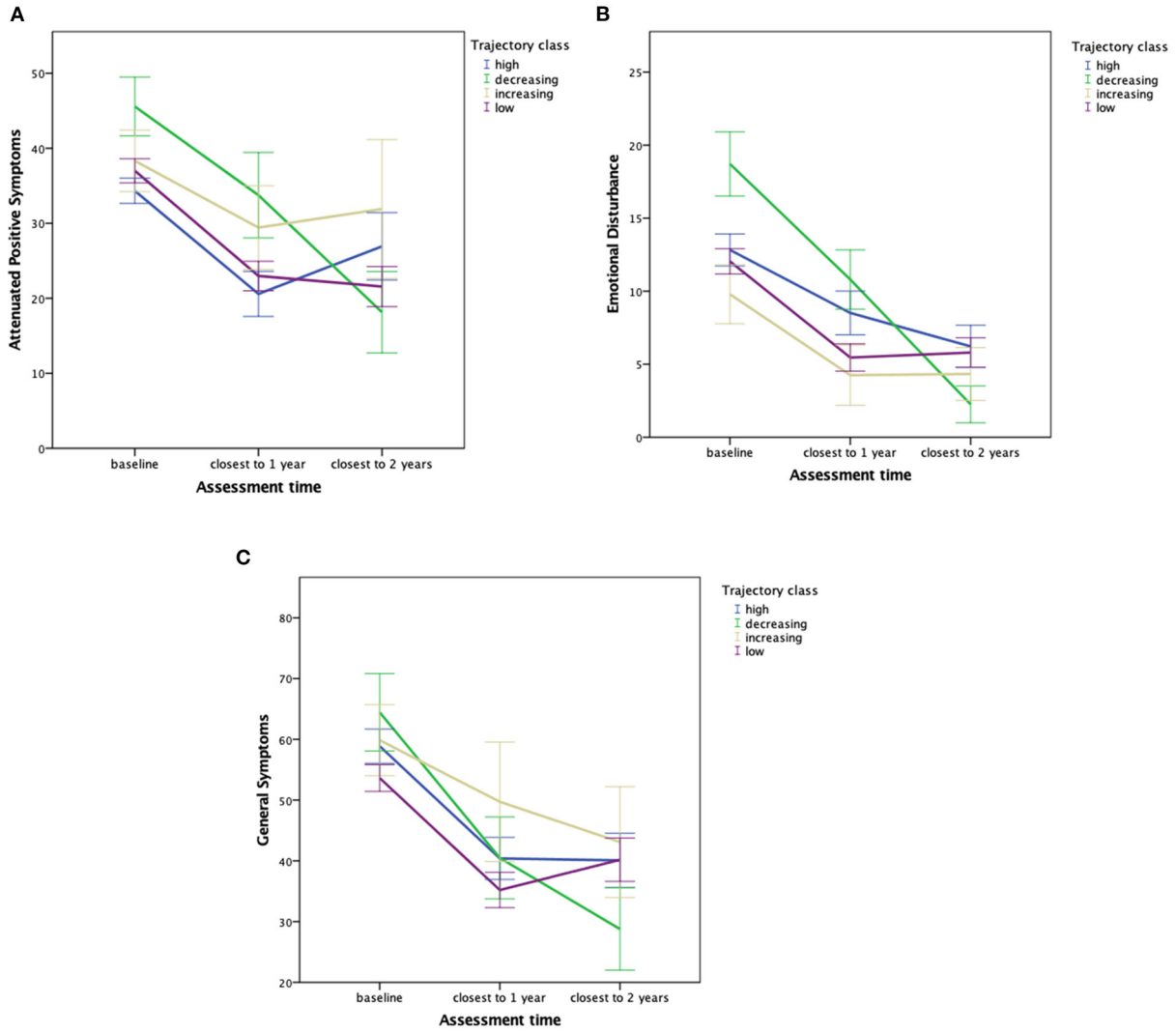

FIGURE 2
(A) Model estimated means and 1-standard errors of APS scores predicted by most likely trajectory class membership and assessment time. **(B)** Model estimated means and 1-standard errors of emotional disturbance scores predicted by most likely trajectory class membership and assessment time. **(C)** Model estimated means and 1-standard errors of general symptom scores predicted by most likely trajectory class membership and assessment time.

identified trajectory class membership were found (see Table 2). Unfortunately, information on psychological interventions during the course of the study was not available at all sites. To account for between-trajectory differences in cannabis use we controlled for this variable in subsequent analyses, however possible interacting effects of these substances on clinical outcome are worth investigating in larger samples in the future.

Conclusion and clinical implications

Findings showed interrelations between a persistently high level of tobacco use and an unfavorable course of APS severity and a positive interrelation between reduction in tobacco use and an improvement in affective symptoms over time. More research is needed to understand possible covariation and causal interactions. Although a causal direction cannot be established and bidirectional interrelations are most probable in the current study, smoking cessation interventions in this vulnerable group should receive more attention. UHR individuals experience less intense and frequent symptoms than individuals with established psychosis and it might be easier in this phase to quit smoking. Early intervention smoking cessation programs should therefore be offered when UHR individuals present to psychiatric services. Current findings suggest that differentiating UHR individuals based on patterns of smoking behavior might

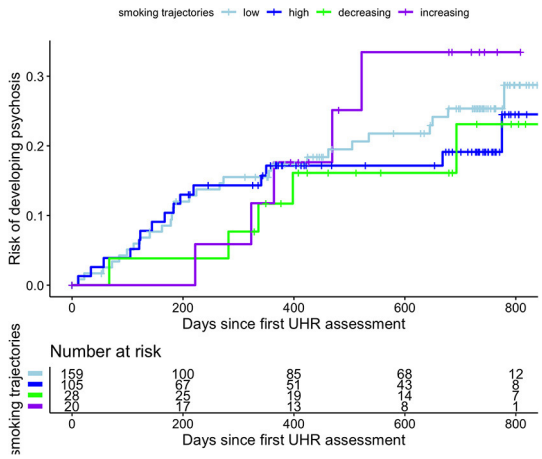

FIGURE 3
Cumulative event Kaplan–Meier function for risk of development of psychotic disorders in 312 ultra-high risk (UHR) individuals stratified for smoking trajectory class.

contribute to identifying subgroups with a higher risk for an unfavorable outcome.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Materials, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Local Medisch Ethische Toetsingscommissie (METC), University Medical Center Amsterdam, Location AMC, Amsterdam, the Netherlands (NL32721.018.10). The patients/participants provided their written informed consent to participate in this study.

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Funding

The European Network of National Schizophrenia Networks Studying Gene-Environment Interactions (EU-GEI) Project was funded by grant agreement HEALTH-F2-2010-241909 (Project EU-GEI) from the European Community's Seventh Framework Programme. Additional support was provided by

a Medical Research Council Fellowship to M Kempton (grant MR/J008915/1). BN was supported by an NHMRC Senior Research Fellowship (1137687).

Acknowledgments

We are grateful for the generosity of time and effort by participating individuals.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.869023/full#supplementary-material

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frontiers | Frontiers in Psychiatry

TYPE Original Research
PUBLISHED 25 August 2022
DOI 10.3389/fpsyt.2022.868212

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

RECEIVED 02 February 2022
ACCEPTED 01 August 2022
PUBLISHED 25 August 2022

CITATION
Faint N, Cuesta-Briand B and Coleman M (2022) An evaluation of junior doctors' experience in smoking cessation training in a rural mental health setting. *Front. Psychiatry* 13:868212. doi: 10.3389/fpsyt.2022.868212

An evaluation of junior doctors' experience in smoking cessation training in a rural mental health setting

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Introduction: Smoking prevalence remains high amongst people with mental illness, however, they are less likely to be screened for tobacco dependence and offered treatment to quit. Smoking cessation and education training are insufficient in medical schools, despite a positive relationship between training and practice once qualified. However, the question as to whether there is adequate skill and expertise to address smoking in people with mental illness within Australian mental health settings is unclear. Furthermore, people living in rural and remote areas smoke at higher rates, quit at lower rates than those in urban areas, and experience limitations in their ability to access smoking cessation supports. The Smokers' Clinic is an initiative established in a rural Australian mental health service offering a smoking cessation service to patients and staff employed by the service.

Aim: This study aims to assess the change in the knowledge and confidence of resident medical officers in their understanding of nicotine dependence, smoking cessation strategies and prescribing nicotine replacement therapy in a community mental health setting. It was hypothesized that providing education and supervised clinical experience would improve knowledge, increasing confidence and motivation in managing smoking cessation in mental health patients. The research was undertaken using data collected through a questionnaire obtained from surveying resident medical officers administering the Smokers' Clinic following a 10-week rural community mental health rotation.

Materials and methods: Twenty resident medical officers completed the 10-week rotation, with 14 completing the questionnaire. Knowledge of tobacco smoking, nicotine dependence and smoking cessation interventions improved with the experience of the Smokers' Clinic during the clinical rotation. Resident medical officers were motivated to spend additional time engaged in self-directed learning and all reported continued use of acquired experience and information in their clinical work after the rotation.

Conclusion: This study indicates the utility of a novel approach in delivering education, training, building clinical expertise, and facilitating sustained clinical capacity amongst junior medical staff for smoking cessation in a rural community mental health setting. It offers an efficient approach for mental health services to deliver smoking cessation services to reduce the morbidity and mortality burden associated with tobacco smoking.

KEYWORDS

mental illness, tobacco cessation, rural, rural mental health, junior doctor education, smoking

Introduction

Smoking is the leading cause of preventable disease burden in Australia, and worldwide (1, 2). Economically, the net cost for smoking to Australian society was $136.9 billion in 2015–2016 (1). Although tobacco can be snorted and chewed, smoking is the predominant form of consumption in Australia (1). Across the greater Australian community, the prevalence of smoking continues to decline, however, it remains high among those with mental illness (3). The prevalence of adults smoking daily has declined from 12.8% in 2016 to 11.6% in 2019, however, it remains high at 20% in those with mental health conditions (1). People with mental illness have higher levels of nicotine dependence, lower rates of smoking cessation and consequently suffer from higher rates of morbidity associated with smoking compared to the general population (4). Prevalence rates are highest in those diagnosed with bipolar affective disorder who are three and a half times more likely to smoke than the general population, and schizophrenia who are more than five times as likely to smoke than the general population (3). They are also more likely to die from smoking-related illnesses, such as cardiovascular disease, respiratory disease and cancer, as opposed to their mental illness (5–11).

Public health interventions to reduce demand (advertising restrictions, plain packaging, mass educational campaigns, legislation restricting advertisement) (12), reduce harm (subsidization of pharmaceuticals to assist with cessation, legislation mandating smoke-free workplaces) (13), and reduce supply (tobacco taxation, restriction of sales to minors below 18 years of age) (12), have been effective in decreasing the prevalence of smoking in the Australian population. In recent years, many countries have prohibited patients from smoking in mental health facilities, or on hospital grounds. However, many of these interventions have had minimal effect on smoking rates in people with mental illnesses, likely due to the lack of strategic targeting to address distinct barriers to cessation in this population (14).

Tobacco smoking has long been embedded within mental health service culture: "smoking rooms" have acted as social hubs for patients; smoking itself has provided structure and social activity for patients and staff alike; and cigarettes have been used to both placate or engage with patients (15, 16). Historically, tobacco companies have supplied either free or low cost cigarettes to institutions and have actively blocked efforts to institute smoking bans (17). The most popular explanation for high smoking rates among people with mental illness is the self-medication hypothesis, which posits this as an attempt to manage negative symptoms due to underlying neurobiological deficits associated with mental illness, leading to cognitive impairment (18). Rates of smoking amongst mental health professionals remains high compared with other professions, perpetuating the embedding of tobacco smoking within mental health culture (19).

With respect to accessing smoking cessation interventions, people with mental illness are less likely to be screened for tobacco dependence and offered treatment to assist in quitting (20). Mental health professionals hold attitudes and misconceptions that may undermine the delivery of effective smoking cessation interventions (21, 22). Myths surrounding smoking cessation for people with mental illness continue to persist. These include: people with mental illness are not motivated to quit smoking; smoking cessation is not possible for people with mental illness; smoking cessation is a lower priority for people with mental illness; smoking assists with stress; and smoking cessation is harmful to people with mental illness (10, 18, 23).

People with mental illness respond to interventions, and tolerate pharmaceutical interventions used to assist in cessation and abstinence from tobacco in the same way as those without mental illness (24, 25). The EAGLES trial, a study designed to evaluate the neuropsychiatric safety of Varenicline, Bupropion, nicotine patch, and placebo when used in smokers with and without mental illness, did not show a significant increase in neuropsychiatric adverse events and demonstrated efficacy of these pharmaceutical interventions in achieving smoking cessation (26). Moreover, people with mental illness prefer support and encouragement from mental health clinicians in their efforts to achieve abstinence from cigarettes, rather than

accessing mainstream quit services (27). Smoking cessation in people with mental illness is associated with improvements in mental health, quality of life and reduction in other substance misuse (28). Mental health professionals are also perfectly placed to address the impact smoking cessation (and tobacco use) has on the metabolism of psychotropic medications (29).

Whilst overall, smoking rates in Australia have declined, these findings are not proportionate across geographical locations (30). People living in rural and remote areas smoke at higher rates and quit at lower rates compared to those in urban areas (30). Accessing community services is more difficult for rural and remote residents compared with urban residents, due to physical distance to services and social isolation. Rural and remote residents need to travel on average 90 min or 102.7 km in order to access healthcare supports (31). Travel times are often increased for Australian Aboriginal residents who are more likely to reside in very remote settings (31). Despite Australian government initiatives implemented to increase funding to rural and remote medical training, worryingly, medical workforce shortages and maldistributions between urban and rural and remote settings persist (32). Decreased availability of health professionals and decreased health expenditure both appear to correlate with increasing remoteness (33). Pro-tobacco social norms, lower socioeconomic and educational attainment, and different cultural attitudes are seen as significant contributing factors (30). Cumulatively, these factors may result in rural and remote residents experiencing limitations in their ability to access healthcare, maintain health beliefs that support cigarette smoking, and prevent access to smoking cessation medications and supports (30).

Countless opportunities are missed in addressing the disproportionately high prevalence rates of tobacco smoking in people with mental illness. A national survey of United Kingdom medical schools concluded that smoking cessation and education training was insufficient, and may have worsened over the preceding decade (34). This is despite research demonstrating retention of knowledge and skills among medical students who receive education on smoking assessment and interventions during medical school (35–37). A positive relationship exists between education received in medical school and consequential increases in knowledge, and the development of positive perceptions regarding role in initiating smoking cessation interventions for patients once qualified (38). However, the question as to whether there are adequate levels of skill and expertise to address smoking in people with mental illness within Australian mental health settings is unclear.

Previous studies have demonstrated that psychiatrists are less likely than general practitioners to advise people to quit smoking (39, 40). This may be due to reluctance in managing smoking cessation given a lack of evidence-based advice offering guidance for prescribing pharmacotherapies in people with mental illness, with low prescribing rates and utilization of behavioral interventions (18, 41, 42). In studies that led to United States Food and Drug Administration (FDA) approval for smoking cessation medications, people with mental illness were excluded. This lack of information has made it difficult for clinicians to manage smoking cessation in people with severe mental illness. It has also led to the non-use of these products, as clinicians fear they may not be safe (18, 43).

Nicotine replacement therapy (NRT) remains the mainstay of interventions offered to people with mental illnesses. This intervention is usually offered in the context of inpatient treatment and, invariably, with little attention to smoking cessation, but rather nicotine withdrawal management within non-smoking facilities. Training and education of mental health practitioners must be a priority in order to address the sustained high rates of tobacco smoking, morbidity and mortality in this vulnerable at-risk group.

The Smokers' Clinic

The Smokers' Clinic is an initiative established in a rural Australian mental health service offering a smoking cessation service to patients (inpatient and outpatient) and staff employed by the service, based on the assessment protocol from the Brain Mind Research Institute (BMRI) at The University of Sydney (44). It offers clients an initial 1-h face-to-face assessment followed by weekly 30-min follow-up assessments (face-to-face, telephone, or video conference) for 6–8 weeks. The initial assessment consists of a comprehensive biopsychosocial history focused on the patient's smoking history, allowing the implementation of a customized treatment plan. The clinic is accessible to patients and staff who utilize tobacco in all forms, along with e-cigarettes. It was established to meet an unmet need amongst this group of patients.

The Smokers' Clinic is administered and conducted by a resident medical officer (RMO) who is undertaking a 10-week community mental health rotation within the service. As a junior medical practitioner, their experience of mental health settings, presentations and interventions is limited. The RMO receives an initial 1-h education session provided by their supervisor, an addiction consultant psychiatrist, in addition to ongoing weekly supervision to discuss issues related to tobacco smoking, nicotine dependence and treatment which includes pharmacotherapy and non-pharmacotherapy options. The Smokers' Clinic is provided in parallel to the patient accessing mental health treatment as usual from the service. This initiative is advantageous as it offers mental health patients concurrent management of both mental health and substance use disorders. RMOs work in close collaboration with the patient's treating team, assisting in the assessment of other substance use disorders. The Smokers' Clinic also allows medication reviews to occur, as psychotropic medication dosages may need to be altered, due to drug interactions

and metabolic changes that occur in the context of smoking cessation (25).

All clients undergo a comprehensive initial assessment including: standardized history and examination consistent with the BMRI protocol (44); the Fagerstrom Test for Nicotine Dependence (FTND) – an instrument that provides universally accepted detailed measure of nicotine dependence (low, low-moderate, moderate, high) in people with and without mental illness, to guide interventions (45, 46); and a Carboxymeter reading measuring expired Carbon Monoxide (eCO) levels. eCO levels can be used to confirm smoking status, make comparisons throughout follow up, and confirm abstinence. Correspondence pertaining to the patient's progress is provided to their general practitioner and treating psychiatrist. Pharmacotherapies including combination NRT, varenicline, bupropion and nortriptyline are offered and were provided via prescription or available to purchase at a discounted rate from local pharmacies. Behavioral interventions such as individual counseling, motivational interviewing, and mindfulness-based strategies are utilized and incorporated into patients' treatment plans. These are derived from and consistent with the Royal Australian College of General Practitioners (RACGP) Clinical Guidelines for Smoking Cessation (9). Quitline referral was offered to all clients.

Aim

The aim of this study was to assess the change in the level of knowledge and confidence of RMOs in their understanding of nicotine dependence, smoking cessation strategies and prescribing NRT in a community mental health setting. This includes assessing their experience of their initial training and supervision from an addiction consultant psychiatrist during their 10-week rotation. It is hypothesized that providing *in situ* education and supervised clinical experience would result in an improvement in knowledge, increasing confidence and motivation in managing smoking cessation in mental health patients.

Materials and methods

The research was undertaken using largely quantitative measures with two open-ended questions, obtained from a brief survey of RMOs administering the Smokers' Clinic whilst undertaking a community mental health rotation. RMOs who undertook the rotation between 2016 and 2021 were sent an email at the conclusion of their rotation, containing information on the project and a hyperlink to complete an anonymous 19-question online questionnaire. Consent was assumed if the RMO completed the questionnaire. RMOs who completed more than one rotation were invited to complete the questionnaire only once. The questionnaire, developed by the investigators, recorded knowledge and confidence in the assessment and management of smoking cessation, knowledge, and confidence in relation to specific treatments and the applicability of this knowledge beyond the Smokers' Clinic. The knowledge domains assessed were smoking, smoking cessation, and NRT. Results were recorded on five-point Likert-scales. For example, knowledge was assessed with "1" correlating with "none," and "5" correlating with "excellent," and for confidence "1" correlated with "not confident at all," and "5" correlating with "very confident." RMO knowledge was assessed before and after completion of the rotation, whilst confidence was assessed after completion of the rotation. There were two open questions where RMOs were invited to input a free text response. The questions asked RMOs to elaborate further on additional training they may have undergone, and to provide any additional comments at the conclusion of the questionnaire (the questionnaire administered can be provided upon request).

Descriptive statistics were used to summarize findings. A paired-samples *t*-test was used to compare RMO knowledge before and after completing their rotation operating the Smokers' Clinic, with statistical significance set at $p < 0.05$. A basic content analysis was conducted on the responses to the two open-ended questions. Ethics approval was obtained through the Western Australia Country Health Service (WACHS) Health Research Ethics Committee (approval number RGS230).

Results

A total of 20 RMOs completed a 10-week rotation in the community mental health setting over a 5-year period and were responsible for operating the Smokers' Clinic. Of these 14 completed the questionnaire (70% response rate). At the time of completing the survey, three (21%) RMOs were undertaking their second postgraduate year (PGY), two (14%) were undertaking their third PGY, and the remaining nine (64%) had greater than 3 years experience.

Resident medical officers did not appear to encounter difficulty learning about *nicotine dependence* and *smoking cessation*, rating it as "very easy" (n = 5, 36% and n = 4, 29%, respectively), "easy" (n = 7, 50% and n = 7, 50%, respectively), or "moderate" (n = 2, 14% and n = 3, 21%, respectively). All RMOs spent additional time acquiring knowledge outside of the education provided by the addiction consultant psychiatrist with most reporting an additional 1–2 h (n = 7, 50%) of self-directed learning.

A variety of case complexity was experienced during clinic encounters with the majority of RMOs (n = 8, 57%) reporting moderate patient complexity. The majority of RMOs rated the amount of supervision from the addiction consultant psychiatrist as appropriate (n = 13, 93%).

Prior to the commencement of the rotation, all RMOs rated their knowledge of smoking, smoking cessation, and NRT as "poor," "below average," or "average," whereas after the rotation RMOs rated their knowledge as "above average" or "excellent" (refer to **Figures 1–3**). The improvement in knowledge for RMOs operating the Smokers' Clinic was statistically significant for smoking ($t = -17.73$, $p < 0.001$), smoking cessation ($t = -21.66$, $p < 0.001$), and NRT ($t = -16.52$, $p < 0.001$) (refer to **Table 1**).

All RMOs have continued to use the acquired information for clinical work beyond the "Smokers' Clinic" with the majority reporting use on a weekly basis ($n = 8$, 57%). All RMOs agreed they had a duty of care to advise and aid patients in their efforts to cut back and/or quit smoking. The majority of RMOs ($n = 11$, 79%) had not received any further training in smoking cessation or nicotine dependence beyond that experienced from the Smokers' Clinic. Those RMOs who had further training were asked to elaborate – further training experiences were General Practitioner (GP) fellowship training, non-specific fellowship training, self-directed study, or conference presentations.

At the completion of their rotation, the majority of RMOs ($n = 11$, 79%) rated themselves as "very confident" in assessing for nicotine dependence, with all rating their confidence in administering treatment of nicotine dependence and smoking cessation as "moderately confident" ($n = 6$, 43%) or "very confident" ($n = 8$, 57%). When looking at "very confident" ratings for treatment interventions, NRT was the highest ($n = 13$, 93%), followed by Varenicline ($n = 7$, 50%), and behavioral interventions ($n = 5$, 36%). With respect to Bupropion, no RMO's rated themselves as "very confident" with the majority ($n = 5$, 36%) rating themselves as moderately confident in prescribing and managing this agent. Regarding the recognition of drug interactions and changes in metabolism of psychotropic medication in the setting of smoking cessation in mental health patients, the majority of RMO's ($n = 8$, 57%) rated themselves as "somewhat confident" with ($n = 5$, 36%) rating themselves as "moderately confident" and only one ($n = 1$, 7%) rating themselves as "very confident" (refer to **Figure 4**).

Resident medical officers were invited to provide additional feedback regarding their experience of the Smokers' Clinic. Three comments were provided – two of which identified the educational/training benefits of the Smokers' Clinic and the utility within their clinical practice, whilst one noted their lack of experience in using bupropion and indicated a necessity to further review drug interactions.

Discussion

Junior doctors' knowledge of tobacco smoking, nicotine dependence and smoking cessation interventions increased with the experience of the Smokers' Clinic during their 10-week rotation. Furthermore, the relative ease at which learning occurred, the knowledge and clinical practice reported by RMOs are of significant educational and clinical importance. This is particularly the case in view of the relatively short experience and training resources required to enable this experience, and has significant implications in the context of a low resource rural setting. RMOs were exposed to a range of patient complexity which only serves to further contribute to building capacity within their training and confidence when assessing and managing mental health patients prescribed psychotropic medications. The Smokers' Clinic structure and governance appeared to motivate RMOs to engage in their own self-directed learning outside of the provided education sessions.

Confidence in the assessment and management of smoking cessation by using NRT was high in this study. This is unsurprising given NRT is available for purchase without prescription (47), has proven safety over 30 years of use (48), and is recommended as first line pharmacological agents (9). Interestingly, study participants rated themselves as confident in prescribing Varenicline to patients with mental illnesses – contrasting with reports within the literature about psychiatrists' attitudes toward this pharmacological agent for smoking cessation (26), and trends showing decreasing rates of Varenicline prescribing over the preceding 10 years (48). However, Bupropion was not used by most participants, and therefore, confidence ratings reflected the lack of exposure to this pharmacotherapy. This may also suggest that success, and dropout, meant that opportunities to progress to Bupropion did not occur. There may also be apprehension in prescribing due to reports within the literature of adverse effects (44). A variety of reasons may account for this finding, including the relatively short intervention period, a lack of continuity of patients over periods greater than 10-week, a clinic-based process rather than assertive follow-up, offer plausible explanations. Literature reporting adverse effects for both Varenicline and Bupropion have consisted of uncontrolled case reports with unconfirmed causal links. Both pharmacological agents have proven safe and effective for assisting people with mental illness in achieving smoking cessation (26). In 2016 the FDA revised and removed mental health warnings for both medications (49).

Junior doctor attitudinal change toward smoking cessation was evident in this study. RMOs appeared to appreciate the detrimental health impacts of smoking and the importance of their role in facilitating smoking cessation, with all reporting a perceived duty of care to advise and aid patients in cutting down and quitting smoking. This is consistent with literature demonstrating increases in advice-giving by clinicians and patient quit attempts after completion of training programs (50). The value in achieving improved and sustained knowledge and clinical practice in smoking cessation was further highlighted by the reported dearth of further training opportunities in junior doctor training, outside of GP training. The increase in knowledge and improvement in confidence within RMOs was consistent with previous research showing similar results

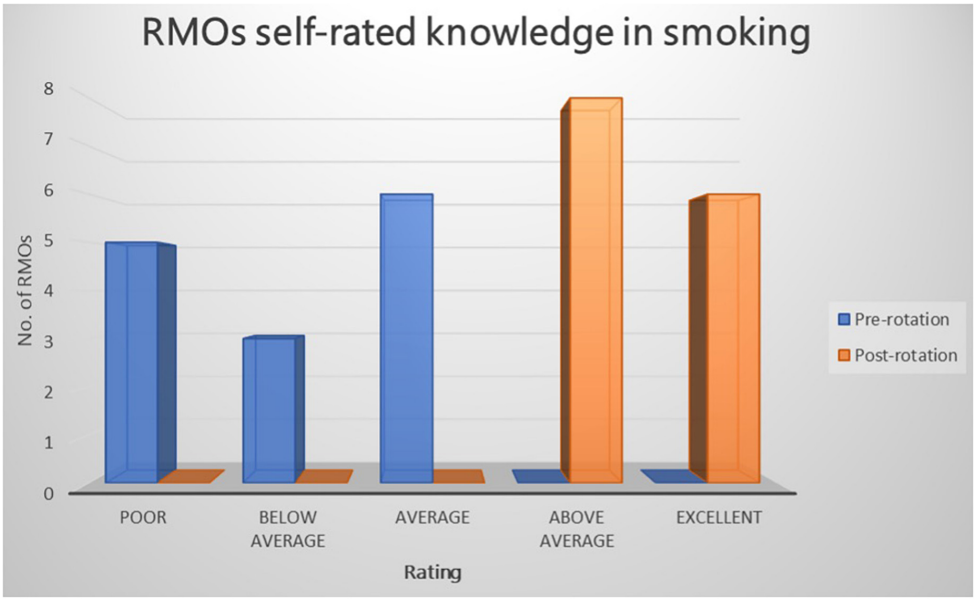

FIGURE 1
Graph illustrating the RMOs rated knowledge of smoking pre-rotation and post rotation in a community mental health setting using a five-point Likert-scale.

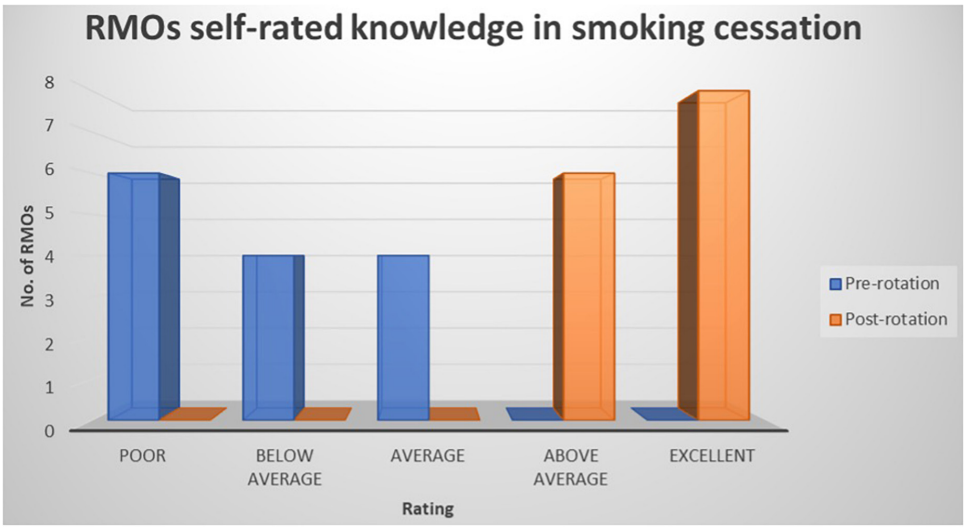

FIGURE 2
Graph illustrating the RMOs rated knowledge of smoking cessation pre-rotation and post rotation in a community mental health setting using a five-point Likert-scale.

for junior medical officers within mental health, receiving training and education for the assessment and treatment of tobacco dependence (51, 52). Given the significant health burden associated with tobacco smoking worldwide, this novel clinic in a mental health setting provides a real-world and generalizable medical education and training opportunity for junior medical staff. With higher rates of smoking and lower quit rates experienced by rural and remote residents (30), this clinic offers an option to address a health discrepancy. As people with mental illness residing in rural and remote Australia are underserviced due to a "severe shortage" of consultant psychiatrists and an inclination for trainee psychiatrists to practice in urban centers (53), the Smokers' Clinic offers an easily implementable solution to deliver smoking cessation services to this vulnerable group in remote locations. The Smokers' Clinic initiative employs effective clinician education

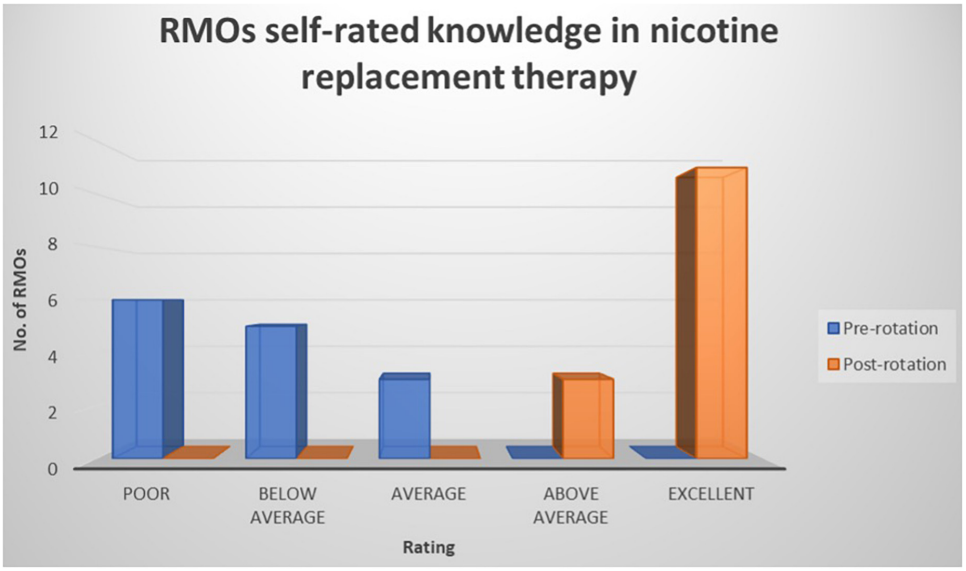

FIGURE 3
Graph illustrating the RMOs rated knowledge of nicotine replacement pre-rotation and post rotation in a community mental health setting using a five-point Likert-scale.

TABLE 1 Paired *t*-test comparing RMO rated knowledge of smoking, smoking cessation, and NRT before and after completing a community mental health rotation.

Knowledge domain	Pre-rotation M (SD) $N = 14$	Post-rotation M (SD) $N = 14$	t	P-value
Smoking	2.07 (0.92)	4.42 (0.86)	**−17.73**	**<0.001**
Smoking cessation	1.86 (0.86)	4.57 (0.51)	**−21.66**	**<0.001**
NRT	1.79 (0.80)	4.79 (0.43)	**−16.523**	**<0.001**

Values in bold indicate statistically significant results.

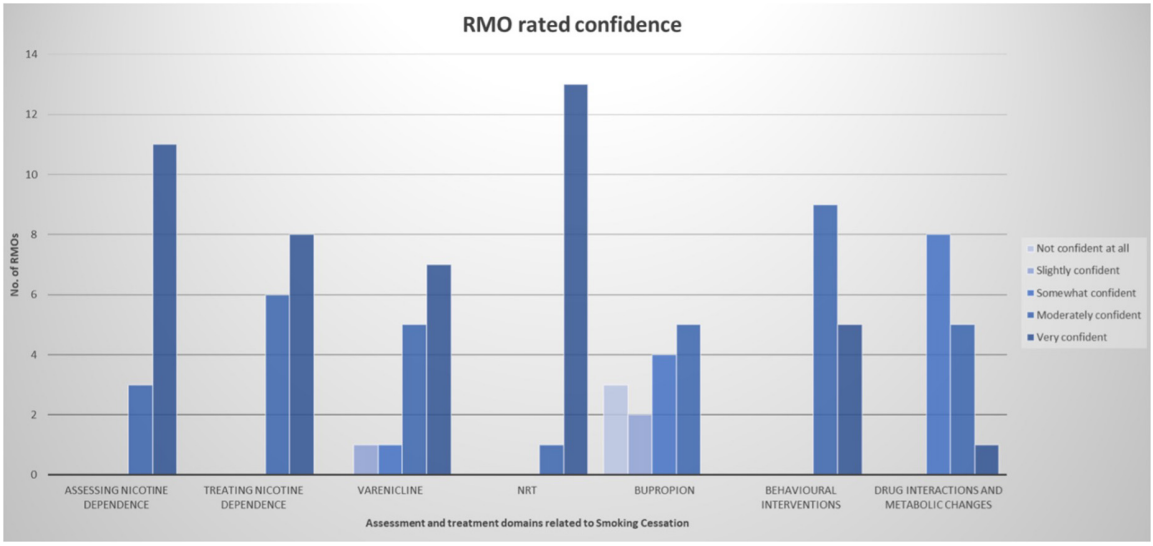

FIGURE 4
Graph illustrating the self-rated confidence of RMOs in various assessment and treatment domains related to smoking cessation after completing their rotation operating the Smokers' Clinic using a five-point Likert-scale.

models (54), whilst utilizing essential strategies previously identified to overcome challenges in implementing smoking cessation programs in rural and remote settings – selection of tobacco dedicated staff; improvement in collaboration between health services; flexible access for patients; provision of subsidized pharmacotherapies; and boosting staff morale (55).

The most notable limitation to this study was the small sample size, which raises the question of generalizability – further research using a larger sample size would be beneficial. The small sample size may have resulted in the study being underpowered. Selection bias was thought to be less relevant given the favorable response rate (70%) but was considered as those RMOs who received a beneficial experience operating the Smokers' Clinic may have been more inclined to respond. This novel approach to assessing and managing smoking cessation requires further evaluation in other mental health service settings, with the potential for application into other medical settings to target at-risk patients across a range of other medical disciplines. Future research assessing the client's subjective experience with the clinic would be insightful and beneficial for the purposes of improvement of service delivery.

Conclusion

This study demonstrates the utility of a novel approach in delivering education, training, building clinical expertise, and facilitating sustained clinical capacity amongst junior medical staff for smoking cessation in a rural and remote mental health setting. Confident knowledge, skills and positive attitudinal change can result from brief but supportive teaching and supervision of junior medical staff that may be applied to settings beyond a community mental health service. It offers an efficient and novel approach for mental health services to deliver smoking cessation services whilst enhancing and building capacity in the medical workforce for the future with the aim of reducing the burden of morbidity and mortality associated with tobacco smoking. The Smokers' Clinic proved invaluable in a rural and remote setting. Given the disproportionate health outcomes for rural and remote residents, particularly those with mental illness, and the ongoing difficulties in medical workforce training and retention, it offers an innovative solution to address physical and mental health disparities within such a vulnerable group.

Author disclosure

This manuscript has been submitted to The Royal Australian and New Zealand College of Psychiatrists (RANZCP) as a Scholarly Project (a summative assessment item for the RANZCP Fellowship Program) for NF.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by the WA Country Health Service Human Research Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work, and approved it for publication.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Psychiatry

TYPE Original Research
PUBLISHED 06 October 2022
DOI 10.3389/fpsyt.2022.868032

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to
Addictive Disorders,
a section of the journal
Frontiers in Psychiatry

RECEIVED 02 February 2022
ACCEPTED 14 September 2022
PUBLISHED 06 October 2022

CITATION
McCarter K, McKinlay ML, Cocks N, Brasier C, Hayes L, Baker AL, Castle D, Borland R, Bonevski B, Segan C, Kelly PJ, Turner A, Williams J, Attia J, Sweeney R, Filia S, Baird D and Brophy L (2022) The value of compassionate support to address smoking: A qualitative study with people who experience severe mental illness. *Front. Psychiatry* 13:868032. doi: 10.3389/fpsyt.2022.868032

The value of compassionate support to address smoking: A qualitative study with people who experience severe mental illness

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Introduction: People experiencing severe mental illness (SMI) smoke at much higher rates than the general population and require additional support. Engagement with existing evidence-based interventions such as quitlines and nicotine replacement therapy (NRT) may be improved by mental health peer worker involvement and tailored support. This paper reports on a qualitative study nested within a peer researcher-facilitated tobacco treatment trial that included brief advice plus, for those in the intervention group, tailored quitline callback counseling and combination NRT. It contextualizes participant life experience and reflection on trial participation and offers insights for future interventions.

Methods: Qualitative semi-structured interviews were conducted with 29 participants in a randomized controlled trial (intervention group $n = 15$, control group $n = 14$) following their 2-month (post-recruitment) follow-up assessments, which marked the end of the "Quitlink" intervention for those in the intervention group. Interviews explored the experience of getting help to address smoking (before and during the trial), perceptions of main trial components including assistance from peer researchers and tailored quitline

counseling, the role of NRT, and other support received. A general inductive approach to analysis was applied.

Results: We identified four main themes: (1) the long and complex journey of quitting smoking in the context of disrupted lives; (2) factors affecting quitting (desire to quit, psychological and social barriers, and facilitators and reasons for quitting); (3) the perceived benefits of a tailored approach for people with mental ill-health including the invitation to quit and practical resources; and (4) the importance of compassionate delivery of support, beginning with the peer researchers and extended by quitline counselors for intervention participants. Subthemes were identified within each of these overarching main themes.

Discussion: The findings underscore the enormity of the challenges that our targeted population face and the considerations needed for providing tobacco treatment to people who experience SMI. The data suggest that a tailored tobacco treatment intervention has the potential to assist people on a journey to quitting, and that compassionate support encapsulating a recovery-oriented approach is highly valued.

Clinical trial registration: The Quitlink trial was registered with ANZCTR (www.anzctr.org.au): ACTRN12619000244101 prior to the accrual of the first participant and updated regularly as per registry guidelines.

KEYWORDS

tobacco treatment, quitline, peer worker, mental illness, severe mental illness, health disparities

Introduction

Severe mental illness (SMI) refers to a mental illness that results in serious functional impairment, which substantially interferes with or limits one or more major life activities (1, 2). People who experience severe mental illness (SMI) smoke tobacco at much higher rates than the general population and die on average 10–20 years earlier (3). Most of this mortality gap is attributed to smoking-related diseases such as cardiovascular disease, respiratory disease, and cancer (4). Smoking is therefore one of the major modifiable risk factors for premature mortality in this population. Evidence suggests that people who experience SMI are as motivated to quit as the general population (5). However, they have lower overall success with cessation (6, 7), which has been attributed to a range of factors including not routinely receiving tobacco treatment (8–10).

Gold standard interventions for tobacco treatment encompass pharmacotherapy (e.g., combination nicotine replacement therapy (NRT), varenicline, bupropion) coupled with multi-session behavioral counseling (11). Telephone delivery (i.e., a quitline) of tobacco treatment counseling has the potential to improve access and is beneficial for people who experience SMI (12–15). However, quitline services are underutilized (16) and more effort is required to enable engagement for people experiencing mental ill-health. Similarly, despite evidence for the effectiveness of pharmacotherapy for cessation for people who experience SMI (17–19), NRT is also underutilized in this population (20). To try to enhance uptake of both quitline and pharmacotherapy, we developed, in collaboration with the Victorian (Australia) Quitline, a tailored intervention for smokers who experience SMI that aims to address common cessation issues for people experiencing SMI, e.g., concerns that stopping smoking might worsen mental health, coping with more severe withdrawal symptoms due to higher levels of nicotine dependence, managing potential increases in medication side-effects and the upfront costs of combination NRT. The "Quitlink" quitline counseling intervention included structured monitoring of mental health symptoms, nicotine withdrawal symptoms, and medication side-effects (21), a dedicated Quitline counselor plus 8 weeks of free combination NRT.

Mental health peer workers can play a role in enhancing tobacco treatment interventions for people who experience SMI. Peer workers bring their lived experience of mental ill-health and recovery to engage and support consumers of mental health services. Recovery can be conceptualized as a process of building a meaningful and satisfying life, as defined by the person themselves, whether or not they are experiencing ongoing or recurring symptoms or problems associated with illness (22). Principles of recovery-oriented practice include openness, collaboration as equals, a focus on the individual's inner resources, reciprocity, and a willingness "to go the extra

mile" (23). The growing recognition of the value that lived experience expertise can provide, along with recovery-oriented practice (24) means that peer workers have a significant role to play in supporting and empowering people who experience SMI to engage with tobacco treatment. Marginalization and stigma can play a role in reinforcing smoking behaviors and peer workers offer hope and connection (25).

People who experience SMI and smoke encounter complex barriers to tobacco use recovery, including higher levels of nicotine dependence and the potential for more severe withdrawal symptoms, greater likelihood of living with smokers, increased financial stress as well as stigma (including internalized stigma), social exclusion as well as the impact of mental illness and treatment (25). To evaluate tobacco treatment trials, consideration for the participant context and experience is necessary. Qualitative methodology can illuminate participant trial experience and engagement and provide a nuanced understanding of participants' broader context. The aim of the present study was to explore the experiences of participants in the "Quitlink" trial, particularly regarding quitting smoking and tobacco treatment.

Methods

This study is reported according to the consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist (26). Ethical approval was granted by St Vincent's Hospital, Melbourne (HREC Reference Number: HREC/18/SVHM/154), the University of Newcastle HREC (HREC Reference Number: H-2018-0192) and the Cancer Council Victoria, HREC (HREC Reference Number: 1807).

This qualitative study was nested within the "Quitlink" trial (27). Depending on recruitment strategy, participants were "invited" to the "Quitlink" trial *via* different methods including peer researcher presentation at mental health services, clinician referral, direct mail postcard, and Facebook advertising. The active control condition included advice to quit, encouragement to use NRT, and a Quit Victoria pack of written materials to motivate a quit attempt and encourage use of the Quitline service. The Quitlink intervention participants received the above and additionally, a proactive referral to Quitline counseling tailored to meet the needs of people experiencing SMI and up to 8 weeks of combination NRT. This tailored counseling was based on cognitive behavioral therapy and included structured monitoring of mental health symptoms, nicotine withdrawal symptoms, and medication side-effects to help distinguish temporary withdrawal symptoms from psychiatric symptoms; and a focus on psychoeducation including the relationship between smoking and mood; goal setting; identification of triggers to smoke; and facilitating problem solving and skills building, including the use of mood management strategies that also act to aid cessation (27).

For the current study, participants were recruited from both control and intervention arms of the trial.

Sample

Eligible participants were those who participated in the "Quitlink" trial and provided consent to be contacted about participating in qualitative interviews. To be eligible for the main trial, participants smoked at least 10 cigarettes a day and were accessing treatment or support from participating mental health agencies. The majority of people accessing these services will have been experiencing SMI. As a result of slow recruitment and COVID-19, eligibility criteria were expanded during the trial to include people accessing support or treatment from their general practitioner, for a mental health or alcohol and other drug use condition. The Mini International Neuropsychiatric Interview [MINI; (28)] was administered at follow-ups to obtain lifetime mental health diagnosis. The McLean Screening Instrument for Borderline Personality Disorder (29) was administered to verify participant self-reported main diagnosis. Diagnoses were grouped into "psychotic" and "non-psychotic" disorders.

Peer workers were employed as peer researchers to help recruit participants, conduct baseline assessments, deliver brief advice and facilitate engagement with the study (27). Participants were randomized to either an active control condition or the Quitlink intervention and were blinded as to which group they were in. The quantitative component of the trial included subsequent follow-ups at 2-, 5-, and 8-months post-baseline. The focus of this paper is the qualitative interviews conducted soon after participants had completed 2-month follow-up (which marked the end of the "Quitlink" intervention period for those in the intervention group). Participants were also invited to further follow-up qualitative interviews to enable them to share their experiences over time: these results will be presented elsewhere.

To achieve variability, a decision was made to wait until a proportion of participants had completed their 2-month quantitative follow-up assessments before selecting and contacting participants. However, due to slower than expected and lower recruitment to the main trial, the intended purposive sampling strategy for the current study was replaced by convenience sampling. Subsequent delays in commencing the qualitative part of the study meant the first 25 people who had agreed to be contacted about an interview were already at the 5- or 8- month follow-up stage and were therefore not contacted to participate in the 2-month qualitative interviews. No participants who were recruited to the main trial *via* the initial recruitment strategy of face to face, peer researcher presentation participated in the 2-month qualitative interviews. Thus, they were invited to be included in 5- and 8-month qualitative interviews (these data will be presented in future papers).

Procedures

Following completion of the 2- month follow up assessment, participants were interviewed about their experiences of being in the study to that point in time. Recruitment and interviewing were undertaken by a team of female researchers including the peer researchers (NC, MM, and CB) and the trial coordinator (KM). NC, MM, and CB (PhD) are peer researchers with a range of experience, and NC and MM recruited and delivered brief advice to participants as part of the main trial. KM (PhD) is a clinical psychologist and had previous experience leading qualitative research. Written or verbal recorded consent was obtained.

In order to facilitate recruitment and engagement and provide access to peer support for the main trial, peer researchers NC and MM were embedded within the mental health services where participants were recruited. The interviewers were supervised by LB (a senior investigator of the project with a social work background). Participants were aware that those conducting the interviews were a part of the main research trial team. Participants had previously interacted with the peer researchers and were aware that they were bringing their lived experience including their experience with mental ill-health and recovery and smoking to the study. However, peer researchers did not interview any of the participants they specifically recruited to the main trial.

Interviews were conducted *via* telephone with only the interviewer and interviewee present. A semi-structured interview guide was used (see Supplementary material). The interview guide was developed by LB in collaboration with investigators from the main trial and explored:

- Participant history of getting help to address smoking and current experience
- Perceptions of assistance from peer researchers to address smoking
- Impressions of Quitline counseling
- The role of NRT in participants' quit attempts
- Support received from other services, health professionals or support workers

The interviews were audio recorded and transcribed verbatim. Participants received an AU$40 gift card as renumeration for participation.

Data analysis

Thematic analysis, employing a general inductive approach was applied (28, 29), identifying themes and patterns within the data, with no preconceived theories applied. While a general inductive approach is aligned with grounded theory, the underlying assumptions of a general inductive approach include that data analysis relates to both the research objectives and interpretation of raw data (30). To begin, KM conducted open coding of the first half of transcripts independently of the other authors, using NVivo 12. A series of team meetings were then held in which four transcripts were open coded by the other coders to identify, review, and refine the codes. Axial coding was then performed by KM to draw connections between codes, and categories were created.

Categories and codes were organized in a word document to assist in gaining a clearer sense of the data. From here, preliminary themes were identified by the team. This process allowed for discussion and deepened the interpretation of meaning within the data and aimed to increase the trustworthiness of the findings (30). Again, a series of weekly team meetings were conducted to review, confirm, and refine the themes and subthemes. We used a consensus approach to agree on themes and sometimes this led to lengthy discussions. The team were able to benefit from the input of the lived experience expertise of the peer researchers in the analysis. A summary of preliminary themes and illustrative quotes from the interviews was sent to participants (who had previously consented n =19) for their feedback.

Results

For the current study, 29 interviews were conducted. Participant information can be found in Table 1. Participants in the qualitative study had a similar profile to the trial sample overall (31). Most of the participants in the current study were recruited to the main trial *via* direct mail postcard, followed by online advertising. The average age of participants was 46 years old and over half (59%) were female. Most participants met criteria for a psychotic disorder [MINI; (32)], the average number of cigarettes per day at recruitment was 20 and most participants scored in the moderate range for tobacco dependence as measured by the Heaviness of Smoking Index (33). Participants represented both intervention ($n = 15$) and control ($n = 14$) arms of the trial and a range of tobacco use recovery outcomes at their 2-month quantitative follow-up assessment (including cut down, quit, relapsed and continued smoking). Engagement with Quitline (from recruitment to 2-month quantitative follow-up assessment) ranged from 2 to 11 calls for intervention participants. Two of the control participants contacted Quitline independently following the brief advice provided to all participants at baseline (and received either one or four calls).

We identified four main themes, reflecting (1) the long and complex journey that illustrated the quitting histories of participants; (2) their considerations of the factors that affect quitting smoking; (3) the perceived benefits of a tailored approach for people experiencing mental ill-health; and (4) the

TABLE 1 Participant characteristics (collected in Quitlink trial baseline assessments) ($N = 29$).

Characteristic	*n* (%)	Mean (range)
Age		46 (20–64)
Female	17 (59%)	
Marital status	3 (10%)	
Married/defacto/widowed		
Separated/divorced	9 (31%)	
Single/never married	15 (52%)	
Other	2 (7%)	
Education		
Primary school/years 7–9	2 (6%)	
School certificate/intermediate/year 10/4th form	7 (24%)	
HSC/leaving/year 12/6th form	2 (7%)	
TAFE certificate/diploma/trade certificate or apprenticeship	12 (41%)	
University/College of advanced education/Some other tertiary institute degree or higher	6 (21%)	
Employment status		
No job	16 (55%)	
Housework/stay at home parent	1 (3%)	
Studying	2 (7%)	
Volunteer	1 (3%)	
Part time/casual/temporary worker	7 (24%)	
Full time	2 (7%)	
Diagnosis* (mini international neuropsychiatric interview)		
Psychotic disorders (schizophrenia spectrum disorders, bipolar 1 disorder, bipolar 1 disorder with psychotic features, or major depressive disorder with psychotic features)	20 (69%)	
Non-psychotic disorders (major depressive disorder, post-traumatic stress disorder, generalized anxiety disorder, borderline personality disorder)	7 (24%)	
Inconclusive	2 (7%)	
Cigarettes per day at recruitment		20 (11–35)
Nicotine dependence		
Low	1 (3%)	
Moderate	22 (76%)	
High	6 (21%)	
Recruitment type		
Face to face	0	
Postcard	24 (83%)	
Online	5 (17%)	
Allocation		
Intervention	15 (52%)	
Control	14 (48%)	
Time between recruitment and interview (days)		107 (65–145)
Time between quantitative 2-month follow-up and interview (days)		48 (18–84)

*Assessed at Quitlink trial follow-up assessments.
Defacto, partners in a relationship who live together as a couple but are not married; HSC, Higher School Certificate; TAFE, Technical and Further Education.

importance of compassionate delivery of support. Subthemes were identified within each of these overarching main themes.

Theme 1: A long and complex journey

The interviews provided an understanding of how smoking is contextualized within participants' lives. Most described a long and complex journey with smoking and tobacco use recovery. Their comments highlighted the deeply intertwined intersection between smoking, challenging and disrupted lives and histories of multiple attempts to quit.

Subtheme: Disrupted lives

Participants reported disrupted and unpredictable lives. They spoke about grief, homelessness, trauma, their poor mental health and other problematic substance use.

Many illustrated the impact that disruption had on attempts to quit smoking. As one participant explained:

> "Well yeah I was homeless and that's pretty depressing…Hard to quit smoking… but I've been on and off homeless for about 4 years since my mother passed away."
> (*Intervention participant)*

Others expressed the connection between the chaos of life and relapse to smoking.

> "I had a quit date in November and I was doing really well, I quit for probably a couple of weeks, and then I had a lot of stresses in my life, and I started just having one or two cigarettes again, and then at Christmas time I was very stressed and I started smoking a little bit more frequently… I was moving house, and I had to downsize, my partner died last year and there was a lot of things going on…It's very lonely without him."
> (*Intervention participant)*

Sometimes this impression of disruption reflected the powerlessness and lack of choice that comes from the poverty that was a common feature of peoples' lives. For some of our participants, smoking cigarettes meant they could not afford necessities.

> "Exactly that's right, because it's easier to get by without food if you've got cigarettes, but getting by without cigarettes for the food, that's no fun, that's not a thing we're going to do."
> (*Intervention participant)*

There was a sense of isolation and stigma that connected financial difficulties and being a smoker.

> "Yeah that's right. It's easy for the non-smokers to go—"*Oh the smokers are lepers anyway and who cares how expensive it is*"—you know, like if they just end up dying that's going to do everybody a favour."
> (*Intervention participant)*

In the context of these disrupted lives, smoking could be a distraction, a friend, a conduit for social connection, or a pleasurable pastime during mental health difficulties.

> "I sort of find it's like a friend in a way you know it's time just to chill out and focus on something different and not what is at hand, you know, like not to be concerned with what I'm doing that particular day. I sort of think "I'll have a cigarette, bugger that" and just drift off a bit, …I don't have to worry about things."
> (*Intervention participant)*

Other substance use issues also intersected with smoking for some participants. For example, one participant stated:

> "… and I think the first time that I actually started smoking cigarettes regularly was as a quitting mechanism for the cannabis."
> (*Control participant)*

Subtheme: Quitting histories driven by persistence and desire

Our discussions highlighted determination and desire to quit despite the challenges outlined above. In the context of difficult circumstances, most participants stated they had made multiple quit attempts previously.

> "Made an attempt to quit? Yeah plenty of times."
> (*Control participant)*

Many had previously used a variety of methods to try to quit including both "cold turkey" and NRT.

> "I've tried, I went to my doctor and we tried patches…Yeah tried like the gum and the mist and stuff like that."
> (*Control participant)*

For a small number of participants from both intervention and control groups, reflecting on these previous attempts to quit offered a hopeful perspective that they were now on a journey to successful quitting.

> "No, like I said this is my 50th thousandth time I've tried, so yeah, I don't know, I guess for me it's just about not being disheartened every time I, like every time I quit I'm one step closer to quitting for good."
> (*Control participant)*

Theme 2: Factors that participants perceive to impact quitting smoking

Participants discussed a range of factors perceived to influence the success of quitting smoking including the desire to quit, their confidence and self-esteem, barriers and facilitators to change, and reasons for quitting.

Subtheme: Desire to quit

Many control and intervention participants spoke about the importance of having a desire to quit and demonstrate "self-control" to engage with tobacco treatment.

> "But at the end of the day it's up to you, if you want to do something you have to make it happen for yourself, you know like you've got to—you can get outside support or help, but you've got to do it, you have to want to do it yourself."
> *(Control participant)*

Some participants took this idea further in talking about the need for that desire to be solidified and committed to. For some participants, this "want" to quit was linked to ideas around the requirement of an internal or mental shift about being "done" with smoking.

> "Yeah I think because everyone's so different you know and some people might be like sick to death of smoking … and the health hazards and stuff like that whereas I am not overly concerned, like sometimes I think 'Oh well, I am just going to end up dying from smoking and I am going to get cancer from it', but all those things go through your mind sometimes but I am not at the point … where I just hate it and I want to stop."
> *(Intervention participant)*

It appears that participants often believed that wanting to quit was essential to successfully ceasing smoking and that this had to happen within the right conditions. For example, one participant spoke of the importance of timing:

> "Yeah it was just sort of at the right time that I sort of sought to get the support to help me and yeah it was just all timing. Probably if I had attempted to do it six months

> earlier it might not have worked or it might have taken a lot longer."
> *(Control participant)*

Some people described a lack of desire to quit smoking as being linked to living with their mental health challenges, including the will to live, and not feeling deserving of a better, healthy life.

> "I mean I think that definitely in the past you know probably being depressed hasn't helped because there's sort of like a fatalistic . . . [and] 'I don't even deserve to be healthy' sort of vibe going with that."
> *(Control participant)*

Subtheme: Barriers and facilitators

Unsurprisingly, numerous barriers and facilitators for quitting smoking were raised. These could be described as encompassing the personal (stress, mental health, boredom) and intersecting social domains (family, friends, living situation, environment, financial resources, and COVID-19).

Personal

Many participants spoke about smoking being interlinked with stress including as a coping response. Participants identified smoking as a reaction to daily stressors, mental health difficulties and sometimes boredom, particularly in the absence of other strategies for responding to these challenges.

> "So, in the past it's been very difficult for me to stop because I get stressed out with things happening in life that I need stress relief, and I thought the cigarettes were actually helping me."
> *(Intervention participant)*

Stress was also described as a major trigger for relapse.

> "I had a stressful thing happen and I started smoking again you know."
> *(Control participant)*

Most participants spoke about mental ill-health as a barrier to quitting. Smoking was described as a way to cope with poor mental health.

> "Yeah, because I find that mental illness and smoking go hand in hand .... I know I've used it as a crutch to deal with my mental illness and in some ways it has helped to get through the tough times, even though it was causing me such great harm, but at the same time it did help me cope."
> *(Control participant)*

Severity of mental ill-health was seen as a barrier to quitting. As one participant stated:

> "Yeah, I think if someone's really crook with mental health issues and they've only just been diagnosed it's going to be harder for them to stop than anyone else."
> *(Intervention participant)*

Others discussed that deterioration in their mental health could serve as a trigger for relapse to smoking.

> "I have triggers if something goes wrong in my life, I start thinking about cigarettes again when things aren't going so good. So, if I start getting depressed or something goes wrong, I'll think I really do need a cigarette you know, that's usually how I've broken and ended up back on them."
> *(Intervention participant)*

Several participants commented that to be successful in cessation, mental health must also be addressed.

> "When you're stressed and everything it's not a good time, you've got to address your mental health."
> *(Intervention participant)*

Social

Some participants referred to friends, family or partners who smoked when discussing barriers to cessation.

> "I had friends that smoked too so that was a bit difficult obviously being around them and them smoking."
> *(Control participant)*

One participant described smoking as almost inevitable in the context of family history.

> "My brother, he doesn't even try to give up. Really, I think he sort of settles for the fact that he's a smoker and my dad was a smoker all his life as well, so it runs in the family and both of my sisters are smokers, but they managed to quit maybe five, six, seven years ago. They both gave up but the males in the family they don't have such luck."
> *(Intervention participant)*

A small number of participants also described friends, family, or partners as facilitators to quitting, although one participant highlighted the fragility of this support.

> "And my partner he smokes, so—he's supportive but also you know if he's having a cigarette, he's not going to go 'Oh, you can't have one'."
> *(Intervention participant)*

The lack of a safe, supportive environment for cessation was described as a barrier.

> "Yeah definitely, no, it's not a supportive and safe enough environment for me to be comfortable to be vulnerable and to fail, and I need that space before I can think about doing it."
> *(Control participant)*

Developing this theme, a small number of participants spoke about a change in environment as conducive to quitting. Specifically, their statements reflected the impact of escaping stressful or negative environments.

> "Yeah, there were people, they were smoking cigarettes, or they were smoking other substances as well, and I've got them out of my life completely, and because that's why I wanted to move home, it wasn't a nice environment, it was too expensive, and I needed to be around people who wanted (inaudible). And I've moved by myself, and I'll be getting somebody else to move in, but hopefully I'll be requesting that they're a non-smoker, you know."
> *(Intervention participant)*

About half of our participants spoke about the impact of COVID-19. These participants described how the boredom and isolation associated with the pandemic made quitting harder.

> "I think COVID-19 for me made it harder because I was stuck inside, I wasn't able to do my normal social things, so I was stuck at home, I was doing a lot of study on the computer, and I felt like I couldn't do anything else, so I thought 'I'll have a cigarette'."
> *(Control participant)*

Only one participant described COVID-19 as a facilitator, stating that it made them more determined.

> "It has been harder, but it's just made my resolve stronger."
> *(Intervention participant)*

The financial barrier to quitting centered on the challenge in getting started which potentially requires purchasing NRT products and cigarettes simultaneously and not having the money to do both.

> "Yeah that's a barrier maybe for a lot of people you know—especially in my position I'm on a pension and stuff like that—the cost even though…I know that you can get all the products through the doctor, all the different sort of products and you know I was in the chemist the other day and noticed the price of them, I thought 'Oh my god, there was no way I would have bought any of that!', I just literally would not have been able to afford to do that."
> *(Intervention participant)*

Subtheme: Reasons to quit and benefits

Reasons for attempting to stop or to cut down included physical health and financial benefits.

> "The money I saved in the time I started, since I've really (inaudible) smoking now but I also appreciate the money I saved, that I spent on cigarettes before."
> *(Intervention participant)*

Two participants linked motivation to their children.

> "And you know I'm driven by that motivation to quit, because I want to be a good role model for them."
> *(Intervention participant)*

Theme 3: The benefits of a tailored approach for people with mental ill-health

As part of the study, all participants were invited into the study, completed an initial assessment and peer researchers provided brief advice and written materials on stopping smoking. Across control and intervention arms, participants valued the components of the tailored approach that they were exposed to. There were varied experiences of difficulty in quitting and different levels of success.

Subtheme: An invitation to quit

Those who expressed gratitude for an invitation and the opportunity to participate in the "Quitlink" study were exclusively recruited to the trial *via* the direct mail postcards strategy. For some it appeared that they had minimal opportunities in the past to be involved in a tailored offer of support.

> "If you hadn't made contact, I wouldn't have known to ring up and ask for help. Yeah, I feel very lucky to be pulled out of the hat and given a chance you know."
> *(Intervention participant)*

Subtheme: Assessments as motivating and clarifying

A number of control participants spoke about the study assessments as clarifying and motivating.

> "Oh, it sort of made me…think about how much I was smoking and how much I'm spending and what I'm missing out on…Oh yeah because I spend all my money on cigarettes…Oh well it really makes me think about and consider having another attempt at getting them out of my, giving up smoking you know."
> *(Control participant)*

Subtheme: The value of lived experience

Some did not recall or distinguish the involvement of peer researchers who undertook recruitment, baseline assessment data collection provision of brief advice and written materials,

from the research assistants who subsequently collected follow-up data *via* telephone. However, for those who valued peer researcher involvement, the importance of a unique shared understanding and experience of mental ill-health and smoking and recovery is reflected.

> "I loved that she had you know that she was a peer researcher, that she had the experience of smoking and of mental health, and you know the impacts that they have together. So really just, you know, talking to (peer researcher) and knowing that she had that same experience and that kind of thing, was really helpful."
> *(Control participant)*

Subtheme: Experienced support from Quitline counselors

Participants identified a range of important study components that reflected an appreciation of relevant and experienced, continuous support.

The studies' deliberate use of experienced Quitline counselors (for the intervention group) was particularly appreciated. Several participants spoke about the helpfulness of Quitline counselor information to do with NRT use.

> "I think the most helpful thing was having the phone calls with the Quitlink person or the—who was able to, you know, answer my questions how to use the products and also just helping me clarify my own thinking."
> *(Intervention participant)*

Others valued the skills and strategies offered by Quitline including recognizing and managing cravings, setting a plan, and creating specific and feasible goals.

> "Yeah, the support he's given has been good. And just like being able to recognize going 'Oh, I'm just having a craving right now, I don't need a cigarette'……Yeah, much more manageable having it kind of set out in a little, like you know, and he'd go 'Are you comfortable with that?', you know, it was never kind of forced or—but I've kind of felt like yeah I can do that... So that I've found the most helpful, like getting little mini goals and achieving them and feeling good about achieving them."
> *(Intervention participant)*

Beyond information and skill building, participants valued Quitline counselors' support in meeting people "where they were at" and their continued encouragement. Furthermore, participants emphasized gratitude for a collaborative model of working.

> "The goals that we set together, (inaudible) to achieve before the next phone call…Like the first one I think was 'don't have a cigarette first thing in the morning, delay it'. So and I didn't think I could do that, so she talked me through it and like the possible problems and just yeah helped me comprehend that I could do it. And yeah, I did do it, that was the first goal."
> *(Intervention participant)*

Appreciation of the proactive referral and dedicated counselor approach that was employed in the intervention condition was highlighted.

> "And yeah, not relying on a person to call the quitline off their own back, you know like have people asking the question like—but then you don't want to nag I guess, because that might, people might get resentful at that. But you know just be like 'Oh hey, are you comfortable with this, or…'?"
> *(Intervention participant)*

Four intervention participants spoke about the dedicated counselor and the increased appreciation of the intervention this brought.

> "The quitline was brilliant…I had the same counselor every time, and she would call me, and she was wonderful, she had like great ideas, she was on point with where I was at…like we'd set a goal together and then I'd report back to her in a week's time, and it was really good."
> *(Intervention participant)*

One control participant's suggestion for proactive referral to Quitline (where the Quitline contacts the participant, which was offered to intervention participants only) further highlighted the value of having a dedicated counselor for each person who could offer continuity of care.

> "It could be helpful to have that ongoing contact and … what would be important about that is maybe making … sure that the person feels like they don't have to retell their story, or they've been, you know you're working on I guess maybe what's happened in the last week and why or why not you weren't successful kind of specific things rather than the same message?"
> *(Control participant)*

One intervention participant described the benefit of this relationship building to their progress.

> "I think talking to the same person every time has been good, because he can kind of work on my progress with me and you know get to know me a little bit and—…I think if I just rung up and got a different person every time I spoke with them, it would be a bit weird. I think it's been good that I get to speak to the same person."
> *(Intervention participant)*

Further to the finding that some participants would not have actively sought tobacco treatment without the study invitation, a number of participants spoke about the fact that they also would not have engaged with Quitline if not for the study.

> "…until I got the postcard about the study, I would never, I don't think I would've ever rung up and gone 'Oh hi, I want to quit', like… I don't know I think maybe…for me I don't feel like smoking is like a big problem, I feel like maybe it would be …something I'd go to as a last resort, like if I had to quit smoking for health reasons... I think ringing up a place like that would kind of be like admitting defeat where I didn't want to admit defeat."
> *(Intervention participant)*

A couple of participants had trouble with access/availability of Quitline, although others found the opposite.

> "Once I tried to ring in and the complaint I've got about that is I couldn't get through to anyone. I was really, really, desperate, and I rang the numbers, and I couldn't get through."
> *(Intervention participant)*

> "I rang her yesterday because tomorrow I've got my quit date, but…she was supposed to be calling me in the morning, and I rang her just to reschedule the appointment, and she rang me straight back and we worked it out so that I can do both."
>
> *(Intervention participant)*

For those who did not engage with Quitline, this was due to not feeling comfortable with telephone, not feeling as though they needed that form of support; or as one participant described, a perception that the counselors could not be helpful without lived experience of smoking and quitting.

> "I don't agree with talking with someone that's never smoked—I find that frustration because how can you honestly say relate to them in that way in regards—well you've never had a cigarette how can you counsel me if it's something you've never done."
> *(Intervention participant)*

Subtheme: Practical resources

Participants valued the physical resources that were provided: Quit brochures (both control and intervention) and NRT (intervention only). For a small number of control participants, the Quit information resources prompted a call to Quitline.

> "Oh yeah, all the resources helped a lot because I never thought about even using Quitline and I ended up calling them and getting their support too."
> *(Control participant)*

However, for most control participants, these resources were not sufficient to prompt them to engage with Quitline. Intervention participants discussed the helpfulness of being provided free NRT.

> "Yeah, well it was really good to get the parcel that had all the goods in it, because I wouldn't have been able to afford them on my income, I'm on a disability support pension… it was cheaper to go and buy a packet of cigarettes than it is to buy the nicotine patches and the spray and the lozenges, and the inhalers. So, I was really grateful to receive that."
> *(Intervention participant)*

Beyond their appreciation, participants said NRT was useful for managing cravings.

> "I tried one day just wearing a patch just to see what would happen, but I found that I still craved a cigarette, so I thought 'Ooh they're not going to work', but then with this study if you're having the NRT products—or the other ones the inhaler and the vaporiser I've found that was enough just to get me through that moment when I really wanted a cigarette I had something else I could do."
> *(Intervention participant)*

A minority of intervention participants were not motivated to use the NRT products, didn't find them helpful or had side effects.

> "But for me, yeah, I didn't, and like I said I don't know why, but I didn't want to use them."
> *(Intervention participant)*

Similarly, a small number of both control and intervention participants spoke about using vaping as an additional product (not provided by the study intervention) during their study participation, to help them quit.

Subtheme: Varying difficulty and success in quitting

Within the theme of the benefits of a tailored approach sits ideas about the difficulty of quitting or cutting down as well as the varied levels of success experienced. Across control and intervention groups, some participants found quitting or cutting down difficult and frustrating.

> "It is difficult.… You've got to change your whole kind of like way of doing things and thinking and being and stuff yeah, which is a lot you know."
> *(Intervention participant)*

However, a control participant who had made independent contact with Quitline noted:

> "Look it's been frustrating; it's been very rewarding as well."
> *(Control participant)*

Some intervention participants that reported having quit for a length of time noted that they did not find it as difficult as they had imagined, even in the context of later relapsing back to smoking.

> "Well, I think if someone had told me that it's—that quitting with support this way is relatively easy and certainly not as hard as I thought, I think that's the message, it's not as you think, I would have found that reassuring and more attractive."
> *(Intervention participant)*

The varied tobacco use recovery outcomes that participants spoke about highlighted the challenges of quitting but also confirmed that many were prepared to try.

Subtheme: Instilling hope and building belief for future quit attempts

Intervention participants spoke about next steps, trying again, working toward quitting and knowing they could do it now that reflected a sense of confidence and intent to try quitting again.

> "In the past they (attempts to quit) weren't very good at all, but using the nicotine replacement products this time around and (inaudible) been a lot better, I know that I can quit now…It is, because…I honestly didn't think I could do it, and to have had just (inaudible) without a cigarette at all, that was amazing."
> *(Intervention participant)*

Theme 4: A compassionate approach

An overarching theme of compassion was identified. This encompassed ideas about the importance of health provider/service consideration of tobacco treatment for this population and the importance of their non-judgmental approach.

Subtheme: Consideration

There was mixed evidence for support from participants' current health professionals (psychiatrists, GPs, psychologists, support workers) during their study participation. Support received varied in quality and what impact it had on participants' experience of care. What was evident in those who had support and those who didn't, was that encouragement and compassion were key elements they appreciated.

> "Yeah, they don't listen and like my doctors, for example, like I had to get stitches yesterday, and every time I see him it's give up cigarettes, give up cigarettes, it's like I just know he's going to say it, and I don't feel there's much compassion there."
> *(Intervention participant)*

> "I mean I didn't really, I haven't really spoken to my psychologist about smoking, I mean when I first started seeing him, we did talk a lot about my alcohol consumption, and he did a little survey that they had for that. So, I don't know maybe—I actually have never had a psychologist ask me "Do you want to reduce your smoking?"
> *(Intervention participant)*

This mixed support from health professionals was in marked contrast to the culture of compassion that participants generally described in our study across both control and intervention arms.

> "Yeah, yeah look (Quitline counsellor)…but she was even beautiful. But I mean I was crying, like talking to them…opened up a lot about my mental health, and they were very compassionate."
> *(Intervention participant)*

The importance of encouragement was further highlighted by comments about support from others, e.g., friends, family.

> "They encouraged me, you know my family and social worker I had at the time…That it was a very hard thing that I was doing, and it's like giving up something really big in your life, you know, something that played a big part in your life that wasn't there anymore, they were helping me get through that you know."
> *(Control participant)*

One participant spoke about the lack of consideration and compassion at a societal level, for people with mental ill-health.

> "And I'm really glad that someone is taking an interest because the impression that I get…and the impression that we tend to get within our culture is that we are disposable, that we are disposable people … there is less interest in giving a shit basically."
> *(Intervention participant)*

Subtheme: Connection

Both control and intervention participants spoke about the study as providing an understanding point of contact and connection in their efforts to quit smoking.

> "People think I should be able to just quit cold turkey and—whereas the people in the study . . . understand what's going on, have a little bit less judgement. . . I've got a good (inaudible) got a bad week because I've got a mental health diagnosis and I'm trying to do the best that I can you know. . . I've been grateful for someone being at the other end of the phone and it's really helped."
> *(Intervention participant)*

The importance of this was underlined by some control participants reporting they would have liked more contact.

> "Just to have that reminder. . . because then I've fallen off the horse and then all of a sudden in 2 months' time I'm like 'Oh yeah, shit that's what I wanted to do'."
> *(Control participant)*

Subtheme: Non-judgmental approach

In the context of a compassionate approach, the appreciation of a non-judgmental stance was specific to intervention participants and discussions about the relationship with Quitline counselors. Participants reported feeling safe in the knowledge that the counselors would not judge them for smoking relapse and in fact help them find learnings from this.

> "But the person that I've been speaking with is very understanding, like even if I say "Oh I smoked a packet today", he'll go 'Okay what can we learn from that?', you know."
> *(Intervention participant)*

Subtheme: Engagement and support

In addition to the importance of the dedicated counselor (described in Theme 3) which was a component of the "Quitlink" intervention, an emphasis was placed on the counselors themselves and how essential it was for them to be consistently positive and supportive, so that participants could feel engaged in the relationship.

> ". . . and you know she's just been a real support. She's actually like an angel, she really has been a supporter to me you know."
> *(Intervention participant)*

Discussion

The present study explored participant experiences of a tobacco treatment trial for people who live with SMI, through interviews of participants assigned to either the active control or intervention conditions. The findings underscore the enormity of the challenges that our targeted population face and the considerations in providing support for them. They suggest that tailored tobacco treatment such as "Quitlink" has the potential to assist people on a journey to quitting, that often includes small gains, and that the multi-component interventions that include free combination NRT and evidence-based, compassionate support demonstrating a recovery-oriented approach are highly valued elements.

One of the most important findings was the appreciation from participants recruited exclusively *via* direct mail postcards of simply the invitation to join a tobacco treatment study. It is well established that the offer of tobacco treatment for people who experience SMI is suboptimal (8–10). This discrimination in provision of care and discrepancy in access is further evident in some of our intervention participants' expressions of feeling fortunate to be offered the invitation to engage with Quitline counseling and NRT.

Although all our participants were engaged with mental health service provision, and many also mentioned other primary care providers, it appears that most had not previously engaged with tobacco treatment or what had been offered to them was not person-centered and seemed ineffectual. This is despite other indicators that they were willing to engage with quitting. Our direct mail postcard approach yielded the greatest number of participants to the main "Quitlink" trial (31) and suggests utility in engagement of people who are often isolated and are at particular risk of being excluded from proactive support to cease smoking.

This finding adds to the evidence for the effectiveness of direct mail recruitment strategies found for other populations and interventions (34–36). Beyond being relatively low cost and low resource intensive (24), our participant perspectives on the value of invitation enrich our understanding of why this strategy can be successful. It may be that this approach bypassed the "gatekeeping" that can be a feature of recruitment that relies on staff to approach potential participants (37). Future tobacco treatment trials and mental health services should consider how direct mail recruitment strategies can be deployed to enable engagement and participation.

Most participants—across control and intervention arms—reported a general appreciation for the support offered by the study. Some participants appreciated being asked (during study baseline and follow up assessments) in an in-depth way about their smoking and found this clarifying and motivating; this was particularly so for the control participants. It may be that for control participants, who did not receive the "Quitlink" intervention, these research study assessments were helpful in supporting participants to understand their smoking behaviors as well as demonstrating consideration and "interest" in supporting people who experience SMI to quit smoking. People who smoke and experience SMI are not routinely asked about or provided with smoking cessation assistance and encouragement to quit from health care providers (38, 39). One of the barriers to this is the lack of knowledge reported by mental health staff about tobacco dependence and potential relationships between smoking and mental ill-health (40). Our

findings highlight the value that people who smoke with SMI find in being asked about their smoking and the importance of continued efforts to upskill health professionals to engage in this conversation. This may include education and promotion of the effectiveness of quitlines and reminders to refer consumers.

Participants also valued the input of people with lived experience which is reflective of the growing evidence base for the role of peer support for people with mental ill-health (41). This role could be expanded in future tobacco treatment research and intervention efforts. This also relates to the value of a recovery-oriented approach to smoking cessation. Prior research has identified that recovery-oriented practice training in community mental health services positively impacted the process of personal recovery for consumers (42).

Predictably, the perceived value of the study and engagement with supports appeared greater for participants randomized to the intervention condition. This is consistent with the significantly more intensive support provided to this group. Many of the components of the Quitline counseling that intervention participants reported as helpful (recognizing and managing cravings, setting a plan and creating specific and feasible goals) are central to the quitline cognitive behavior therapy-based approach (43).

Most participants from the intervention arm reported that they would not have engaged with Quitline if they were not involved in the trial, hence demonstrating the value and importance of proactive approaches to tobacco treatment for people living with SMI. Routine assessment of smoking and provision of brief advice that proactively links people to underutilized best practice treatments such as Quitline and combination NRT has huge potential to improve the quality of life for people experiencing mental illness who smoke but it remains an ongoing challenge for both health and mental health services. Relying on spontaneous use of tobacco treatments means that many will miss out on valuable treatment that they need and deserve. The success evident in the current study in engaging and connecting people who experience SMI and smoke with quitline is an important outcome in terms of demonstrating that it is an acceptable and valued service.

Beyond the need for increased engagement with tobacco treatment, the findings of the current study suggest tailored and relevant intervention for this population is crucial. This is evident in participant appreciation for peer researchers and Quitline counselors experienced in supporting people experiencing SMI to stop smoking. The counselors appeared to support not only cessation behaviors but also elements of recovery, for example, hope and respect (44). Future trials should include a recovery measure to assess this more formally.

One of the key findings that arose from the qualitative analysis of participant interviews is the importance that participants placed on the compassionate approach they perceived the study to offer. Although a compassionate approach was not a key component of the original trial or intervention design, it seems that this style was initially established by our peer researchers and followed through by quitline counselors (for those allocated to the intervention) as well as by the follow-up assessors. Therefore, whilst evidence-based interventions such as quitline and NRT are critical to tobacco treatment, the spirit of delivery is also highly valued. Our participants were attuned to the experience of feeling judged and not being heard, a frequent experience of past interventions. This suggests that, in addition to smoking cessation expertise, tobacco treatment services, should continue to employ professional counselors and highlight the importance of foundational counseling skills including openness, a non-judgmental stance, and compassion, that are aligned with a recovery-oriented approach for clients experiencing SMI (45). This finding also adds to the value of quitline services for this population and future efforts should include highlighting this evidence-based but also supportive approach to increase linkage and engagement between mental health services, consumers and quitlines. The extra training that quitline counselors received for this project in tailoring their intervention for people experiencing SMI likely added to the value that participants found in the support. Around one third of quitline users in Victoria Australia report mental-ill-health and it is closer to a half of U.S. quitline clients (13) thus ongoing professional development for quitline counselors in assisting clients experiencing mental ill-health remains a key priority area for both training and individual and group supervision.

The intervention offered in this trial was designed with consideration for the difficulties faced and additional support required for smokers experiencing SMI. However, our interviews illuminated the picture of the significant life challenges of our participants and reflected the entrenched social, financial, and psychological disadvantages common to this population (25). Smoking and multiple previous attempts to quit were intertwined with these disrupted lives and depicted a long and complex history for our participants before entering the trial.

The barriers and facilitators to tobacco use recovery raised by participants continued the thread of disrupted lives that ran through the interviews. Whilst there were components within the psychological and social milieu that sometimes worked for or against participants' engagement with tobacco treatment, there was an overall sense of competing imperatives that made it extremely difficult to make quitting smoking a priority. The complex life stressors often endured by people who experience SMI was the main barrier reported by our participants. Considering this, the resources required to pursue a quitting journey while balancing these complexities and potential fluctuations in an individual's mental health, and the erosion of self-efficacy from repeated failures to quit smoking (46) poses a significant challenge. A small number of participants spoke about using electronic cigarettes as an additional product they used to support their attempts to quit smoking. Future research among people experiencing SMI is needed to monitor

how e-cigarettes are being used, their impact on mental health and their effectiveness for smoking cessation.

Many participants felt that both a desire and a solid commitment to quitting are crucial for tobacco use recovery. Descriptions of this were somewhat intangible. This is reflective of findings with smokers from the general population that have demonstrated a belief that an unambivalent desire to quit is a necessary condition for successful tobacco use recovery (47). It is important to consider myths around motivation when engaging people in tobacco treatment, including that, when making behavior change, ambivalence is normal (48), motivation may fluctuate, relapse is common, and that a commitment to change can be made in spite of this. This may be particularly important for people who experience SMI, where self-doubt is prevalent, feeling vulnerable may be difficult, and the possibility of failure feels perilous and disheartening (49). The notion of an environment conducive to quitting was described as a potential facilitator, which fleshed out the idea that in addition to the desire to quit smoking, participants felt a supportive environment where it was safe to fail was important. In the context of disrupted lives, there are often systemic barriers to cessation, for example, during in-patient hospitalization (50) and supported residential facilities (51). Even though these are now often smoke free, our participants suggested congregate housing settings and stressful living environments can disrupt tobacco use recovery efforts.

Despite the numerous barriers, many participants did speak about making quit attempts. This contrasts with attitudes that people with mental illness are not interested in quitting (52). Our participants' comments supported previous findings that people with mental illness are highly motivated to stop smoking (5). Further, some participants assigned to the Quitlink intervention, who successfully quit, found that with support, tobacco use recovery was not as challenging as they imagined. The benefits of trial participation went beyond the immediate; including instilling hope, confidence and building belief to try quitting again in the future. This is an important finding; whilst we need to acknowledge the challenges for this population and how these impact quitting, as researchers and service providers we need to be cautious that in doing so, the message is not communicated to either consumers or health professionals that quitting smoking for people experiencing SMI is so difficult that it is not worth attempting or may endanger their mental health (53). Health messaging should be non-discriminatory and hopeful, challenging low expectations. The barriers are not insurmountable and quitting with the help of tailored and evidence-based support is possible.

Strengths and limitations

Due to the challenges with recruitment to the main trial (31), a convenience sampling method replaced the intended purposive sampling strategy for the current study. Delays in recruitment for this qualitative study led to participants that were recruited in the main trial *via* the face-to-face initial recruitment strategy being not represented in these 2-month interviews. These participants were largely from supported living services and likely to have experienced greater mental ill-health symptoms (than subsequent recruits who were recruited *via* direct mail postcard or online). There will be opportunities to explore their experience in the 5- and 8-month interviews and new themes may be identified. However, participants from both control and intervention arms of the trial took part in our interviews and the sample characteristics were comparable to that of the overall trial population (see Table 1).

The participants in the current study reflect the views of those who agreed to participate in a tobacco treatment trial and subsequently to share their experiences in an interview. Consequently, the findings may not generalize to those with lower levels of engagement with the study. However, our findings offer insight into a group of participants who did not necessarily want to quit smoking but were interested in or open to being offered tobacco treatment support options. Peer researchers were involved in all aspects of the current study including recruitment, data collection and analysis. Their lived experience was one of the key perspectives guiding this research and adds to the value and uniqueness of our findings (54, 55).

Conclusions

Although people who experience SMI face unique difficulties in quitting smoking, our findings support previous evidence that people who experience mental illness are often highly motivated to stop smoking (5) and can engage with tobacco treatment when support is appropriate and tailored (56, 57). Our findings add nuance to this evidence in demonstrating that people who experience SMI highly value health professionals and services (e.g., peers and quitline counselors) who understand the complexities of mental ill-health and intersecting challenges and employ a compassionate approach. Our findings suggest that in addition to the importance of tobacco treatment services and programs employing evidence-based and tailored support for people who experience SMI, there is a clear need for a recovery orientation.

Data availability statement

The datasets presented in this article are not readily available because this would limit participant confidentiality. Requests to access the datasets should be directed to kristen.mccarter@newcastle.edu.au.

Ethics statement

The study was reviewed and approved by St Vincent's Hospital Melbourne HREC, Cancer Council Victoria HREC, and University of Newcastle HREC. The patients/participants provided their written informed consent to participate in this study.

Author contributions

The first draft of the paper was written by KM with significant input from LB, MM, NC, CB, and LH, followed by the remaining authors. All authors contributed to manuscript revision, read, and approved the submitted version.

Funding

This project was funded by the National Health and Medical Research Council (APP1139125). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. AB holds a NHMRC Fellowship (APP1135901) and Faculty of Health and Medicine, University of Newcastle, Gladys M Brawn Fellowship.

Acknowledgments

Many thanks to the people who participated in the study and the staff of organizations involved.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.868032/full#supplementary-material

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frontiers | Frontiers in Psychiatry

TYPE Original Research
PUBLISHED 05 December 2022
DOI 10.3389/fpsyt.2022.868084

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Addictive Disorders, a section of the journal Frontiers in Psychiatry

RECEIVED 02 February 2022
ACCEPTED 18 November 2022
PUBLISHED 05 December 2022

CITATION
Lodge S, Bartlem K, Gibson L, Fehily C, Bradley T, McKeon E, Reakes K, Rickards S, Hastings P and Bowman J (2022) Characteristics and service use of NSW Quitline callers with and without mental health conditions. *Front. Psychiatry* 13:868084. doi: 10.3389/fpsyt.2022.868084

Characteristics and service use of NSW Quitline callers with and without mental health conditions

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Introduction: Smoking rates remain higher for people with a mental health condition compared to the general population and contribute to greater chronic disease burden and premature mortality. Quitline services offer telephone-based smoking cessation support to the public and have been shown to be effective. There is limited research exploring the characteristics of smokers with a mental health condition who use the Quitline or the impacts of using the service on their smoking behaviors.

Methods: This observational study aimed to compare demographic and smoking related characteristics, service use and quit attempts of callers to the New South Wales Quitline (2016–2018) with and without a mental health condition ($N = 4{,}219$).

Results: At baseline, 40% of callers reported a current mental health condition. Desire to quit smoking was similar for both groups, however participants with a mental health condition had higher nicotine dependency and had made more quit attempts prior to engaging with the service. During program enrolment, quit attempts and 24 hours smoke free periods were similar, however participants with a mental health condition engaged in a greater number of calls and over a longer period with Quitline compared to those without.

Discussion: The findings suggest Quitline efficacy for people with a mental health condition in making a quit attempt for at least 24 h. Increasing the use of Quitline services and understanding service use for this critical group of smokers will increase the likelihood that their quit attempts are transformed into sustained periods of smoking abstinence. Future research should explore whether tailoring of Quitline service provision for people with mental health conditions may increase the likelihood of quit success.

KEYWORDS

smoking, cessation, mental health, Quitline, chronic disease

Introduction

Tobacco smoking accounts for more than 8 million deaths globally every year, making it one of the leading causes of preventable death (1), largely due to chronic diseases such as cancer, cardiovascular disease and lung disease (2). The global prevalence of tobacco smoking has declined for the general population from 26.9 in 2000 to 20.2% in 2015 (3). However, for people with a mental health condition smoking prevalence has remained relatively unchanged with higher prevalence associated with more severe mental health conditions e.g., schizophrenia (64%) and bipolar disorder (44%) (4, 5). In Australia, people with a mental health condition live an estimated 12.0 years less for women and 15.9 years less for men compared to the general population (6). This is largely due to chronic diseases of which smoking is a major factor (6). Addressing this gap in life expectancy is recognized as a priority with national, state and local policies implementing strategies to support smoking cessation for this population (7).

Evidence suggests that smokers with a mental health condition are equally likely to want to quit (8) and to attempt to do so (9). Certain characteristics that typify smokers with a mental health condition however (e.g., low socio-economic status, living in smoky environments and high nicotine dependency) (10), may nevertheless make it harder for those who access support for quitting to change their smoking behavior. As a result, it is important to understand how to maximize the effectiveness of cessation supports for this group to increase the likelihood of continued abstinence.

The World Health Organization recommends national toll-free telephone Quitlines as a population level strategy for countries to support smoking cessation (11). Quitline services have a broad reach and have been identified as a cost-effective means of delivering smoking cessation support (12, 13). In Australia, each state government is responsible for Quitline service delivery. Inbound calls to the service incur call costs, with outbound calls delivered at no cost to the participant. The New South Wales (NSW) Quitline service has been in operation since 2002 and is facilitated by the Cancer Institute NSW. The primary aim of the NSW Quitline is to provide smoking cessation support and information to smokers, ex-smokers and the general population. Few studies have explored the characteristics of smokers with a mental health condition who use the Quitline or the benefit they may gain from doing so (14).

To address this gap in the research literature, the study aimed to compare participants with and without a mental health condition with respect to their:

1) demographic and smoking-related characteristics upon enrolment with the NSW Quitline callback service; and
2) service use and changes in smoking behavior (quit attempts and 24 h smoke free periods) during enrolment.

Materials and methods

Design and setting

The study involved secondary analysis of data routinely collected as part of service delivery by the NSW Quitline between February 2016 and February 2018. NSW Quitline is staffed by professionals who provide advice, information and support to people seeking help to quit smoking. They can provide one-off calls, or offer an outbound call service, offering up to six "callbacks", both pre-quit (preparing and setting a quit date), plus calls at 3, 7, 14, and 28 days (monitoring and supporting a quit attempt). Follow up calls are offered at 3, 6, and 12 months (ongoing cessation and relapse support). The number of calls people enrolled in the callback service may receive is determined by the individual. Counselors may discuss how the client can access additional support such as nicotine replacement therapy, or other support services. In 2017–18, the NSW Quitline actively recruited mental health professionals to enhance the services available to people with mental health conditions.

Participants

For Aim one, eligible participants were current smokers who enrolled in the Quitline telephone callback service during the study period, aged over 18 years and who had provided a response to the mental health condition screening question indicating the presence/absence of a mental health condition. Of the 16,211 callers who contacted the NSW Quitline service during the study period, 4,219 participants met the inclusion criteria. For Aim two, the same criteria applied, however, callers who were still actively enrolled in the program were excluded from the analysis as they had not yet completed the program, and therefore were not appropriate for an examination of change in smoking behavior. During the 2-year study period, 2,253 of the 4,219 enrolled participants had finalized their enrolment (e.g., were no longer actively engaged as they had graduated, withdrawn, suspended or been referred on) in the callback program.

Data collection procedures and measures

At enrolment, participants were asked "Do you currently have a mental health condition that you have been seeing a doctor about?" (Yes/No). Of those who responded "Yes", data was collected about specific diagnoses where participants could report more than one mental health diagnosis. Participants

were also asked a series of questions relating to demographic and smoking-related related characteristics (see Table 1). At each follow-up call, participants were asked "Did you try to quit?" (No/Yes–failed/Yes–succeeded; defined as a period of 24 h without a cigarette). The number of contacts were documented on the participants' record.

Statistical analysis

Nicotine dependence (low 0–1, medium 2–4, high 5–6) was calculated using the Heaviness of Smoking Index (HSI) (15), see footnote Table 1. Two smoking cessation variables were calculated based on participant responses to "Did you try to quit?" (No/Yes-failed/Yes-succeeded): (1) Any quit attempt (No vs. Yes–failed, Yes-succeeded) and (2) 24 h smoke free period (Yes–succeeded vs. Yes–failed). Due to this question being asked at each follow-up call, a participant was classified as having made any quit attempt, or having a 24 h smoke free period, if they reported so at any point during the callback service.

Chi-square tests were conducted to compare demographic and smoking related characteristics, and a *t*-test to compare mean number of calls, between participants with and without a mental health condition. Logistic regression analyses were undertaken to examine whether self-reported mental health condition (yes/no) was associated with either making a quit attempt or sustaining a 24 h smoke free period during enrolment with the service, when adjusting for variables that may impact smoking outcomes (education, employment, heaviness of smoking index) (16). Due to the large sample size and multiple tests being undertaken, the threshold for statistical significance was $p < 0.01$. Analyses included all available data.

Results

Mental health conditions

Of the 4,219 enrolled participants, 40.1% self-reported the presence of a mental health condition. Depression was the most frequently reported diagnosis (47.2%), followed by anxiety disorder (33.1%), schizophrenia/schizoaffective disorder (17.2%) and bipolar disorder (13.5%).

Demographic and smoking-related characteristics of enrolled participants

Participants with a mental health condition were significantly more likely to be female (56.6 vs. 41.1%), unemployed (42.1 vs. 17.8%), living alone (34.8 vs. 20.9%), and less likely to be married/partnered (35.4 vs. 54.1%) or living in a smoke-free environment (55.0 vs. 58.6%) compared to participants without a mental health condition.

There were no significant differences in desire to quit smoking at enrolment for participants with and without a mental health condition. Participants with a mental health condition were significantly more likely to report a high nicotine dependency (51.5 vs. 41.2%) and to have made more than five quit attempts prior to enrolment (30.8 vs. 24.0%) compared to those without a mental health condition (see Table 1).

Service use and smoking outcomes of finalized enrolments

Service use

During enrolment, participants with a mental health condition engaged in a significantly greater number of calls with Quitline callback services (M = 5.7, SD = 8.3, range = 178) compared to participants without a mental health condition (M = 4.4, SD = 3.3, range = 32), $p < 0.001$. Similarly, length of treatment (e.g., number of days from first to last call) was greater for participants with a mental health condition (M = 81, SD = 135, range = 745) compared to those without (M = 64, SD = 103, range = 621).

Quit attempts and 24 h smoke free periods

During Quitline enrolment, there were no significant associations between participants mental health condition status (yes/no) and the likelihood of having made at least one quit attempt or having achieved at least one smoke free 24 h period (Table 2). Of those with available data, 75% of participants with a mental health condition made a quit attempt, compared to 71.9% of those without a mental health condition. Likewise, 57.9% of participants with a mental health condition had a 24 h smoke free period, compared to 66.7% of those without.

Discussion

To the authors' knowledge, this is the first study to explore use of the NSW Quitline, and changes to smoking behavior, for people with a mental health condition. Among all enrolments, participants with a mental health condition were just as likely to want to quit smoking as participants without a mental health condition. Among finalized enrolments, those with a mental health condition were just as likely to report a quit attempt, and to have at least one such attempt result in a smoke free period of at least 24 h as those without mental health conditions.

Of the 4,219 participants in the study, more than a third (40.1%) self-reported the presence of a mental health condition; most commonly depression, followed by anxiety. Consistent with findings from previous Quitline studies in

TABLE 1 Comparisons between demographic and smoking-related characteristics of participants enrolled in the NSW Quitline callback service.

	All ($N = 4,219$)		Mental health condition ($N = 1,693$)		No mental health condition ($N = 2,526$)		*p*
	n	%	*n*	%	*n*	%	
Demographic characteristics							
Gender							<0.001
Male	2,214	52.5	733	43.3	1,481	58.6	
Female	2,004	47.5	959	56.6	1,045	41.1	
Trans/Other[a]	1	0.0	1	0.1			
Age							
18–34	1,171	27.8	499	26.5	722	28.6	<0.001
35–54	1,804	42.8	796	47.0	1,008	39.9	
55+	1,244	29.5	448	26.5	796	31.5	
Mean age (SD)	45.4	(14.7)	44.7	(13.65)	45.8	(15.3)	0.015
Marital Status	($N = 1,405$)		($N = 534$)		($N = 871$)		<0.001
Married/De-facto	660	47.0	189	35.4	471	54.1	
Previously or never married	745	53.0	345	64.5	400	45.9	
Education	($N = 3,857$)		($N = 1,533$)		($N = 2,324$)		0.018
University	634	16.4	221	14.4	413	17.8	
Vocational[b]	760	19.7	320	20.9	440	18.9	
High school or less	2,362	61.2	945	61.6	1,417	61.0	
Employment	($N = 4,126$)		($N = 1,642$)		($N = 2,484$)		<0.001
Employed	2,007	48.6	517	31.5	1,490	60.0	
Unemployed	1,134	27.5	692	42.1	442	17.8	
Retired/home duties/student	734	17.8	286	17.4	448	18.0	
Living arrangements	($N = 3,110$)		($N = 1,318$)		($N = 1,992$)		<0.001
Alone	876	26.5	459	34.8	417	20.9	
Not alone	2,434	73.5	859	65.2	1,575	79.1	
Living environment	($N = 2,432$)		($N = 857$)		($N = 1,575$)		0.083
With smokers	1,038	42.7	386	45.0	652	41.4	
With non-smokers	1,394	57.3	471	55.0	923	58.6	

(Continued)

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TABLE 1 (Continued)

	All ($N = 4,219$)		Mental health condition ($N = 1,693$)		No mental health condition ($N = 2,526$)		*p*
	n	%	*n*	%	*n*	%	
Smoking related characteristics							
Heaviness of Smoking Index (HSI)[c]	($N = 3,720$)		($N = 1,424$)		($N = 2,296$)		<0.001
Low	528	14.2	158	11.1	370	16.1	
Moderate	1,512	40.6	532	37.4	980	42.7	
High	1,680	45.2	734	51.5	946	41.2	
Desire to quit (1–10)[d]	($N = 3,652$)		($N = 1,449$)		($N = 2,203$)		0.024
1–3 (Low)	46	1.3	23	1.6	23	11.9	
4–7 (Medium)	432	11.8	193	13.3	239	10.8	
8–10 (High)	3,174	86.9	1,233	85.1	1,941	88.1	
Previous quit attempts	($N = 3,703$)		($N = 1,497$)		($N = 2,206$)		<0.001
0–2	1,803	48.7	696	46.5	1,107	50.2	
3–4	909	24.5	340	22.7	569	25.8	
5 or more	991	26.8	461	30.8	530	24.0	

Responses of "Declined to answer", "Null" and missing data are excluded from analyses.

[a]Trans/Other category excluded from chi-square analysis.

[b]Includes advanced diploma, associate diploma, certificate II and trade certificate.

[c]HSI was calculated from the sum of the two responses to CPD and TTFC which were coded as follows: 0 (0–10 CPD; TTFC ≥ 61 min), 1 (11–20 CPD; TTFC, 31–60 min), 2 (21–30 CPD; TTFC, 6–30 min) or 3 (31 CPD; TTFC, 5 min). A scale from 0 to 6 was used to categorize low (0–1), medium (2–4), and high (5–6) dependency.

[d]Self-reported on a scale where 1 = not at all, 10 = a lot.

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TABLE 2 Comparisons between mental health conditions, quit attempts and 24 h smoke free periods for finalized participants in the NSW Quitline callback service.

	All ($N = 2,253$)		Mental health condition ($N = 957$)		No mental health condition ($N = 1,295$)		OR [95% CI]	*p*
	n	%	*n*	%	*n*	%		
Smoking outcomes								
Quit attempt[a]	($N = 550$)		($N = 212$)		($N = 338$)			0.349
Yes	402	73.1	159	75.0	243	71.9	0.81 [0.52, 1.26]	
No	148	26.9	53	25.0	95	28.1	1.00	
24 h smoke free period[b]	($N = 402$)		($N = 159$)		($N = 243$)			0.136
Yes	254	63.2	92	57.9	162	66.7	1.4 [0.89, 2.30]	
No	148	36.8	67	42.1	81	33.3	1.00	

[a]Responses to the question "Did you try to quit" were used to calculate quit attempts and included participant responses "No", "Yes-Failed" or "Yes-Succeeded", where succeeded is defined as a smoke free period of at least 24 h.
[b]Responses to the question "Did you try to quit" were used to calculate 24 h smoke free quit attempts and included participant responses "Yes-Failed" or "Yes-Succeeded".
Models adjusted for education, employment, and heaviness of smoking index.
Reference = no mental health condition.

Australia (10), participants with a mental health condition were more likely to be single, unemployed or live with other smokers when compared to participants without a mental health condition. Consistent with previous international research (17), participants with a mental health condition tended to smoke more cigarettes daily and were more likely to have a high nicotine dependence, factors which mitigate against the likelihood of quitting success.

Participants with a mental health condition had made a greater number of quit attempts prior to enrolment compared to participants without a mental health condition. The present research stands in contrast to the documented beliefs among some health clinicians that those with a mental health condition are not interested in quitting (18). It is important to address health clinicians' beliefs about this population (as they often make referrals to Quitline) to ensure they know there is a desire to quit and that, when offered support to do so, people with a mental health condition are likely to make at least short-term changes to smoking behavior.

The similar number of quit attempts and 24 h periods of abstinence during enrolment suggests that both participants with and without mental health conditions received adequate levels of support from the Quitline callback service to make at least short-term changes in their smoking behavior. However, participants with a mental health condition engaged in significantly more telephone calls with the service over a longer period when compared to participants without a mental health condition. This finding is consistent with previous research (19) and suggests that people with a mental health condition may require additional support when making a quit attempt due to additional barriers such as higher nicotine dependence and limited social support. This could have implications for Quitline services to work toward tailoring, through strategies such as routine provision of nicotine replacement treatment starter packs to help address cessation challenges such as more severe withdrawal, financial hardship and social isolation. Some studies have attempted to address these barriers through trialing different models of smoking cessation care that include monitoring the effects of nicotine withdrawal during a quit attempt (20) and utilizing peer workers to provide encouragement (21). Further research is required to examine the optimal level and type of support Quitline services might provide to people with mental health conditions to increase the likelihood of quit success and effectiveness in supporting long term cessation.

Limitations of the study include the capacity to look at only short term changes in smoking behavior, such as a 24 h period of abstinence as opposed to a measure such as 7-day point prevalence; although, 24 h abstinence is a measure commonly used in tobacco research (22). A lack of participant data at follow-up meant it was not possible to report on long-term cessation attempts. Challenges of real-world data collection and using service data not primarily designed to address

research questions, contributed to such instances of missing data and difficulty in discerning the underlying reasons—such as participant drop out from the program, lack of rigor in data collection or other factors. The individualized nature of Quitline service delivery and resultant variation in data collection points led to some inconsistency with respect to "when" data pertaining to changes in smoking behavior was collected. It should also be acknowledged that during the study period the Quitline service began to employ some staff with mental health qualifications. Exploring to what extent participants with a MHC received their calls from a mental health professional, and possible associations of having a mental health advisor with service use and cessation related outcomes, would be valuable to address in future research.

Smokers with a mental health condition engaging with the NSW Quitline experienced high nicotine dependence, were more likely to be living in smoky environments and less likely to have partner support. Despite this, such smokers who commence with the Quitline service are equally likely to want to quit and report having made more previous attempts to do so than people without a mental health condition. Furthermore, people with a mental health condition are equally likely to make a quit attempt and cease smoking for at least 24 h whilst enrolled when compared to smokers without a mental health condition. Further research is required to understand long-term smoking outcomes of people with mental health conditions, and whether tailoring of Quitline service provision to consider the needs and characteristics of this group of smokers will increase the likelihood that quit attempts are translated into smoking cessation.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: The data is stored electronically in a confidential file on a password-protected computer at the School of Psychological Sciences at the University of Newcastle. Data published contains aggregate results only. Requests to access these datasets should be directed to Simone Lodge, simone.lodge@newcastle.edu.au.

Ethics statement

The studies involving human participants were reviewed and approved by NSW Population and Health Services Research Ethics Committee 2018HRE0702. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

JB and KB: conceptualization, methodology, validation, and supervision. SL: formal analysis, investigation, writing—original draft. LG: conceptualization, methodology, formal analysis, and writing—review and editing. CF and TB: formal analysis and writing—review and editing. EM: investigation and formal analysis. KR, SR, and PH: writing—review & editing. All authors contributed to the article and approved the submitted version.

Funding

KB is supported by a National Health and Medical Research Council Early Career Fellowship (#1142272).

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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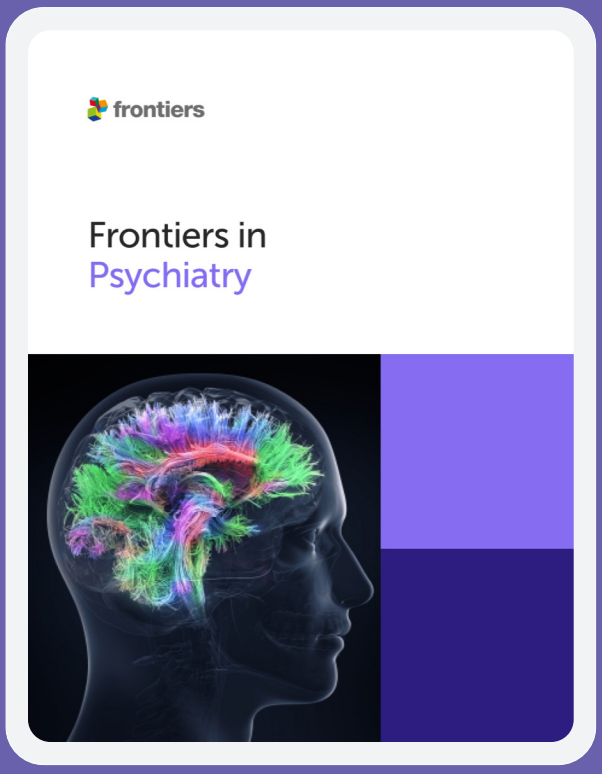

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