

ORIGINAL PAPER

ΕΠΕΥΝΗΤΙΚΗ ΕΡΓΑΣΙΑ

Smoking cessation for people with severe mental illness

A pilot, randomized controlled trial

OBJECTIVE To examine the feasibility and acceptability of an intervention for tobacco harm reduction among smokers with severe mental illness (SMI). **METHOD** A pilot randomized controlled trial was conducted involving SMI smokers (n=43). With a simple randomization procedure (1:1 ratio), participants were assigned to the intervention (behavioral support and e-cigarette use, n=21) or control group (behavioral support only, n=22). The primary outcome was self-reported smoking cessation, biochemically validated by ≤ 6 ppm levels of expired carbon monoxide (eCO) at 6 months. The secondary outcome measures included potential changes in nicotine dependence, physical and mental health, and quality of life (QoL). **RESULTS** At six months, nicotine dependence fell significantly in both groups, as compared to baseline. In this period, the intervention group's cessation rate was remarkably higher (33.3%) than that of the control group (13.6%). In addition, the intervention group's general health and QoL significantly improved overall. **CONCLUSIONS** Following a personalized smoking cessation program, SMI smokers can acquire the skills necessary to manage nicotine addiction, quit smoking or reduce smoking-related harm.

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ΑΡΧΕΙΑ ΕΛΛΗΝΙΚΗΣ ΙΑΤΡΙΚΗΣ 2026, 43(2):205-211

G. Papadosifaki,^{1,2}

V. Psarra,³

A. Andreopoulou,²

C. Touloumis,²

C. Tzavara,¹

E. Sakellari,¹

A. Barbouni,¹

K. Farsalinos¹

¹Department of Public and Community Health, School of Public Health, University of West Attica, Athens

²Psychiatric Hospital of Attica, Haidari, Attica

³Psychiatrist in Private Practice, Athens, Greece

Διακοπή καπνίσματος σε άτομα με μείζονα ψυχική διαταραχή. Μια πιλοτική τυχαιοποιημένη ελεγχόμενη δοκιμή

Περίληψη στο τέλος του άρθρου

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As the fundamental cause of tobacco-related diseases, smoking aggravates the risks of morbidity and premature mortality. With a typical prevalence two to three times higher than that in the general population, heavy smoking and serious dependence seem endemic and persistent in individuals with severe mental illness (SMI). This suggests a failure to implement tobacco control policies.¹

Explanatory hypotheses emphasize various contributors, such as genetic/biological, social or psychological predispositions, inadequate coping mechanisms, and smoking used as self-medication to combat the symptoms of mental illness or the side effects of antipsychotics.²⁻⁴ Cigarettes are also commonly used in mental health services to reward SMI

patients for good conduct or medication adherence, which further hinders the discontinuation of tobacco smoking.⁵

E-cigarettes are novel, nicotine-containing products that mental health facilities abroad widely used as part of their strategies for smoking cessation and harm reduction.⁶ E-cigarettes also contain very few or no traces of the polycyclic aromatic hydrocarbons found in cigarette smoke.^{7,8} These hydrocarbons induce specific liver enzymes (P450 CYP1A2, 2B6) that accelerate the metabolism of several psychotropic medications and, therefore, require the rigorous monitoring of their levels.

To the best of our knowledge, there has never been a smoking restriction in inpatient/outpatient mental health

facilities in Greece, despite the smoke-free legislation currently in place. Therefore, this first-ever study among SMI smokers in Greece aimed to test whether combining behavioral support with e-cigarettes would be a feasible and acceptable intervention for tobacco harm reduction and smoking cessation, as opposed to only providing behavioral support.

MATERIAL AND METHOD

The study protocol and all procedures were approved by the Ethics Committee, the Scientific Committee and the Management Board of the Psychiatric Hospital of Attica and by the University of West Attica Research Ethics Committee. All participants were individually informed about the program. They signed consent forms specifying they reserved the right to withdraw at any time, without unfavorably affecting the health services they received from the hospital.

Participants and procedures

This was a randomized controlled trial testing the combination of behavioral support with e-cigarette use (intervention), compared to behavioral support only, for smoking cessation (control) in SMI smokers. Of the 105 individuals initially consenting to participate (cf. flow diagram), some were excluded for various reasons, reducing the sample size to 50 participants (fig. 1). The research team decided to conduct a pilot study with the remaining 50 individuals in order to assess and refine methods, procedures and tools, while identifying the potential challenges of a full-scale study. The recruitment process, which lasted for over 7 months, took place during a cross-sectional study in Greece, designed to

examine SMI smokers' knowledge, beliefs and attitudes towards smoking.⁹ Eligibility criteria included: Age (18–70 years old); diagnoses of ICD-10¹⁰ documented schizophrenia, schizotypal and delusional disorders (F20–F29) or mood (affective) disorders (F30–F39); minimum smoking of five cigarettes/day for at least 2 years; biochemically verified smoking status of >6 ppm levels of expired carbon monoxide (eCO); adequate verbal command and comprehension of Greek; good general physical health; full legal capacity. Exclusion criteria included: Severe cognitive impairment; pregnancy/breastfeeding; psychiatric hospitalization (6 months prior); recent participation in a smoking cessation program/use of smoking cessation medication; alcohol/substance abuse history (12 months prior); suicidal ideation/suicide attempt (12 months prior); significant physical comorbidity.

Eligible participants were individually invited to be informed, sign consent forms and establish baseline measurements. As specified in the consent forms, they would not be compensated for their involvement in the study. With a simple procedure (1:1 ratio), they were randomly assigned to an intervention or control group. The intervention group was to bear the cost of purchasing e-cigarettes and e-liquids from certified stores of their choice, guaranteeing product compliance with safety standards. However, since the vast majority of the participants smoked smuggled cigarettes, it was feared that their low economic status might affect the program outcomes. Contrary to initial design, the research team decided to have the e-cigarette pod kits provided free of charge by a tobacco and related products company. The intervention group were offered the refillable, rechargeable Innokin Kroma Z or ISNON Hybrid kits they preferred, as well as discount coupons for vape supplies. They were instructed to start using e-cigarettes on their cessation date, particularly when intense cravings caused the management strategies for nicotine withdrawal to fail. After switching to the e-cigarette smoking routine, they were strongly advised to avoid flavored e-liquids, purchase refill liquids adjusting the nicotine percentage to their smoking status and gradually reduce the percentage.

To support participants on their path to smoking cessation, the principal investigator (occupational therapist) contacted them by telephone and text messages on the day prior to, on and post their cessation date. A free helpline (9:00 a.m.–9:00 p.m., 24/7) was also available for the duration of the study. Regular telephone contact allowed the principal investigator to record any changes or side effects stemming from smoking cessation/reduction or e-cigarette use. Further telephone or face-to-face support was offered in cases of smoking relapse or unsuccessful attempts to quit. Additionally, in collaboration with both groups' treatment teams, the research team regularly provided individualized counseling and psychological support. On a weekly basis, they held similarly structured psychoeducation sessions individually or in groups (maximum 12 attendees), lasting 40 minutes and 2 hours, respectively. To avoid influencing the control group, the intervention group was instructed to mention e-cigarettes only in individual sessions.

Towards the end of the third month, to motivate the participants to change their daily routines, those who were unemployed

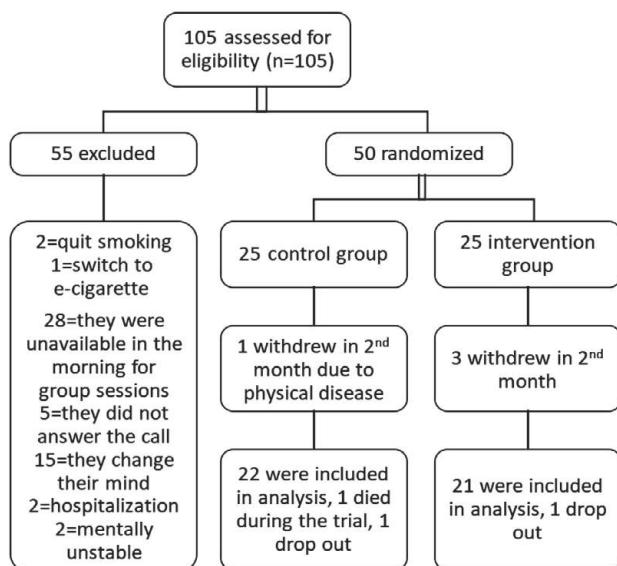


Figure 1. Flow diagram.

and or not attending day centers were referred to the corresponding services as per their needs and wishes. In tandem, the principal investigator organized smoke-free group activities (a museum visit, theater attendance, etc.). Telephone support and one-on-one sessions were continued even after completion of the 3-month program.

Measures

Primary outcomes

The primary outcomes of this study featured self-reported smoking cessation, which was biochemically validated (eCO \leq 6 ppm), and self-reported smoking reduction (\geq 50%), also biochemically validated by an eCO reduction, as compared to the eCO reference value. For both outcomes, eCO assessment and measurements were performed at baseline, 3 months and 6 months post cessation date, using the Bedfont piCOTM Smokerlyzer® breath CO monitor.

Secondary outcomes

The secondary outcomes documented changes in nicotine dependence using the Fagerström Test for Nicotine Dependence (FTND) for smokers¹¹ and the e-cigarette Fagerström Test of Cigarette Dependence (e-FTCD) for vapers.¹² Quality of life (QoL) was assessed using the World Health Organization Quality of Life-BREF (WHOQOL-BREF).¹³ Physical and mental health was assessed using the 36-item Short Form Health Survey (SF-36).¹⁴ Respiratory symptoms (shortness of breath, wheezing, cough, and phlegm) were also recorded. For all outcomes, assessment was performed at baseline and 6 months post cessation date.

Statistical analysis

The Kolmogorov-Smirnov test was used to check quantitative variable distribution normality. The research team used independent-samples Student's t-tests to compare between-group mean values, Chi-square and Fisher's exact tests to compare between-group qualitative variables, and McNemar tests to compare between-measurement qualitative variables. Repeated measures tests (ANOVA) were used to analyse variance and evaluate the between-group changes observed in the SF-36 and WHO-QOL BREF scales (follow-up period). All the reported p values are two-tailed. The Statistical Package for Social Sciences (SPSS) software (version 26.0) was used for statistical analysis, whereas statistical significance was set at $p < 0.05$.

RESULTS

Consisting of 43 patients (intervention group: 21, control group: 22), the sample had a mean age of 46 years (standard deviation [SD]=8.9 years). Table 1 features the participants' characteristics by group: most were male, Greek, high school graduates, unmarried/single and living

Table 1. Sample characteristics by group.

	Group		p
	Control (n=22; 51.2%)	Intervention (n=21; 48.8%)	
	n (%)	n (%)	
<i>Gender</i>			
Men	14 (63.6)	12 (57.1)	0.663*
Women	8 (36.4)	9 (42.9)	
<i>Age, mean (SD)</i>			
	48.3 (9.7)	43.6 (7.6)	0.088***
<i>Educational level</i>			
Primary-, Middle-, High school	13 (59.1)	11 (52.4)	0.605**
College, university	9 (40.9)	10 (47.6)	
<i>Family status</i>			
Unmarried/single	15 (68.2)	13 (61.9)	0.333**
Married/in a relationship	0 (0)	2 (9.5)	
Divorced, separated	7 (31.8)	6 (28.6)	
<i>Participants</i>			
Outpatient	18 (81.8)	19 (90.5)	0.644**
Living in mental health housing	4 (18.2)	2 (9.5)	
<i>Diagnosis</i>			
Emotional disorder	7 (31.8)	10 (47.6)	0.289*
Schizophrenia	15 (68.2)	11 (52.4)	

*Pearson's Chi-square test, **Fisher's exact test, ***Student's t-test

SD: Standard deviation

with others. Diagnosed with schizophrenia, the majority lived at home, not in residential community services for SMI individuals, and engaged in group, rather than individual, therapy. No significant between-group differences were found in baseline characteristics.

At baseline, both groups displayed similar respiratory symptoms. At 6 months, the intervention group's phlegm percentage was significantly lower than that of the control group, while no significant differences were recorded in dyspnea, wheezing or cough. Within groups, the control group's symptoms remained constant between baseline and 6 months. Nevertheless, the intervention group's dyspnea, cough and phlegm percentage diminished significantly at six months.

According to the SF-36, substantial changes were observed in physical and mental health. Compared to baseline, the control group had significantly better general health measurements at 6 months. Between-measurement scores for physical functioning, role functioning-physical, vitality, role functioning-emotional, mental health and physical

health increased similarly and significantly in both groups. Only the intervention group's bodily pain score increased significantly.

The intervention group's overall scores for QoL and social relationships were significantly greater at six months. With the exception of the control group's overall QoL, almost all other WHO-QOL BREF dimensions increased significantly in both groups.

The intervention group's percentage of participants who successfully quit smoking (CO ≤ 6) at 3 and 6 months (tab. 2) stood at 33.3%, which was significantly greater than the corresponding control group's percentage (13.6%). Furthermore, one intervention group member completely switched from combustible tobacco to e-cigarettes, which resulted in significant eCO (CO ≤ 6) and possible harm reduction (tab. 2).

The levels of nicotine dependence were similar in both groups at baseline and 6 months ($p>0.05$). However, as compared to baseline, they both displayed significant between-measurement decreases in nicotine dependence at 6 months. Compared to baseline measurements, the intervention group's number of cigarettes also significantly diminished at 3 months (intervention group: -65.1% versus control group: -38.8%, $p=0.007$) and 6 months (intervention group: -64.6% versus control group: -44.4%, $p=0.049$).

DISCUSSION

Intensive interventions for smoking cessation are more effective than shorter ones.¹⁵ Therefore, ours was designed

Table 2. Participants' percentages harm reduction and successful smoking cessation.

	3 months	6 months	p**
	n (%)	n (%)	
<i>Harm reduction (CO ≤ 6)</i>			
Control group	3 (13.6)	3 (13.6)	>0.999
Intervention group	9 (42.9)	8 (42.9)	>0.999
p*	0.033	0.033	
<i>Successful smoking cessation (self-reported smoking abstinence and CO <6)</i>			
Control group	3 (13.6)	3 (13.6)	>0.999
Intervention group	3 (14.3)	7 (33.3)	0.125
p*	>0.999	0.162	

*Pearson's Chi-square test/Fisher's exact test, **McNemar test

*p-value for group effect, **p-value for time effect

in accordance with all core criteria of an intensive intervention (individual) group training to recognize trigger situations and employ management strategies; motivational/behavioral counselling; at least 4 follow-up meetings in person, each more than ten minutes long except for the use of harm a cotherapy for smoking cessation. Moreover, telephone counselling, self-help material and web-based cessation aids were personalized to consider individual needs and preferences. A similar intervention among SMI smokers in Denmark displayed a 29% rate of successful smoking cessation, comparable with our intervention's 33.3% rate.¹⁶ Similarly, our control group's 13.6% rate of successful smoking cessation is comparable with that of other relevant studies.^{17,18} The high cessation rates in the intervention group could be attributed to e-cigarettes imitating the "hand-to-mouth" smoking ritual, which alleviates tobacco withdrawal symptoms. Likewise, gradually diminishing the nicotine levels in e-liquids may have helped combat nicotine withdrawal, as was evident in similar studies in the general population.¹⁹ According to suggestive yet insufficient evidence,^{20,21} the use of e-cigarettes with nicotine is linked with higher cessation rates than the use of e-cigarettes without.

The vast majority of the participants smoked heavily (about/over two packs of cigarettes/day). With the intervention, the total number of cigarettes fell significantly as cigarette consumption diminished considerably in both groups (control: -44.4%, intervention: -64.6%). eCO levels also dropped between baseline and 6 months, consistent with the results of other similar studies in SMI smokers using e-cigarettes.²²⁻²⁵ A substantial reduction in daily cigarette consumption could lead to lower nicotine dependence, as shown by the Fagerström test.

With the exception of a mild throat irritation occasionally mentioned by a few intervention group participants, there were no reports of significant side effects or negative impacts on physical/mental health. On the contrary, an improvement was observed in both groups, consistent with the results of other studies.^{18,22,23,25} Without nocturnal awakenings to smoke, several participants reported a great improvement in sleep quality. These findings offer corroborating evidence that a smoking cessation strategy is not harmful to mental health.

This program for smoking cessation and/or harm reduction took place from November 2020 to September 2021. In the first groups (November 2020 to January 2021), intervention was implemented under stringent anti-COVID-19 measures, including strict lockdowns, restrictions on citizens' movement and protective mask use. In the following

groups (February 2021 to April 2021), intervention was also implemented under lockdown and strict measures. The COVID-19 containment measures were gradually lifted from 5.4.2021, but mainly from 14.5.21 onwards.

The timing of this study was critical as numerous and conflicting pandemic-related factors influenced smokers' behavior. Several studies have reported changes in smoking patterns during the lockdowns, such as substantial increases in smoking rates and high rates of successful attempts to quit.²⁶⁻²⁸ COVID-19 may have presented "a teachable moment", prompting smokers to become more health-conscious and motivated to quit smoking in order to boost their health and resistance against the coronavirus.²⁹⁻³¹

One limitation of this study was that the baseline measurements were conducted during the lockdown, while the 6-month measurements were conducted without the COVID-19 restrictions. This may have been a confounding factor in the significant changes recorded when both groups self-assessed their QoL, physical/mental health and respiratory symptoms. SMI smokers reported poorer levels of health-related QoL during the pandemic, consistent with the results of previous studies.^{32,33} Another limitation of this pilot study was the use of self-report for various measures, resulting in recall bias. According to the findings of a randomized controlled trial,³⁴ subjectively and objectively evaluated QoL measures can vary significantly in individuals with schizophrenia. When comparing subjective and objective measures, patients with depression symptoms self-evaluated their QoL lower than did those with low insight. By default, our intervention could not be blinded; this may have favored those positively inclined toward e-cigarettes in their attempts to quit. A further limitation was the small sample size. This resulted in a pilot, proof-of-concept study, which was, therefore, not registered in any international clinical trial registry.

The pandemic measures and restrictions caused widespread occupational deprivation. However, the toll was heavier on already vulnerable groups, such as SMI individuals, and often led to occupational marginalization. The small sample size seemingly facilitated the development of a strong therapeutic alliance with the participants. This allowed the principal investigator to recommend personalized plans which would redesign the participants'

daily routines, fostering healthy habits and engagement in meaningful activities. Changing daily life patterns enables smokers to better manage withdrawal symptoms, while strong social networking contributes to smoking cessation success.³⁵

To the best of our knowledge, this is the first pilot study into smoking cessation/harm reduction ever conducted among SMI smokers in Greece. It proved that similar interventions are feasible, achievable and acceptable to SMI individuals. Although recruitment and engagement are major issues in trials of this kind,^{36,37} our 14% dropout rate was comparable with that of previous studies.¹⁸ All participants, dropouts included, evaluated the program as a positive experience. A significant number of those failing to quit stated they would like to participate in a subsequent smoking cessation program, in line with previous findings.³⁸

At all trial stages, the research and the clinical team collaborated closely, which greatly facilitated the study, consistent with other study findings.³⁷ Digital illiteracy among mental health service users was one of the barriers, preventing them from using mobile applications, web-based materials or online sessions for smoking cessation support.³⁹

Despite its small sample size, the findings of this study are encouraging. At 3 months, the rates of smoking cessation were equivalent in both groups; at 6 months, the rates doubled in the intervention group, which indicates e-cigarettes could be a viable tool for harm reduction. Though suggestive, these findings require fully powered and larger sample size studies into the efficacy and safety of e-cigarettes for smoking cessation. It is crucial to integrate such programs with mental health services, providing SMI smokers with personalized interventions.

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ΠΕΡΙΛΗΨΗ

Διακοπή καπνίσματος σε άτομα με μείζονα ψυχική διαταραχή. Μια πιλοτική τυχαιοποιημένη ελεγχόμενη δοκιμή

Γ. ΠΑΠΑΔΟΣΗΦΑΚΗ,^{1,2} Β. ΨΑΡΡΑ,³ Α. ΑΝΔΡΕΟΠΟΥΛΟΥ,² Χ. ΤΟΥΛΟΥΜΗΣ,²
Χ. ΤΖΑΒΑΡΑ,¹ Ε. ΣΑΚΕΛΛΑΡΗ,¹ Α. ΜΠΑΡΜΠΟΥΝΗ,¹ Κ. ΦΑΡΣΑΛΙΝΟΣ¹

¹Τμήμα Δημόσιας και Κοινοτικής Υγείας, Σχολή Δημόσιας Υγείας, Πανεπιστήμιο Δυτικής Αττικής, Αθήνα,

²Ψυχιατρικό Νοσοκομείο Αττικής, Χαϊδάρι, Αττική, ³Ιδιώτης ψυχίατρος, Αθήνα

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ΣΚΟΠΟΣ Διερεύνηση του κατά πόσο είναι εφικτό, επιτεύξιμο και αποδεκτό ένα πρόγραμμα διακοπής καπνίσματος/ μείωσης της βλάβης σε καπνιστές με μείζονα ψυχική διαταραχή (ΜΨΔ). **ΥΛΙΚΟ-ΜΕΘΟΔΟΣ** Διεξήχθη πιλοτική τυχαιοποιημένη ελεγχόμενη δοκιμή στην οποία συμμετέχουν καπνιστές με ΜΨΔ (n=43). Οι συμμετέχοντες τυχαιοποιήθηκαν 1:1 στην ομάδα παρέμβασης (χρήση ηλεκτρονικού τσιγάρου και συμβουλευτική, n=21) ή στην ομάδα ελέγχου (μόνο συμβουλευτική, n=22). Πρωτεύον καταληκτικό σημείο ήταν η αυτοαναφερόμενη διακοπή του καπνίσματος, βιοχημικά επικυρωμένη με ≤6 ppm επίπεδα μονοξειδίου του άνθρακα (eCO) εκπνεόμενου αέρα στους 6 μήνες. Δευτερευόντως, μελετήθηκαν πιθανές αλλαγές στην εξάρτηση από τη νικοτίνη, στην ποιότητα ζωής και στη σωματική και ψυχική υγεία. **ΑΠΟΤΕΛΕΣΜΑΤΑ** Σε σύγκριση με τις αρχικές τιμές, παρατηρήθηκε σημαντική μείωση της εξάρτησης από τη νικοτίνη και στις δύο ομάδες στους 6 μήνες. Ωστόσο, η ομάδα παρέμβασης εμφάνισε ένα αξιοσημείωτα υψηλότερο ποσοστό διακοπής (33,3%) σε σχέση με την ομάδα ελέγχου (13,6%). Επιπρόσθετα, η ποιότητα ζωής και η γενική υγεία των συμμετεχόντων στην ομάδα παρέμβασης παρουσίασαν σημαντική βελτίωση στους 6 μήνες. **ΣΥΜΠΕΡΑΣΜΑΤΑ** Οι καπνιστές με ψυχική διαταραχή μπορούν να αποκτήσουν δεξιότητες για να διαχειριστούν τον εθισμό τους στη νικοτίνη και να επιτύχουν τη διακοπή του καπνίσματος ή να μειώσουν τη βλάβη που σχετίζεται με το κάπνισμα μέσω ενός εξατομικευμένου προγράμματος διακοπής καπνίσματος.

Λέξεις ευρετηρίου: Διακοπή καπνίσματος, Ηλεκτρονικό τσιγάρο, Κάπνισμα, Μείζων ψυχική διαταραχή, Μείωση της βλάβης από το κάπνισμα

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Corresponding author:

G. Papadosifaki, Department of Public and Community Health, School of Public Health, University of West Attica, 196 Alexandras Ave., 115 21 Athens, Greece
e-mail: zeta.papa@gmail.com