

# Clinical Evaluation of a New Smoking Cessation Approach: An Intervention Study

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## ABSTRACT

**Objective:** This study evaluated the effectiveness of a new non pharmacological approach for smoking cessation (COL approach), on a sample of Egyptian smokers.

**Methods:** This study was conducted for 12 weeks on two groups of current smokers willing to quit. An interventional group of 23 current cigarette smokers received a new approach composed of the inter-personal counselling; ready-made meal composed of Avena sativa L seeds in addition to an aromatherapy inhaler device containing an essential oil. A control group of 25 current smokers received interpersonal counselling only, for 12 weeks were compared to the intervention group.

**Results:** The continuous abstinence rate was significantly higher (47.8%) and failure rate was significantly lower (21.8%) among the intervention group at the end of week 12 in comparison to the control group (16.0% and 56.0% respectively; P-value=0.02). The intervention group revealed a significant decline in the mean values of the TCI grade than the control group. In conclusion, the tested approach was effective in increasing the continuous abstinence rate, decreasing the craving numbers, intensity and decreasing the nicotine withdrawal symptoms as compared to the control group.

**Conclusion:** The tested new approach could be embedded as a treatment option within a comprehensive tobacco control strategy. Thus, it is not an alternative but could be complementary for other evidence based strategies

**Keywords:** Smoking cessation, Natural, Aromatherapy, and Oat

## INTRODUCTION

Smoking is a major preventable cause of disability and premature death and it is estimated to cause approximately 450 million deaths in the next 50 years[1].The tobacco epidemic is one of the biggest public health threats in the world being kills more than 8 million people a year around the world[2].Smokers have a 2 to 4 times greater risk of developing coronary heart disease (CHD), a 10 times greater risk of developing peripheral vascular disease (PVD), and a 2 times greater risk of experiencing stroke versus nonsmokers[3]. In Egypt, Tobacco smoking is a prevalent major public health problem and is

associated with cardiovascular disorders and malignant tumors. It is estimated that the number of smokers in Egypt is increasing by 8% each year [4]. According to the most recent survey study in Egypt, the estimated national prevalence of smoking among males is 31.1% and 0.3% among females [5], which seems underestimated. The American heart association (AHA) and the American Stroke Association (ASA) highly recommended smoking cessation to avoid ischemic stroke and subarachnoid hemorrhage [6]. Without any cessation support only 4% of attempts to quit tobacco will succeed [7]. Evidence based studies have consistently shown that three methods of assistance for

smoking cessation namely; behavioral interventions such as brief advice and counseling, nicotine replacement therapy (NRT) and pharmacotherapies such as varenicline and bupropion can significantly increase success rates in quitting. NRT is the first smoking cessation aid approved by FDA [8] but it may be unsatisfactory for many Egyptian smokers as observed practically. Furthermore, several post marketing reports of suicidal thoughts and aggressive behavior in patients taking Varenicline and bupropion as well have recently been reported to FDA. Pfizer, the manufacturer of Varenicline, has submitted several case reports of suicidal ideations to FDA for review [9]. Hence, the need for a simple, safe and accessible approach to help smokers to quit smoking is a public health demand. There is strong evidence that face-to-face behavioral support is effective in its own right, as is pharmacotherapy [10]. Little information is available regarding the use of natural agents in smoking cessation [11]. Oat (*Avena sativa* L.) is a well-known annual crop and recognized in the world as a healthy food containing significant amounts of soluble dietetic fibre,  $\beta$ -glucans, and polyunsaturated fatty acids in addition to fat-soluble vitamin E ( $\alpha$ -tocopherol) which is a major antioxidant component in crude oat [12]. Phytic acid, phenolic compounds, and avenanthramides are the most abundant antioxidants in oat, and flavonoids and sterols are also present. These antioxidants are concentrated in the outer layers of the kernel [13]. Aromatherapy has been defined by the National Association for Holistic Aromatherapy (NAHA) as essential oils derived from the extracts of plants to improve and balance body, soul and mental health [14]. It could be applied topically, internal, orally or by inhalation [15]. In Most studies on the effect of aromatherapy on smoking cessation, lavender, bergamot, black pepper, Angelica and ylang-ylang oils were usually used; however, the most preferred essential oils were black pepper and Angelica oil [16]. The main objective for this work was to investigate the effectiveness of new non pharmacological, non-invasive and accessible

approach on smoking abstinence among a random sample of Egyptian smokers.

## **MATERIALS & METHODS**

### **Study design**

The participants were assigned randomly to one of two groups based on simple randomization technique; a control group have received interpersonal counseling once a week for 12 weeks and an interventional group have received a ready-made oat meal plus aromatherapy inhalation device in addition to the interpersonal counseling. All participants as well as the laboratory staff were unaware of the group to which each patient was allocated as well as the used type of intervention. After the baseline assessment visit, a total 12 weekly based treatment visits were arranged for follow up. Prior to the study, an ethical clearance has obtained from the ethical committee of the National Research Centre, in accordance with Helsinki's Declaration, world medical association, 2013 [17]. Furthermore, a written informed consent was assigned by each participant before starting the study.

### **Participants**

A total number of 55 current smokers were enrolled in the study for smoking cessation of which only 48 completed the follow up schedule (23 smoker in the intervention group and 25 in the control group) and 7 smokers (5 in control and 2 in intervention group) were dropped out in the first 4 weeks of follow up and excluded from the final results. The initial Exclusion criteria included Smokers who started any smoking cessation medication within one year of the registration or follow any other smoking cessation program, those who suffer from nasal allergy, sinusitis or bronchial asthma.

### **Interventions**

#### **A preparatory assessment visit**

At week 0, all recruited smokers were interviewed to fill pre-tested well-structured questionnaire form. Patient's health status characteristics were assessed with detailed smoking history and behavior; to detect their

dependence status. Each participant was given his own pre-designed follow up treatment card. The card includes his serial number in the study, personal data, smoking status, withdrawal symptoms and specific questionnaire for assessment of tobacco craving index (TCI).

### **Aromatherapy preparatory phase**

At week 0, the enrolled smokers in the intervention group were received an Aromatherapy inhaler device which has been made and prepared specifically for the study. It contained an essential volatile oil; citrus Lemon. The device is equipped to retain the smell for long time and prevents the spillage of its internal content. Smokers in this group were asked to use the device for one minute when they feel craving for cigarette and record the time delay to next cigarette in the next 24h. The time delay based on their self-recording was categorized into three categories; (30-60minute), (61-120minute) and ( $\geq 120$ minute). The aim of conducting this phase was to assess the individual impact of using the aromatherapy device before starting the rest of interventions

### **Interpersonal behavioral counseling**

A well prepared face to face health education messages for importance of continued abstinence were introduced verbally for each participant in the two groups weekly during the follow up visits starting from week1 up to week12. Stress management and resiliency strategies were addressed and all explanations were clarified individually for 7-10 minutes

### **Treatment phase**

Eligible subjects were enrolled randomly in either one of two treatment regimens:

### **Intervention group (COL approach)**

Smokers in this group were received both interpersonal counseling sessions(C) in addition to citrus lemon (L) aromatherapy inhaler device and a ready-made meal composed of Avena sativa L seeds (Oat); prepared specifically for the study; for 12 weeks. The enrolled smokers were educated how to prepare the daily oat meal

and how to use the inhalation device when crave to smoke. All of the raw natural materials which have been used in the study were commercially available in the Egyptian market.

### **Control group**

After the preparatory assessment visit, Smokers in this group were received only 7-10 minutes interpersonal counseling weekly for 12 weeks.

### **Definition of outcomes**

The treatment outcome was monitored weekly (7 day primary outcome) during the follow up visits. In the 7-day smoking abstinence, subjects were considered abstinent from smoking if they reported no tobacco use in the previous 7 days confirmed by negative TLC for nicotine detection. The smokers were categorized into one of three outcomes; continuous abstinence, intermittent abstinence or failure. Continuous abstinence; was defined as the state that subjects self-reported quitting smoking continuously for at least the previous 4 weeks, negative result for the presence of nicotine in urine by TLC and showed lower level of urinary cotinine concentration as compared to the previous one. Intermittent abstinence; was defined as the state that subjects may smoke in certain occasions but not on daily basis. Failure of abstinence; was defined as the state in which the treated subject still smoke regularly and on daily basis regardless the number of daily consumed cigarettes.

### **Study assessments**

The baseline body Mass index was calculated as described in Hegazy et al.2016. [18]

**Assessment for Cumulative lifetime smoking** was measured by pack-year index, which was calculated individually for each smoker as described in other studies.[19, 20]

### **Assessment of nicotine dependence**

The nicotine dependence was assessed at week 0 using Fagerström Test for Nicotine Dependence (FTND), and Heaviness of Smoking Index (HIS)[21].FTND is an 8-item self-report questionnaire, with a total score  $\geq 8$  indicative

of high nicotine dependence. Heaviness of Smoking Index is a two item self-report questionnaire, with a total score  $\geq 5$  indicative of high nicotine addiction.

#### **Assessment of tobacco craving**

Tobacco Craving Index (TCI) questionnaire [22] was used at each follow up visit; each smoker was asked to rate his strength of craving and frequency of daily craving over the past week. Smokers were classified into one of four grades based on their responses (0, I, II, III, with III indicating severe craving). The TCI grade from 0-3 was determined by the patient's ratings on the two questionnaire items according to the chart mentioned by Taniguchi et al.2019. [23]

#### **Laboratory assessments**

The self-reported abstinence state was confirmed by:

#### **Qualitative detection of nicotine in urine**

A Thin layer chromatography (TLC) was carried out on aluminum-backed plates pre-coated with silica gel F254 (20 × 20 cm, 200  $\mu\text{m}$ , 60Å, Merck, Germany). The developing system was Chloroform: methanol (90:10). Visualization was accomplished under UV lamp at 254 nm then by spraying with Dragendorff's reagent. The resultant color was observed and retardation factor (hRf) values were recorded [24].

#### **Quantitative determination of cotinine concentration**

The morning urine samples have centrifuged at the speed of 2000-3000rpm for 20-min. the supernatant was removed. The samples kept at -20°C. A cotinine immunoassay has assessed using the commercial used kits from Glory Science Co., Ltd. The concentration of cotinine in the urine was determined by Enzyme Linked Immuno-sorbent assay (ELISA), a colorimetric

method, using a commercial cotinine Elisa kits from Sigma-Aldrich Co. LLC., USA, according to the manufacturer's instructions and guidelines [25]. Urinary cotinine concentration then expressed as Pg/ml.

#### **STATISTICAL ANALYSIS**

Data were analyzed using SPSS version 20.0. The differences in frequency between the two studied groups have been compared using Chi-square ( $\chi^2$ ) or Fisher's exact test. Student's t test was used to compare the normally distributed quantitative data in the two groups and results was expressed as mean values  $\pm$  standard deviation (SD. Differences were considered significant with p-value  $< 0.05$  (two-tailed).

#### **RESULT**

Table 1 shows the baseline characteristics of the participants with no significant differences were observed between the two treatment groups, except in their daily consumption of cigarettes as well as their pack year index. The smokers in the intervention group were significantly have higher daily consumption (27.5 $\pm$ 12.7 cigarette/day) and higher pack year index (33.9 $\pm$ 19.3) than smokers in the control group (19.7 $\pm$ 8.6 cigarette/day) and (23 $\pm$ 14.6) respectively; p-value=0.03.

#### **Smoking abstinence**

No statistically significant differences in smoking abstinence rates were observed between the two different regimens at the end of week 4 and week 8 treatments. The rate of continuous abstinence was significantly higher (47.8%) and failure rate was significantly lower (21.8%) among smokers in in the intervention group at the end of week 12 in comparison to smokers in the control group (16.0% and 56.0%) respectively; p-value=0.02(Table2). The results of TLC were compatible with the self-reported smoking status in the two groups.

**Table1. Baseline characteristics of the smokers enrolled in the study**

Characteristics	Control group (N=25)	Intervention group (N=23)	p-value
Age (Yrs.) (mean± SD)	40.0±10.3	43.7±8.2	0.2
BMI(kg/m <sup>2</sup> )	27.4±4.5	29±4.3	0.2
Educational level			
High	4(16.0)	6(26.1)	0.5
Medium	18(72.0)	13(56.5)	
low	3(12.0)	4(17.4)	
Occupation			
Administrative workers	14(56.0)	8(34.8)	0.1
Service workers	11(44.0)	15(65.2)	
Comorbidities			
Yes	11(44.0)	13(56.5)	0.4
No	14(56.0)	10(43.5)	
Initial cause for smoking			
Influenced by peers/ relatives	15(60.0)	13(56.5)	0.8
Escaping from problems	4(16.0)	5(21.75)	
Curiosity	6(24.0)	5(21.75)	
Reason for quitting smoking			
Health concerns	11(44.0)	7(30.4)	0.5
Financial concerns	4(16.0)	5(21.7)	
Family pressure	8(32.0)	8(34.8)	
Religious concerns	1(4.0)	0(0.0)	
Smoking is bad habit	1(4.0)	3(13.1)	
Initial age of smoking(yrs.)	17.5±6.4	16.0±7.3	0.3
Smoking duration (yrs.)	21.6±10.2	24.1±8.3	0.3
No. of cigarette/day	19.7±8.6	27.5±12.7	0.03*
Dependence score(FTND)	5.2±2.0	6.0±2.6	0.3
Heaviness of smoking index(HIS)	2.9±1.5	3.6±1.6	0.1
Pack year index	23±14.6	33.9±19.3	0.03*
Previous quite attempts			
Yes	14(56.0)	18(78.3)	0.1
No	11(44.0)	5(21.7)	
Baseline Urinary Cotinine Concentration (pg/ml.)	2487.9±537.5	2368.5±605.7	0.5

**Table2.Smoking abstinence outcomes of smokers enrolled in the study**

Time point	Control group (N=25)	Intervention group (N=23)	P-value
	N (%)	N (%)	
4 week abstinence			
Continuous abstinence	11(44.0)	14(60.8)	0.4
Intermittent abstinence	6(24.0)	5(21.8)	
Failure	8(32.0)	4(17.4)	
8 week abstinence			
Continuous abstinence	5(20.0)	12(52.1)	0.06
Intermittent abstinence	8(32.0)	5(21.8)	
Failure	12(48.0)	6(26.1)	
12week abstinence			
Continuous abstinence	4(16.0)	11(47.8)	0.02*
Intermittent abstinence	7(28.0)	7(30.4)	
Failure	14(56.0)	5(21.8)	

### Nicotine withdrawal symptoms

Smokers in the intervention treatment group showed significant decline in their nicotine withdrawal symptoms as they self-reported during their follow up visits; p-value=0.03. Four smokers in the intervention group (17.4%) versus two smokers in the control group (8.0%)

didn't suffer from any withdrawal symptoms all over the follow-up course. Seven smokers (30.4%) versus six (24.0%) in the control group, reported nervousness while, two smokers (8.7%) versus four (16.0%), reported overeating with lethargy. Lack of concentration or headache was reported only in the intervention group by five

smokers (21.7%). On the other hand, five smokers in the intervention group (21.7%) versus nine (36.0%) in controls, reported tobacco craving. Moreover, there were four smokers

(16.0%) in control group, reported all the previous withdrawal symptoms including tobacco craving (Figure1).

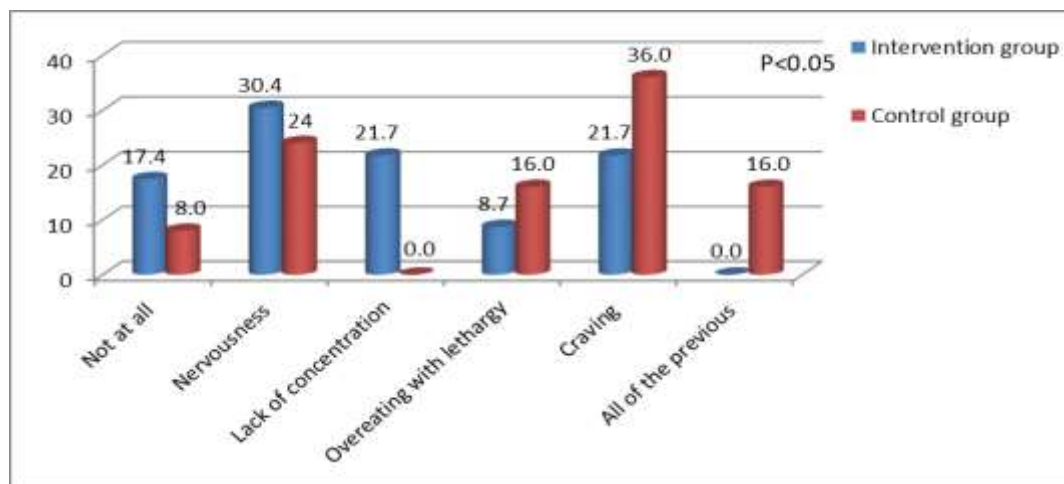


Figure1. Percentages of the reported withdrawal symptoms among the smokers during follow up

### Tobacco Craving

Changes in mean Tobacco Craving Index grade (TCI) among enrolled smokers over 12 weeks of follow up are illustrated in (Figure 2). The participants in the intervention group revealed a significant decline in the mean values of TCI grade when compared to the mean values in the control group. Statistically significant difference was observed in the mean TCI grade at the end of the 1<sup>st</sup> week of treatment among smokers in the intervention group (1.39±0.94) and smokers in the control group (2.04±0.97); (p=0.02). At

the end of the 4<sup>th</sup> week, the mean value of TCI grade in the intervention group was significantly decreased (1.3±1.0) in comparison to the control group (2.4±0.8); (p<0.0001). At the end of 8<sup>th</sup> week and 12<sup>th</sup> week, the participants in the intervention group showed statistically significant lower mean values of TCI grade (1.52±1.27 and 1.34±1.1, respectively) than the control group (2.32±1.0 and 2.56±0.8, respectively); (p=0.02 and p<0.0001) respectively.

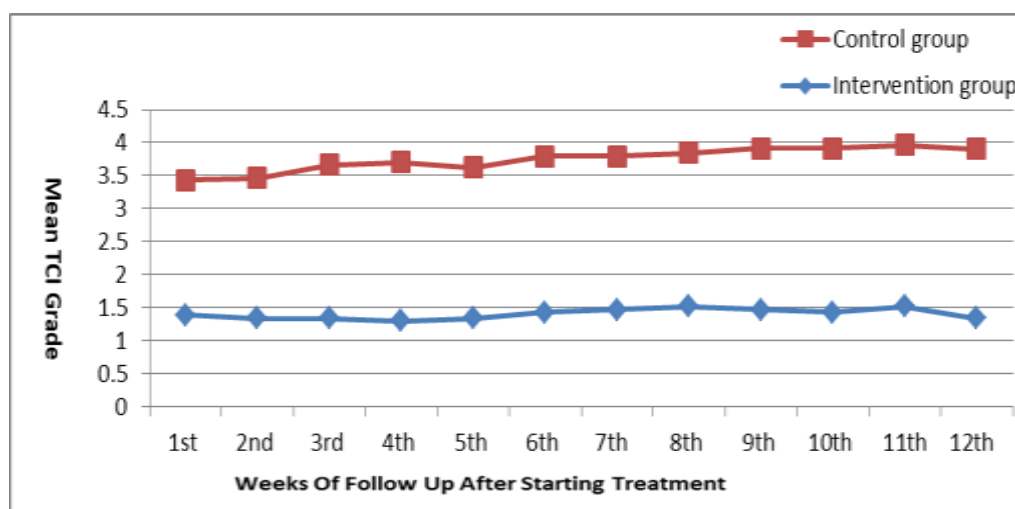


Figure2. Changes in the mean of TCI grade among the smokers over 12 weeks of follow up

### Remote effect of Aromatherapy

Time delay to next tobacco use was self-recorded by the smokers in the intervention group at week 0 in the first 24 hours after the preparatory assessment visit. The time delay

was (30-60 minute) in 60.8% (14/23) smoker, (61-120 minute) in 8.1% (3/23) and 16.1% (6/23) smoker reported time delay for  $\geq 120$  minutes.

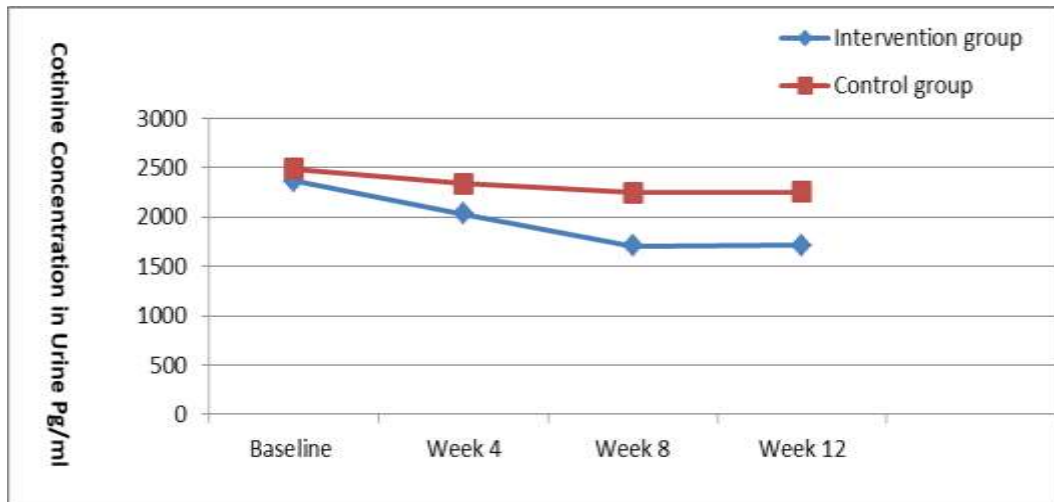


Figure3.Changes in mean values of urinary cotinine concentration before and After Treatment

### Urinary Cotinine Concentration (Ucot)

Changes in the mean values of urinary cotinine concentration before and after starting the treatment are illustrated in (Figure3). No statistically significant differences were observed between the two studied groups in Ucot at baseline as well as at week 4 after starting the treatment. On the other hand, at week 8 and week 12, smokers in the intervention group showed a significant decline in Ucot. ( $1710.9 \pm 303.7$  pg. /ml and  $1716.2 \pm 222.7$  pg. /ml respectively), as compared to their controls ( $2246.9 \pm 619.1$  pg. /ml and  $2257 \pm 617$  pg./ml respectively);  $p=0.008, 0.04$  respectively.

### DISCUSSION

Most of the previous studies focused mainly on pharmacological therapies to help smokers quit smoking, but only a few have shown that there are also natural methods that are effective for smoking cessation. In this interventional study, the effectiveness of a new non pharmacological approach for

smoking cessation has been evaluated. The studied new approach included frequent interpersonal counseling sessions, using a combination composed of two natural products namely; ready-made meal of Avena sativa seeds (oat) and aromatherapy inhalation device containing the essential oil citrus lemon (COL approach). The use of this strategy was evaluated versus the use of counseling alone in the control group. The continuous tobacco abstinence rate among the smokers who received CoL approach was 60.8% at the end of the 4<sup>th</sup> week versus 44% in the control group, and 52.1% of the smokers' maintained continuous abstinence until the end of 8<sup>th</sup> week versus 20.0% of the control group. However, this difference was statistically insignificant ( $p>0.05$ ). At the end of the 12<sup>th</sup> week, the intervention group showed a significant higher continuous abstinence rate (47.8%) than the control group (16.0%). Moreover, the failure rate was significantly higher among the control group (56.0%) in comparison to the

intervention group(21.8%); $p=0.02$  (Table2). By comparing our results to the previous studies that used another natural agents for smoking cessation, Sood et.al.2010[26] reported no effect for St. John's wort herbal supplement (*Hypericum perforatum*) on nicotine abstinence rate at week 12 and 24 while Barnes et al.2006[27] reported continuous abstinence 18% at 3months. One small Japanese pilot study showed that, daily supplements of Oat extract are beneficial in smoking cessation by reducing the consumption of cigarettes from 20 to a fewer than 9 cigarettes/day. [28] Our results are more promising than the Japanese study because we didn't use the extract, but used the whole oat grain with its powerful antioxidant properties present in the outer layer. In addition, the ready-made oat seeds in our study have an integrative role in combination with aromatherapy and frequent interpersonal counseling (COL approach). On the other hand, upon comparison of our continuous abstinence rate with other studies that used pharmacological approaches for smoking cessation. In randomized placebo controlled trial to evaluate the efficacy and tolerability of varenicline in smokers from 11 countries, including Egypt, the continuous abstinence rate (CAR) from the 9<sup>th</sup> to the 12<sup>th</sup> week was notably higher with varenicline administration, compared to placebo (53.59% vs.18.69%;  $p < 0.0001$ )[29]. Furthermore, Bassiouny et al.1998[30], reported that the abstinence rate among smokers after using nicotine patches for nine weeks was 50.6%, 28% after six months and 25.8% at the end of the year. Upon evaluation of the impact of citrus lemon essential oil inhalation on tobacco craving, it revealed reduction in the craving intensity among aromatherapy inhalation device users. Where 14 smokers (60.8%)

reported time delay to the next tobacco use (30-60 minute), three smokers (8.1%) reported a delay for (61-120 minute) and six smokers (16.1%) reported  $\geq 120$  minute time delay. Moreover, the tobacco craving among COL approach users was significantly lower than the observed among the control group as presented by Tobacco Craving Index grades (Figure 2), beginning with the 1<sup>st</sup> week of treatment and continuing through 4<sup>th</sup>, 8<sup>th</sup> and 12<sup>th</sup> weeks of treatment. The reduction in craving seen in the present study is comparable to the effects seen previously with citric acid aerosol[31], black pepper and angelica essential oils[32], and with nicotine skin patch treatment[33,34]. On the contrary, Newsham G., 2001[35], reported no difference in the cravings after using 20 drops of lavender in the nebulizer. The conflicting results in this respect may explore the specific individual impact of each studied essential oil. When smokers abstain from nicotine, withdrawal symptoms which include irritability, impatience, depression, anxiety, increased appetite and impaired concentration, may set in[36]. In the present study, the smokers in the intervention group had significantly less withdrawal symptoms than their control group (Fig.1). They had less overeating, lethargy, nervousness and craving. Moreover, about one fifth of the smokers (17.4%) pass through the treatment period (12 weeks) without suffering from any withdrawal symptoms at all. Also, no one in this group suffered from more than one withdrawal symptom indicating lower intensity of symptoms in comparison to smokers in the control group. Cotinine is the main metabolite of nicotine and has longer half-life with relatively high sensitivity and specificity; compared to expiratory a CO level which has short half-life (2h), so



urinary cotinine is a reliable indicator of recent nicotine intake [37]. Testing urinary cotinine levels in smokers who quit smoking provides a biochemical evidence of cessation [38]. The marked gradual decline in Urinary cotinine levels among the intervention group after the 4<sup>th</sup> week of treatment with sustaining decline all over the follow up period, is another indicator for the efficacy of this approach in comparison to the control group.

### CONCLUSION

The tested new approach was effective in increasing the continuous abstinence rate most probably due to natural detoxification by the ready-made oat meal, as well as through decreasing the craving numbers and intensity via citrus lemon aromatherapy inhalation device. Furthermore, the approach succeeded in decreasing the nicotine withdrawal symptoms which may decrease their chance for relapse later on. Frequent extended follow up is recommended to prevent relapse. This intervention could be embedded as a treatment option within a comprehensive tobacco control strategy. It is not an alternative but could be complementary for other evidence based strategies. The studied aromatherapy device could be used to delay the desire for cigarette smoking and may be marketed as an alternative to smoking for 'situational use' (i.e. where smoking is not allowed).

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**Conflict of Interest:** None

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**Ethical Approval:** Approved

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