

Evidence for the Efficacy of a Bioresonance Method in Smoking Cessation: A Pilot Study

Description

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Summary

Background: Since the 1970s, MORA bioresonance therapy has globally been applied in the context of complementary medicine for various indications. In this regard, practitioners also report successful application in smoking cessation. The present study aims to verify these reports in a controlled study setting.

Methods: In order to achieve the aforementioned objective, we subjected the bioresonance method to a prospective, placebo-controlled, double-blind, parallel-group study involving 190 smokers. In both study groups (placebo n = 95; active bioresonance group; n = 95) the course of treatment and study conditions were standardized.

Results: 1 week (77.2% vs. 54.8%), 2 weeks (62.4% vs. 34.4%), 1 month (51.1% vs. 28.6%), and 1 year (28.6% vs. 16.1%) after treatment, the success rate in the verum group differed significantly from the results in the placebo group. Also, the subjective health condition after treatment and subjective assessment of efficacy, polled after 1 week, were significantly more positive among participants in the active bioresonance therapy group than among those in the placebo group. Adverse side effects were not observed.

Conclusion: According to the findings attained by this pilot study, bioresonance therapy is clinically effective in smoking cessation and does not show any adverse side effects.

Introduction

MORA bioresonance therapy (traditional bioresonance therapy) was developed by physician Franz Morell and electrical engineering technician Erich Rasche in the 1970s, as a result of medical testing in electroacupuncture [1]. Thereby, postulated low electromagnetic oscillations of humans (endogenous bioresonance) or of bioactive substances (e.g. allergens, heavy metals, vitamins, exogenous bioresonance) are collected by plane applicators. The oscillations are electronically postulated phase-constant or inverted phase-constant amplified and superimposed on the human electromagnetic oscillation field for therapeutic purposes. This is supposedly achieved within a range of 1–105 Hz, partially deploying frequency filters in the respective frequency range. In this pilot study, bioresonance therapy is applied with cigarettes as exogenous bioactive substance.

A number of clinical [2–11], biological [12–17], and physical [18–19] studies performed by international teams prove the method's efficacy and effectiveness. With respect to clinical issues, successful studies have been performed in relation to allergies, rheumatic diseases, respiratory diseases, and various pain syndromes. However, with regard to allergic indication, there are also 2 studies [20–21] showing

negative results. Thus, the bioresonance method is still subject of controversy within this field [22–23].

As mentioned above, extremely weak, coherent, and low-frequency electromagnetic oscillations are assumed to carry information on a biophysical level. However, present measurement equipment has so far not been able to produce direct evidence of their existence. Up to now, there are only a few hypothetical explanatory models, such as the temporary working hypothesis partly formulated above. Nevertheless, this hypothesis is supported by various aspects, such as e.g. the electronic storability of substance-specific bioinformation [7, 10, 11, 13, 14].

The methodical approach made by Morell and Rasche [1] was typical for empirical medicine, respectively complementary medicine. The method was developed by input-output studies on the whole (black box) of man. There are only hypothetical, explanatory models about the physical and physiological interactions, much like in homeopathy and acupuncture. However, explanatory concepts are not needed to test the reproducible effect of an intervention.

Smoking is harmful, especially for the bronchial and cardiovascular system. In Europe, about 30% of adult population is smoking. In Turkey, even 44% of adults are smokers. In 85%, smoking leads to lung cancer, chronic bronchitis, and pulmonary emphysema and is the most common cause of death in adults beyond 35 years of age [24, 25]. There is a great need for simply, reliable, and safe therapy methods, that may help in smoking cessation.

Drugs, such as varenicline and bupropion, are effective in smoking cessation, however with partly considerable side effects (see discussion). Various controlled studies [26–29] have shown no effects of alternative therapy concepts, such as acupuncture, acupressure, homeopathy, hypnosis, laser therapy, and electrostimulation in smoking cessation. That is why in a recently published study on alternative smoking cessation therapies, Astrid Becerra et al. [30] proposed to seek new paths.

In Turkey, Isik [31] has been applying bioresonance for smoking cessation in his practice since 2005, reporting high success rates. In this retrospective, non-controlled, and non-selective study, 4,733 participants were treated with bioresonance using the MORA device as described in our study (see methods). The main outcome was the smoking rate for 1 week, 1 month, and 3 months after bioresonance therapy. Smoking anamnesis and basic demographic characteristics of the participants were similar to our trial. The smoking reduction after 1 week was 80.1%, after 1 month 62.1%, and after 3 months 48.2%. No side effects were observed.

To date, no controlled bioresonance studies have been published verifying Isik's observations regarding smoking cessation. Thus, we conducted a placebo-controlled, double-blind study in order to examine whether or not bioresonance holds any actual clinical efficacy and effectiveness in smoking cessation. Prior to the study, none of the performing scientists (AP, CC, ZK, HI, FE, TC, ZG) had gathered any experience with the bioresonance approach or the bioresonance equipment used.

Participants and Methods

Study Design

A prospective, placebo-controlled, double-blind, parallel group study was carried out at Istanbul University, Turkey. The verum and the placebo group included each 95 smokers at the age of 18–75 years, who wanted to quit smoking. Group allocation of participants was performed alternately,

according to their appearance for treatment. The bioresonance treatment was carried out and checked for efficacy after 1 week, 2 weeks, 1 month, and 1 year.

Inclusion and Exclusion Criteria

The test subjects for the study performed were cigarette smokers who had decided to quit smoking. Prior to this study, none of the subjects had ever tried to quit smoking.

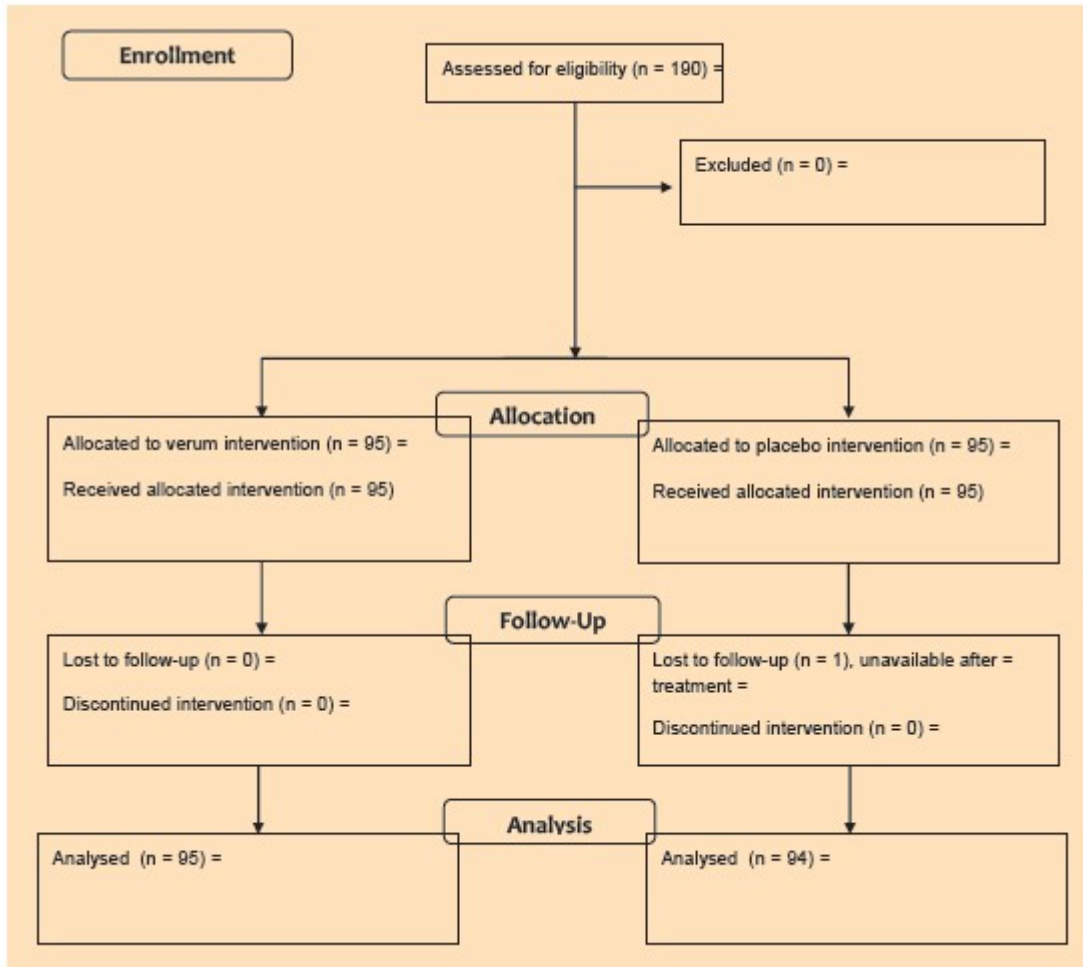
The following criteria for in- and exclusion were applied: Subjects had to be between 18 and 75 years of age; free from any ischemic heart diseases and/or cardiac arrhythmias, and from severe psychiatric disorders, such as schizophrenia or anxiety attacks. The scale value in accordance with the nicotine dependence assessment as per Fagerstrom [32] had to be -7 . Additionally, the participants' written consent was required (see below).

Group Allocation

190 test subjects who met the aforementioned inclusion criteria were recruited at the Smoking Cessation Center, Pulmonology Department at the Medical Faculty, University of Istanbul. The subjects were allocated to a verum group (receiving active bioresonance treatment) and a reference group (subjected to simulated bioresonance therapy). Allocation was based on the following pattern: The first participant treated received active bioresonance therapy, the second received simulated bioresonance therapy, the third active bioresonance therapy, etc., until all 190 test subjects had been allocated. As 1 participant in the reference group was permanently unavailable after treatment, only 189 test subjects were included in the evaluation (fig. 1).

Regarding their age, gender, number of cigarettes smoked per day, number of years smoking, and type of profession, the 95 participants in the verum and 94 subjects in the reference group were statistically equal ($p > 0.05$; table 1). 6 subjects in the verum group took antidepressants; in the placebo group, 14 subjects were on respective medication. In both test groups, no medication for smoking cessation was taken during or prior to the test period. Other types of medicines consumed were not checked.

Prior to the study, all subjects had been informed as to the nature of placebo-controlled double-blind studies and had given their written consent to participate in the study. Subjects were informed about the possibility of receiving ineffective treatment. The study was approved by the ethical review committee at the Medical Faculty, University of Istanbul.



Outcome

The essential outcome parameter was smoking behavior. 1 week, 2 weeks, 1 month, and 1 year after completion of treatment, all subjects were interviewed by telephone so as to ascertain whether or not they had smoked cigarettes. In addition, 1 week after treatment the participants were polled by telephone as per questionnaire (fig. 2) in order to evaluate the therapy's immediate effects on the subjects' condition. The interviewer was unaware of which treatment the respective participant had been subjected to, i.e. whether the test person had been allocated to verum or reference group.

Intervention and Blinding

The bioresonance treatment was carried out only once. Therapeutic procedure and equipment settings (see below) were standardized. Using the bioresonance device MORA-Super (Med-Tronik GmbH, Friesenheim, Germany), the standard therapy was carried out as described below:

Before starting the treatment, the test subjects were requested to smoke 2 half cigarettes and fill the cigarette ash and the remaining halves of both cigarettes smoked into 2 glass tubes. The glass tubes containing cigarette butts and ash were then separately placed into the bioresonance device's input applicators MT1 and MT2. In a second step, the bioresonance treatment was carried out (approximately 45 min).

The test subjects were connected to the hand and foot applicators of the bioresonance device. An applicator for the head, providing 2 adapters, was positioned on the subjects' forehead and connected to the additional contacts for the left and right hand applicators, provided at the rear of the device. A round-shaped magnetic applicator was attached 3 cm below the test subjects' navel, and an additional external amplifier (amplification = 1,000) was connected to the output. The respective input of the amplifier was connected to the contact for right foot, provided at the rear of the device.

	Verum group, active bioresonance (%)	Reliance group, simulated bioresonance (%)	p
Gender			0.20
Male	42 (44.2)	34 (36.2)	
Female	53 (55.8)	60 (63.8)	
Age, years			0.20
15-30	15 (14.6)	9 (9.5)	
30-40	30 (31.6)	29 (30.9)	
40-50	32 (33.7)	30 (31.9)	
50-60	16 (16.8)	22 (23.4)	
>60	3 (3.2)	4 (4.3)	
Cigarettes smoked per day, a			0.20
<10	2 (2.1)	2 (2.1)	
11-20	48 (50.5)	57 (60.6)	
21-30	25 (26.3)	18 (19.1)	
>30	20 (21.1)	17 (18.1)	
Smoking years, a			0.09
<10	10 (10.5)	8 (8.5)	
10-20	37 (38.9)	25 (26.4)	
>20	48 (50.5)	61 (64.9)	
Employment			0.50
Workers and employees	60 (63.1)	40 (42.4)	
Self-employed	8 (8.4)	15 (16.0)	
Unemployed	24 (25.3)	35 (37.2)	

Table 1. Subjects' demographic characteristics and smoking history (absolute frequency, relative frequency in brackets; chi-squared test)

Active bioresonance therapy was performed by applying program 21 first, followed by program 22, whereas the simulated bioresonance therapy deployed programs 11 and 12 (details on programs are provided below). For both treatment variants, the sounds and indications of bioresonance devices were identical. The participants were thus unable to differentiate which of the treatment variants they were exposed to. The performing party applied the first combination of programs to the first participant, the second program combination to the second participant, then again the first combination of programs to the third participant, etc. The performing party recorded which test subject received which treatment, but was unaware of the outcome of the individual program combinations. The performing party had no experience in bioresonance therapy, no training in the operation of the device, and was only able to set the specified programs. He neither knew how to handle the applicator settings nor what they stand for, or what the programming entails. No other party involved knew, which programs were being applied in which manner. Neither the performing nor any other involved parties maintained further contact with the test subjects. Test documentation was not revealed until the study has been completed and analyzed.

In the process of both the active as well as simulated bioresonance treatments, a so-called chip was used as carrier substance. This chip was made of a round-shaped disk of 1 mm thick stainless steel with a diameter of 2.5 cm, and was placed on the bottom of the output applicator twin beaker.

In the course of treatment, a glass bottle containing 92 parts of physiologic saline solution and 8 parts of ethanol-water solution were used as carrier substance, being administered by drops. While the program was executed, the respective glass bottle with the preparation was placed in the same twin beaker mentioned above. At the end of the bioresonance treatment, the respective chip was fixed to a spot 2 fingers below the test subjects' navel using medical tape (meridian: Ren Mai; acupuncture point: Qi Hai) for 1 month. The test persons were asked to instill 5 of the aforementioned therapeutic drops beneath their tongue, whenever they felt the need to smoke. However, the subjects were also informed not to take more than 30 drops a day; otherwise there would be a risk of exacerbation of withdrawal symptoms, similar to an excessive dose of remedies in homeopathy.

Programs and Electrode Wiring of MORA-Super Device

The programs used in the course of therapy were extended MORA programs as described in the following.

Programs 21 and 22 (active bioresonance treatment): Program no. 21 was programmed as detailed in table 2.

Table 2. Program 21 (active bioresonance treatment). All stages were conducted in Ai mode, i.e. phase-constant inversion (amplification of program 22 in brackets)

Program 21	Frequency filter	Amplification	Cycles
Stage 1			24
Channel 1	low pass 1 kHz	90° (80°)	
Channel 2	high pass 1 kHz	70° (60°)	
Stage 2			30
Channel 1	low pass 1 kHz	100° (90°)	
Channel 2	high pass 1 kHz	80° (70°)	
Stage 3			24
Channel 1	low pass 1 kHz	50° (40°)	
Channel 2	high pass 1 kHz	70° (60°)	
Stage 4			30
Channel 1	low pass 1 kHz	60° (50°)	
Channel 2	high pass 1 kHz	80° (70°)	
*Physiologic amplification, cycle times 3s/7s.			

The only difference between program no. 22 and program no. 21 was the amplification. Electrode connection in program 21 and 22 was identical and specified as follows: 1. stage: right hand = input 1, left hand = input 2, right foot = output 2, left foot = output 1, MT-1 = input 1, MT-2 = input 2, twin beaker

= not connected. 2. stage: right hand = output 2, left hand = output 2, right foot = output 2, left foot = output 1, MT-1 = input 1, MT-2 = input 2, twin beaker = output 1 and 2. 3. stage: right hand = input 1, left hand = input 1, right foot = output 1, left foot = output 2, MT-1 = input 1, MT-2 = input 2, twin beaker = not connected. 4. stage: see stage 2.

- 1) Please grade the severity of the urge to smoke you are currently experiencing:
For the first three days:
 - a) Urge to smoke was not so severe
 - b) Urge to smoke was very severe
After the first three days of treatment:
 - a) Urge to smoke was not so severe
 - b) Urge to smoke was very severe
- 2) Have you smoked in the period following your treatment?
 - a) Yes, I started to smoke again
 - b) Yes, I have but only a few times and only a few drags
 - c) No, I no longer smoke
- 3) If you have smoked, your first cigarette
 - a) Made me feel nausea, I could have vomit.
 - b) I was able to smoke without feeling uncomfortable
 - a) I felt the need to put the cigarette out after a few drags and I did
 - b) I smoked most of the entire cigarette
- 4) If you are a smoker:
 - a) I no longer enjoy smoking so much
 - b) I still enjoy smoking just as before
 - a) I feel that my physical desire for nicotine has regressed
 - b) I feel that my physical desire for nicotine remains unchanged
 - a) Actually it's not that I cannot resist smoking.
 - b) I smoke because I cannot stand not smoking
 - a) I do not feel that the treatment has caused any change in my smoking habit
 - b) I do feel that the treatment has caused change in my smoking habit
- 5) If you are a non-smoker
 - a) I do not feel much urge to smoke when there are people smoking next to me
 - b) I feel urge to smoke when I'm in a smoking environment or someone next to me is smoking
 - a) Cigarette smoke disturbs me.
 - b) Cigarette smoke does not disturb me however it triggers the urge to smoke.
 - c) Cigarette smoke does not disturb me neither does it trigger the urge to smoke.
 - a) I do not feel strong urge to smoke at places and times I used to smoke.
 - b) I feel strong urge to smoke at places and times I used to smoke
- 6) Nervousness and irritability
 - a) I feel nervous
 - b) I am generally calm
- 7) Do you think the drops reduce your urge to smoke?
 - a) Yes it suppresses the urge to smoke
 - b) I cannot comment
 - c) No it does not suppress the urge to smoke
- 8) What would you say if you were asked to comment on the treatment you received?
 - a) I can say that I felt that it was effective
 - b) I cannot make a clear judgment on the effectiveness of the treatment
 - c) I can say that I did not feel it had any effect

Fig. 2. Questionnaire (carried out 1 week after treatment).

Program 21	Frequency filter	Amplification	Cycles
Stage 1			24
Channel 1	low pass 1 kHz	90* (80*)	
Channel 2	high pass 1 kHz	70* (60*)	
Stage 2			30
Channel 1	low pass 1 kHz	100* (90*)	
Channel 2	high pass 1 kHz	80* (70*)	
Stage 3			24
Channel 1	low pass 1 kHz	50* (40*)	
Channel 2	high pass 1 kHz	70* (60*)	
Stage 4			30
Channel 1	low pass 1 kHz	60* (50*)	
Channel 2	high pass 1 kHz	80* (70*)	

*Physiologic amplification, cycle times 3s/7s.

Table 3. Absolute and relative number (in brackets) of participants who had quit smoking (chi-squared test)

Participants' condition	Active bioresonance therapy, %	Simulated bioresonance therapy, %
No desire to smoke in the first 3 days after treatment.	45	21
No desire to smoke in the second 3 days after treatment.	62	38
Smokers who enjoyed smoking after treatment.	41	73
Non-smokers who, after treatment, did not feel any need to smoke, even when being surrounded by smokers.	85	59
Non-smokers who felt nervous.	18	39
Participants believing that the drops had reduced their desire to smoke.	48	24
Participants believing in the treatment's being effective.	67	33

Table 4. Significant findings obtained from supplementary interviews, regarding the participants' condition after treatment (relative number of participants, chi-squared test)

Programs 11 and 12 (simulated bioresonance treatment): Programs no. 11 and 12 were set equally to program no. 21, except for the fact that amplification was set to 0 in each stage and channel and the in-

and output of the MORA device remained unconnected. As a result, the oscillation could neither get in nor out of the device. For the participants of both groups, however, the treatment seemed identical. The performing parties were also unable to distinguish if participants received verum or placebo.

Statistics

The test statistics for the findings presented in tables 1, 3, and 4 were performed by applying the chi-squared test [33]. The respective threshold of significance was $p < 0.05$.

Results

After 1 week, 77.2% of the members in the verum and 54.8% in the placebo group had quit smoking ($p = 0.001$); after 2 weeks, 62.4% vs. 34.4% ($p < 0.001$); 1 month after treatment 51.1% vs. 28.6% ($p = 0.002$). Even after 1 year, a significant difference between the members of verum and placebo group was recorded: 28.6% of the participants in the verum and 16.1% in the placebo group had not smoked ($p = 0.04$). Table 3 provides an overview of the results for the main outcome parameter.

The significant findings obtained from supplementary interviews, regarding the immediate efficacy 1 week after treatment, are summarized in table 4. Compared to the placebo group, the desire to smoke was significantly reduced in the verum group over the first 3 and further 3 days after treatment ($p = 0.002$; $p = 0.003$); even if surrounded by smokers, they did not feel any need to smoke ($p = 0.003$); they did not feel nervous ($p = 0.004$); believed the therapeutic drops to have reduced their desire to smoke ($p = 0.001$); and expected the treatment to be effective ($p < 0.001$).

The bioresonance therapy was well tolerated. 1 participant suffered from contact allergic dermatitis which, however, disappeared very soon without any further treatment. No other adverse reactions and/or side effects were observed.

Discussion

Regarding the results of this pilot trial, the application of active bioresonance can be rated as successful. This method differs significantly and noticeably from simulated bioresonance, 1 week (success rate 77.2% vs. 54.8%), 2 weeks (62.4% vs. 34.4%), 1 month (51.1% vs. 28.6%), and 1 year (28.6% vs. 16.1%) after treatment (table 3). The efficacy of bioresonance therapy documented in this study was also confirmed by the findings obtained from the interview that took place 1 week after treatment (fig. 2). The self-rated improvements of health condition as well as subjective expectation toward treatment effectiveness were significantly more positive in the bioresonance than in the placebo group.

Comparing bioresonance method (success rate 28.6% after 1 year) with the most effective pharmacological method using varenicline, the results are similar; yet, they vary in the occurrence of side effects caused by varenicline, such as nausea, insomnia, and partly even attempted suicides. (In 2009, even a warning by the Food and Drug Association was issued). Many studies have been conducted on the medication mentioned above. For example, Oncken et al. 2006 [34] documented the following success rates after 1 year of treatment with varenicline and bupropion: 23.0% for varenicline, 14.6% for bupropion; and 10.3% for placebo, revealing that the 3 treatments differ significantly. These results are in line with findings from a randomized controlled trial by Jorenby et al. [35]. According to

the trial of Tonstad et al. [36], the carbon monoxide content indicating physical nicotine dependence was significantly lower in the varenicline group compared to the placebo group in weeks 13–24 (70.5% vs. 49.6%) as well as in weeks 13–52 (43.6% vs. 36.9%). These results correspond with findings from other studies [37–38]. According to the meta-analysis by Eisenberg et al. [39], on a pharmacological level the most successful results were obtained with varenicline.

With regard to complementary therapies in smoking cessation, so far no comparable effects are known for any other method. In a recent placebo-controlled study on ear acupuncture, former positive results from non-controlled studies could not be confirmed [40]. However, there are also new promising study results in ear acupressure [41] and hypnosis [42].

As the research participants of the bioresonance therapy left the clinic at the end of the intervention and sometimes lived quite far away from the hospital, direct evaluation of the participants' health condition after treatment was not possible. Therefore, follow-up data was gathered via telephone and assessed by participants' self-rating. In this regard, carbon monoxide concentration in blood and other smoking-specific parameters could not be determined in this evaluation period. This could limit the validity of the results, since the assessment of the participants could not be verified by a fully objective measurement.

One participant in the placebo group was unavailable after treatment and thus could not be included in the evaluation. Due to the high number of participants, however, this would not substantially influence the significance of the results.

Six participants in the verum and 14 in the placebo group took antidepressants. These group differences may have influenced the results.

The results of this double-blind pilot study verify the efficacy of the bioresonance approach in smoking cessation and confirm the practice-related results of Isik [31] that showed a success rate of 48.2% with the bioresonance method 3 months after treatment. Regarding this time period, Jorenby et al. [35] reported a success rate of 43.9% in the varenicline group and 29.8% in the bupropion group. Gonzales et al. [38] documented a success rate of 44.0% for varenicline and 29.5% for bupropion. According to the results of Isik, the success rate of the bioresonance method is similar to the best pharmacological results, also after a 3-month observation period, only without any side effects.

The results of this study have to be scrutinized by large-scale randomized placebo-controlled double-blind studies, especially comparing bioresonance with pharmacological methods.

Conclusion

According to the findings obtained from this study, bioresonance therapy is clinically effective in smoking cessation, without involving any adverse side effects.

Disclosure Statement

AP, CC, ZK, HI, FE, TC, and ZG have no conflict of interest in relation to this article. MG was a scientific consultant at Med-Tronik GmbH.

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