Smoking cessation with counselling and Traditional Chinese Medicine (TCM): A randomized controlled trial

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ABSTRACT

Introduction: Non pharmacologic interventions like counselling and Traditional Chinese Medicine (TCM), have been shown to be effective for smoking cessation. In the present study we wanted to evaluate the effectiveness of counselling in smoking cessation combined with true or sham TCM.
Methods: 477 smokers (172 men and 305 women) were randomized into 3 groups: group A (sham TCM and counselling), group B (true TCM and counselling) and group C (true TCM). TCM intervention included pharmacopuncture, plum-blossom needling and auriculotherapy. The main outcome measures were the percentage of non-smokers and the Fagerstrom nicotine addiction score in those still smoking at the end of treatment, and after 6 months and 1 year.
Results: At the end of treatment, the percentage of non-smokers was: 57.1% in Group A, 59.1% in Group B, and 49.4% in Group C. After 1 year, the percentage of non-smokers was significantly lower in group C (19.1%) than in groups A (30.1%) and B (32.7%) (p = 0.015). The Fagerstrom test in the subjects still smoking was not significantly different in the 3 groups at the end of treatment and after 1 year.
Conclusions: TCM could be an effective treatment for smoking cessation when used as a single technique and especially combined with counselling. Further studies are needed to determine its efficacy.

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1. Introduction

Smoking is the leading cause of avoidable morbidity and premature mortality [1], in particular due to lung cancer and chronic respiratory and cardiovascular diseases. There is a strong relationship between the amount of cigarettes smoked and the response in terms of health effects. Smoking cessation improves the health status and reduces the risks for diseases caused by smoking, so interventions to help quitting smoking should be encouraged by all health personnel [2].

Some meta-analyses have concluded that the most effective interventions were based on non nicotinic pharmacological treatments together with a more or less intense psychological support [3–7]. Acupuncture has been used for smoking cessation, and it is one method which could be more safe and economically convenient and could have less side effects that pharmacological treatments [2,8,9]. Some meta-analyses [8,9] suggest that acupuncture may help smokers to quit immediately up to 6-month follow-ups, but the current evidence justifies further well-designed studies of acupuncture, acupressure and laser stimulation [10]. Acupuncture, both somatic and on the ear, has fewer side effects than pharmacological treatments, is better at controlling the symptoms of abstinence, and contributes to quitting smoking or to diminishing the daily dose of tobacco [11–17]. Pharmacopuncture is a technique which has evolved from traditional practices described in old

medical books from the Han Dynasty of China (206 BCE–220 CE). It integrates acupuncture and herbal or pharmacological therapies and is currently widely used in China and in Korea [18,19].

The data in the literature suggest that support groups are effective in smoking cessation up to 1 year of follow-up. Acupuncture and TCM effectiveness in smoking cessation has been shown in fewer studies, but at least an effect in the short term has been documented. The international literature shows that an association of interventions for smoking cessation can be more effective that pharmacological ones [3] but there are few rigorous studies using both interventions, except for Bier et al., 2002 and Cheng et al., 2012 [9,13].

Since smoking has a multifactorial etiology, we evaluated a multimodal intervention with counselling in association with TCM.

The results of the study may help to identify the best techniques for helping smokers to quit smoking in a lasting way, and may guide the choices of public health.

2. Methods

The subjects were enrolled between March 2008 and February 2011 from the area of Florence, Italy, and the surrounding province, using advertisement on media such as newspapers, radio and television. The interview was conducted in an office at two public outpatient clinics of the Florentine health care system, the Center of Traditional Chinese Medicine "Fior di Prugna" and the S. Rosa Clinic. During that meeting inclusion and exclusion criteria were verified, the study characteristics were explained and informative material on smoking cessation and TCM techniques was given, and the subjects signed a consent form. At that time the subjects were informed as to the characteristics and objectives of the trial and to possibility of receiving the sham intervention. They were informed that the same techniques were used in the true and sham treatments, but that the points were different and that they stimulated in a different way. At the end of the interview the subjects were randomized. Inclusion criteria were: age more than 18 years, good knowledge of the Italian language, smoking for at least 1 year, smoking at least 10 cigarettes per day, no concurrent pharmacologic treatment for smoking cessation, no known allergy to local anaesthetics, agreement to participate in the study by signing the informed consent form and privacy statement. Exclusion criteria were: smoking exclusively cigars or pipe.

The study was a randomized controlled clinical trial with three arms. It was approved by the Ethics Committee of Florence ASL10 and was not registered in a public registry.

The treatment provided was:

Group A: sham Traditional Chinese Medicine (TCM) combined with psychological support groups for smoking cessation;

Group B: true TCM combined with psychological support groups,

Group C: true TCM.

Eligible persons were randomly allocated into either group using a randomized block design.

The treatment ended after the 9th session of the psychological support group for Group A and B, and after the 3rd session of TCM treatment for Group C.

Subjects could quit the study at any time and for any reason.

2.1. TCM treatment

The TCM treatment was conducted at the Center of Traditional Chinese Medicine "Fior di Prugna" and the S. Rosa Clinic, and consisted in 3 sessions. In groups A and B the TCM treatment started after the 3rd meeting of the psychological support group, while in group C it started immediately. The second session was scheduled

2–3 days after the first, to give more support in the initial phase and to reinforce the effect of the first treatment, while the third session was scheduled after 4–8 days. The appointments for TCM treatment were scheduled in fixed days of the week. If a subject skipped an appointment, it was rescheduled in the next available opening.

TCM treatment included pharmacopuncture, plum-blossom needle and auriculotherapy. Pharmacopuncture consists in the injection of subclinical doses of drugs into acupoints, plum-blossom needle is made of 7 stainless steel needles inlaid onto the end of a handle and is used to prick the skin superficially by tapping, and auriculotherapy stimulates the auricle of the external ear.

The rationale of the TCM treatment was based on Maciocia's explanation of the effects of smoke on Lungs [20]. In the real TCM treatment pharmacopuncture was done with a 1% lidocaine solution injected bilaterally into the acupoint LI20 (Ying Xiang) and into the ear point zero. The acupoint LI20 disperses wind and clears Lung heat [21] and the ear point Zero regulates the vegetative functions [22]. The needles used were 4 mm long and 0.4 mm in diameter, and the injection was intradermic superficial. The plum-blossom needle was used to stimulate 3 paravertebral lines, from C7 to T5, at a distance of 0.5, 1.5 and 3 Cun from the vertebral spinous processes, for 3 times. In that area there are many acupoints [Fei Shu (BL13), Jue Yin Shu (BL14), Xin Shu (BL15), Po Hu (BL42), Gao Huang (BL43), and Shen Tang (BL44)] which have a psychological action and can decrease anxiety, depression and insomnia [20].

Auriculotherapy was done monolaterally on the ear point Shenmen using vaccaria seeds affixed to the skin with tape. The subject was instructed to self-stimulate the point 8 times a day to overcome the craving for smoking.

In the sham TCM treatment, sham pharmacopuncture was done on the body by superficially pricking the skin bilaterally 0.5 cm below the acupoint LI20 and in the ear antihelical fold on the same transverse line of point zero between shoulder I and shoulder II according to the Chinese ear map. Each point was wet superficially with 0.2 cc lidocaine solution without injecting the solution. The sham plum-blossom treatment was done by using the metallic blunt side of the needle to stimulate 3 paravertebral lines, from C7 to T5, at a distance of 2, 4 and 6 cun from the vertebral spinous processes, for 3 times.

Sham auriculotherapy was done using the vaccaria seed 0.5 cm from the ear point Shenmen, in an area with a different innervation and considered non active (see Fig. 1).

The protocols of true and sham TCM were chosen by a meeting of experts who reached a consensus.

Each TCM session lasted about 30 min. The TCM treatments were administered by medical doctors who were also specialists in acupuncture, having completed a four year course which included a minimum of four hundred hours of theoretical and practical training. In addition they received a more specific training before the beginning of the study consisting of 3 meetings for a total of 12 h of practice, and were supervised by the director of the study (SB).

2.2. Psychological support groups for smoking cessation

The psychological support groups for smoking cessation were held at the Florence section of the Italian League for the fight against tumours (LILT). These groups are designed to help the motivated smokers to quit with the solidarity of the group and with the support of specific psychological techniques, as described elsewhere in more detail [23]. The groups met 9 times in 5 weeks, twice a week for the first 4 weeks and one additional meeting in the 5th week. Each meeting lasted one hour and a half and it included a minimum of 10 people up to a maximum of 15. In the first meetings the work was done on the personal motivation and self-observation, then the participants were encouraged to stop smoking during the
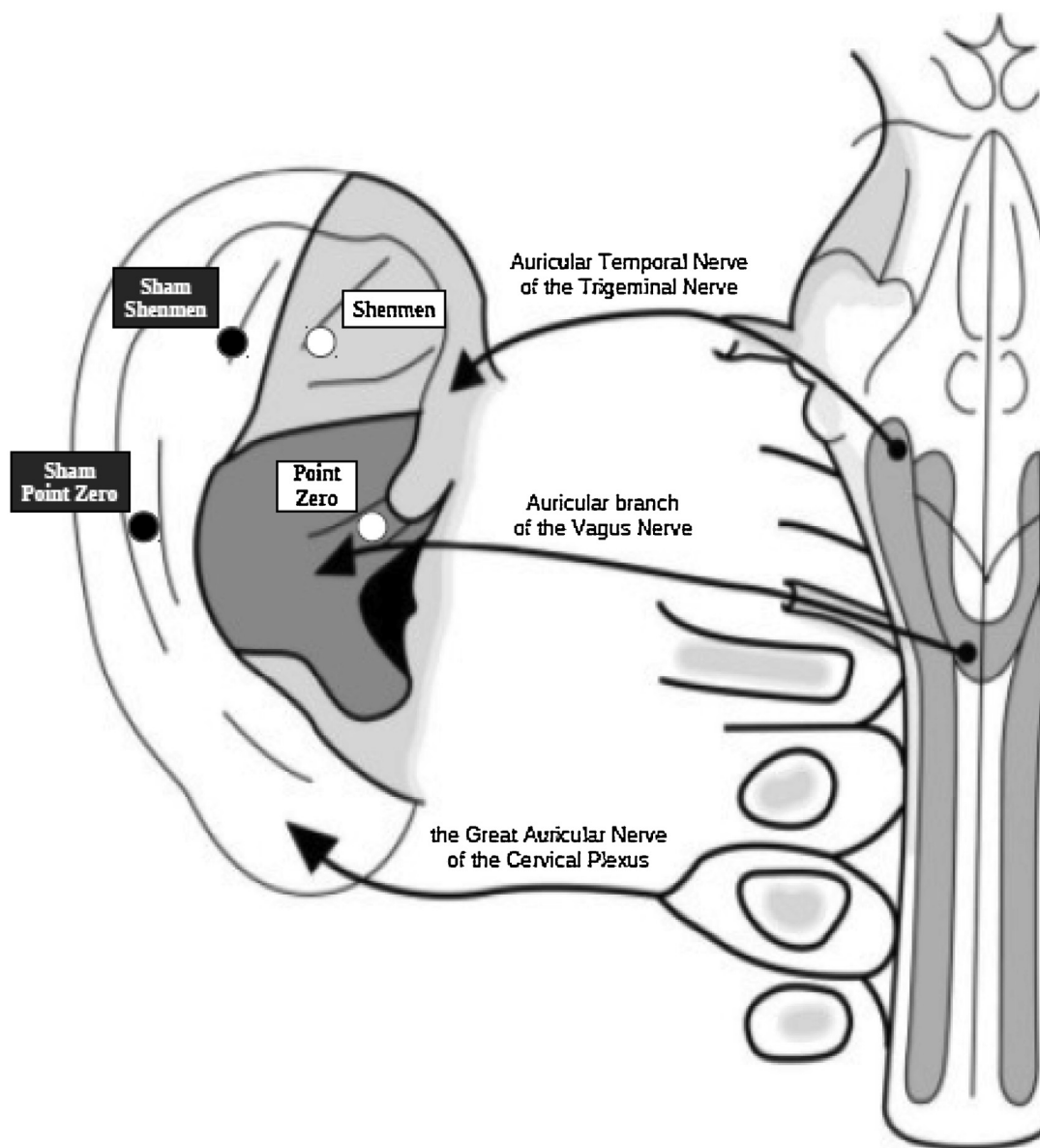
Fig. 1. Ear innervation and localization of the ear point Shenmen and the sham ear point.

4th session for at least 48 h, finally the focus was on maintaining and supporting the former smoker. The groups were led by certified psychologists with a specific training in group programs for smoking cessation.

2.3. Data collection

At enrolment a self-administered questionnaire was filled by participants, containing personal data, information on smoking habits, and the Fagerstrom test for the assessment of nicotine dependence (FTND), a test of nicotine dependence [24] which can vary from 0 to 10 (Classification of dependence: 0–2 Very low, 3–4 Low, 5 Moderate, 6–7 High, 8–10 Very high).

At the end of treatment, at six months and at 1 year after the end of treatment, only the subjects who were still smoking received the FTND again, and the final calculation was done using only the FTND results from those subjects. After 1 year from the end of the treatment 70% of those who said they had stopped smoking were checked for the concentration of carbon monoxide in exhaled air with Spirometer Cosmed model PONY G to assess the reliability of

the statements (8 ppm used as the cut – off to distinguish smokers from non-smokers).

2.4. Statistical analysis

Statistical analysis was performed with Stata SE software (version 12.0). The main outcomes were the proportion of smokers and the FTND in those still smoking at the end of the intervention.

The chi-square test was used to test the differences in categorical variables among the three groups at recruitment, and if there were differences in the proportion of smokers in the three groups at each stage of the study.

The Student t-test was used to test whether there were significant differences in continuous variables between the three groups at recruitment.

The treatment arms were compared in pairs, group B vs group A, group C vs Group A and Group C to Group B. The evaluation of results was carried out taking into account the intention to treat.

A sample size of 510 smokers (170 smokers per arm) was chosen to compare the use of TCM with psychological support groups and

Table 1
sociodemographic and health characteristics of subjects at the time of recruitment.

	Group A		Group B		Group C		
	n	(%)	n	(%)	n	(%)	*p-value*
N	156		159		162		
socio-demographic characteristics							
Sex							
Male	56	(35.9)	57	(35.9)	59	(36.4)	0.993
Female	100	(64.1)	102	(64.2)	103	(63.6)	
Age							
Mean (SD)	47.8	(9.1)	51.4	(10.3)	50.0	(10.4)	0.006
Median (range)	48	(28–71)	51	(26–75)	50	(28–85)	
Education							
Middle-low	37	(24.0)	55	(34.6)	57	(35.2)	0.057
Middle-high	117	(76.0)	104	(65.4)	105	(64.8)	
Occupation							
Employed	122	(78.7)	109	(68.6)	116	(71.6)	0.181
Unemployed	8	(5.2)	7	(4.4)	8	(4.9)	
Housewife	5	(3.2)	11	(6.9)	11	(6.8)	
Student	2	(1.3)	0		0		
Retired	18	(11.6)	32	(20.1)	27	(16.7)	
Civil Status							
Unmarried	37	(23.9)	34	(21.5)	39	(24.1)	0.297
Married	72	(46.5)	82	(51.9)	91	(56.2)	
Divorced	41	(26.5)	33	(20.9)	28	(17.3)	
Widowed	5	(3.2)	9	(5.7)	4	(2.5)	
Health conditions							
How do you rate your health status at this time?							
Very good	6	(3.9)	5	(3.2)	2	(1.2)	0.033
Good	78	(50.0)	84	(53.2)	87	(54.0)	
Acceptable	54	(34.6)	48	(30.4)	66	(41.0)	
Poor	18	(11.5)	21	(13.3)	6	(3.7)	
Were you ever diagnosed with one of these conditions?							
Lung diseases[a]	33	(21.2)	46	(28.9)	43	(26.5)	0.269
Heart diseases[b]	31	(19.9)	30	(18.9)	34	(21.0)	0.893
Digestive problems	28	(18.1)	31	(19.9)	35	(21.6)	0.732
Allergies	13	(8.5)	10	(6.5)	10	(6.2)	0.688
Cancer	9	(5.9)	10	(6.5)	11	(6.8)	0.951
Body mass index (BMI)							
Underweight	5	(3.2)	2	(1.3)	3	(1.9)	0.071
Normal weight	95	(60.9)	90	(56.6)	108	(66.7)	
Overweight	46	(29.5)	43	(27.0)	40	(24.7)	
Obese	10	(6.4)	24	(15.1)	11	(6.8)	

[a] Chronic bronchitis, bronchial asthma, lung emphysema.
[b] Chest pain, myocardial infarction, circulatory problems.

Table 2
Smoking habits at the time of recruitment.

	Group A		Group B		Group C		
	n	(%)	n	(%)	n	(%)	*p-value*
Number of cigarettes smoked daily							
Mean (SD)	23.3	(10.4)	23.3	(9.4)	21.7	(9.1)	0.234
Median (range)	20	(10–80)	20	(10–60)	20	(10–60)	
For how long have you smoked this number of cigarettes daily? (years)							
Mean (SD)	30.8	(9.2)	33.2	(10.8)	32.0	(10.1)	0.121
Median (range)	31	(10–55)	33	(10–58)	32	(11–65)	
Have you tried to stop smoking in the past?							
Yes	117	(75.0)	128	(80.5)	123	(75.9)	0.458
Alone	73	(46.8)	81	(50.9)	70	(43.5)	0.407
NRT	40	(25.6)	45	(28.3)	40	(24.8)	0.763
Support group	35	(22.4)	23	(14.5)	25	(15.5)	0.129
Acupuncture	16	(10.3)	15	(9.4)	20	(12.4)	0.671
Semi-permanent needle	12	(7.7)	19	(11.9)	10	(6.2)	0.166
Other over the counter products	7	(4.5)	12	(7.6)	13	(8.1)	0.390
Pranotherapy	3	(1.9)	5	(3.1)	4	(2.5)	0.787
Hypnosis	4	(2.6)	4	(2.5)	3	(1.9)	0.897
What are your main reasons to stop smoking?							
Fear of future illness	111	(72.1)	112	(70.9)	113	(70.6)	0.955
Desire of more control	97	(65.6)	87	(55.8)	91	(56.9)	0.425
Aesthetic reasons	63	(41.7)	57	(36.1)	49	(30.8)	0.136
among males	14	(25.5)	10	(17.5)	12	(20.3)	0.582
among females	49	(51.0)	47	(46.5)	37	(37.0)	0.129
To be a role model	60	(39.2)	49	(31.0)	56	(35.9)	0.313
Presence of health problems	50	(32.5)	50	(31.8)	52	(32.3)	0.993
External pressure	42	(27.5)	35	(22.2)	35	(22.2)	0.451
Pregnancy	6	(4.0)	4	(2.5)	8	(5.1)	0.490
How much confident are you to be able to quit smoking?							
Not at all	1	(0.7)	3	(1.9)	3	(1.9)	0.916
A little	72	(46.5)	66	(42.3)	67	(41.6)	
Somewhat	71	(45.8)	76	(48.7)	81	(50.3)	
A lot	11	(7.1)	11	(7.1)	10	(6.2)	

TCM. This sample size has 80% power to detect an improvement of success rate of 15% due to TCM use with a 0.05 significance level.

3. Results

Six hundred subjects underwent the initial interview, and 477 met the inclusion and exclusion criteria and were enrolled. 123 subjects were not enrolled because they did not agree to the randomization, refused to sign the informed consent form and/or were already on antismoke drug therapy and/or smoked only cigars or pipe. Of the remaining 477 subjects, 156 underwent sham TCM and group psychological support (group A), 159 true TCM and group psychological support (group B) and 162 only true TCM (group C). (see Fig. 2).

Table 1 reports the socio-demographic characteristics of the study participants. In all three groups, 36% of the recruited subjects were males. The mean age was significantly lower in group A (47.7 years) compared to group B (51.4 years) (p = 0.006) and group C (50.0 years). Group A had a cultural level lower than the other two groups (p = 0.057). There were no significant differences in terms of employment and marital status. The majority of study participants was employed, and about half was married. More than half of study participants reported health good or very good at the time of recruitment. A difference between the three groups was found in the proportion of subjects who declared a state of perceived poor

health, which was higher in group B (13.3%) and in group A (11.5%) compared to group C (3.7%) (p = 0.033). The diagnosis of respiratory diseases varied from 21.2% in group A to 28.9% in group B (p = 0.269), that of circulatory disorders is about 20% in the three groups as well as digestive problems. The proportion of obese was higher in group B (15.1%) compared to groups A and C (6.4% and 6.8%, respectively).

At the time of recruitment the subjects smoked a median of 20 cigarettes per day (range 10–80 cigarettes per day) (Table 2), for slightly more than 30 years (range 10–65 years). More than 75% of the subjects had already tried to quit smoking before the study, mostly alone. Some also had used psychological support groups and acupuncture. The main reasons for which they wished to quit smoking were the fear of future illness and the desire for greater self-control. Among females also prevailed the aesthetic reason. Slightly more than half of the subjects had great or very great confidence to quit smoking. In the three groups we did not find significant differences in important socio-demographic characteristics, in the health status and in smoking characteristics. It has been suggested that the spousal smoking status can influence the ability to quit smoking [25], but our sample was too small to draw any conclusion.

The mean participation in the psychological support groups was for 7.0 sessions for Group A and 7.1 sessions for Group B. The mean number of TCM treatments was 2.65 for Group A, 2.69 for Group B, and 2.84 for Group C.

After the treatment, the percentage of subjects who had quit smoking was 57.1% (Group A), 59.1% (Group B) and 49.4% (Group C), with no significant differences between the groups (p = 0.181) (see Fig. 3).

At the end of the intervention in the subjects who were still smoking the Fagerstrom test dropped from 6.7 to 5.0 (Group A), from 6.6 to 4.9 (Group B), and from 6.5 to 5.0 (Group C), without a significant difference between groups (see Fig. 4).
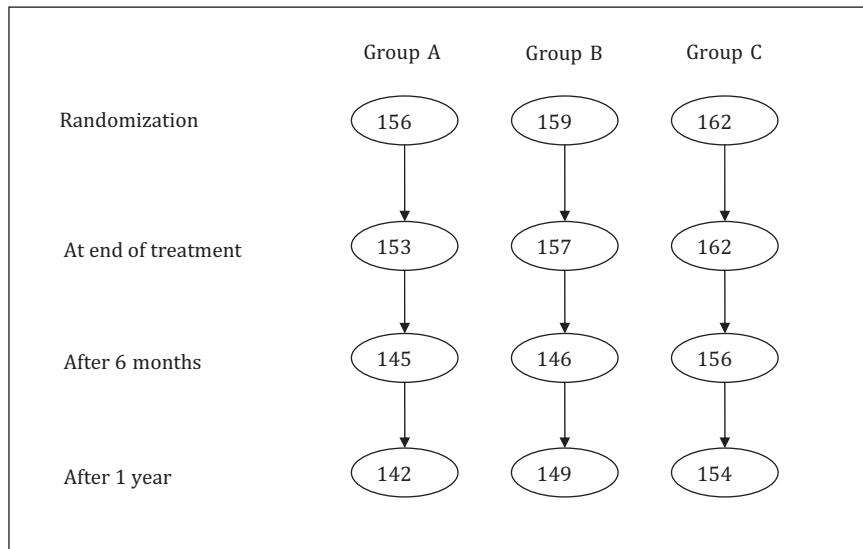
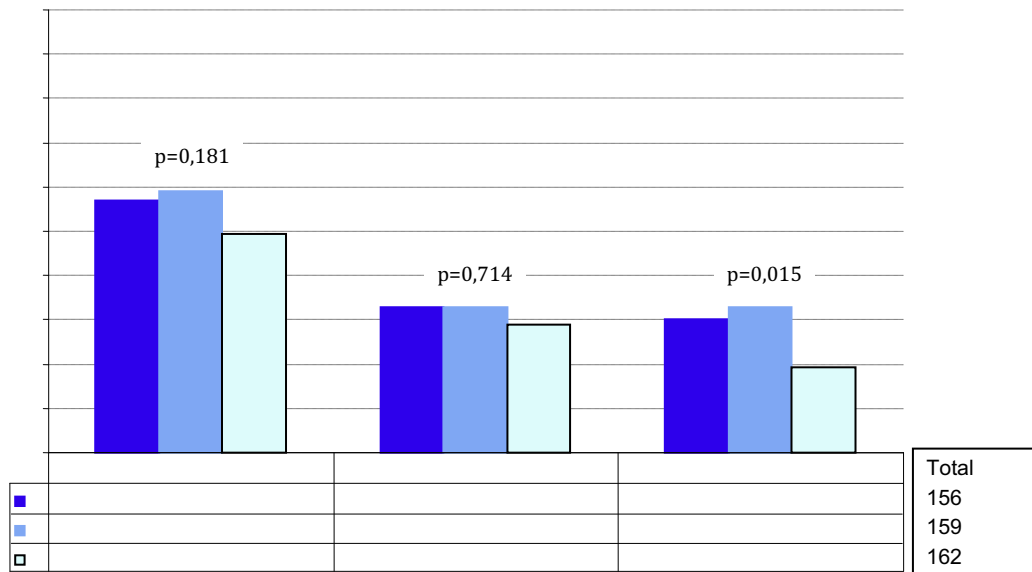**Fig. 2.** Flow chart of randomization and follow-up of the study subjects.

Fig. 3. Percentage of non smokers in the 3 groups at enrolment, at the end of treatment and at follow-up.
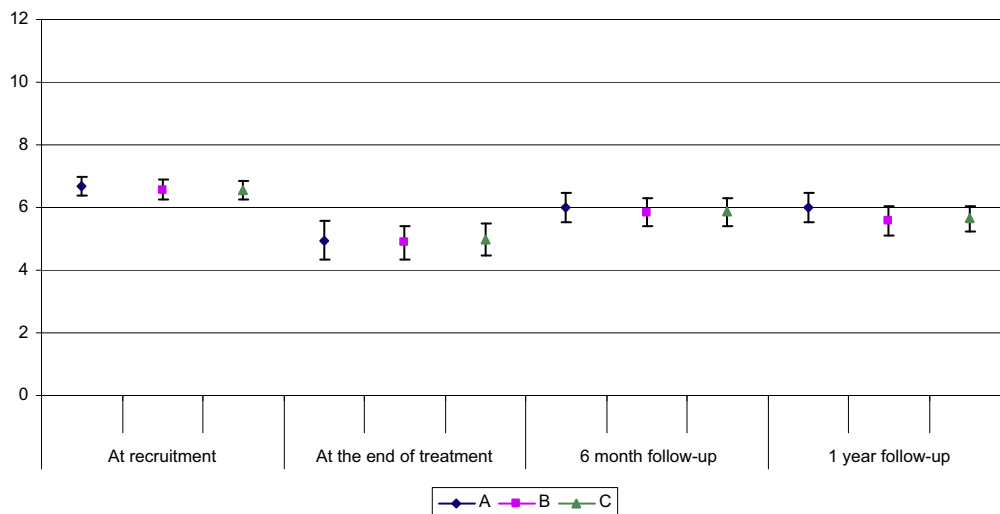

Fig. 4. Mean and 95% confidence interval of the nicotine dependence test in the smoking subjects.

At six-month follow-up, the percentage of non-smokers had decreased. In group A non-smokers were 37.2%, in group B 37.2%, and in group C 29,0%. There were no significant differences between the 3 groups. The average value of the Fagerstrom rose to 6.0 (Group A), 5.8 (Group B) and 5.9 (Group C), with no significant difference between groups.

The main reasons reported by the subjects who restarted smoking were the following: pleasure, habit, weakness, stress.

After 1 year, the percentage of non-smokers was significantly lower in group C (19.1%) than in groups A (30.1%) and B (32.7%), and the Fagerstrom test increased to 6,0 (Group A), 5.6 (Group B) and 5.6 (Group C) without a significant difference between groups.

The concentration of carbon monoxide in the exhaled breath at the annual follow-up was controlled in 70% of those who declared to have stopped smoking. All controls (n = 91) were in the normal range (CO less than 8 ppm).

No serious adverse events associated with either real or sham TCM were reported by the subjects except for occasional minor bleeding.

4. Discussion

Our study shows remarkably relevant results in terms of percentage of smoking cessation, also after 1 year of follow-up. In the group with TCM alone (Group C) the percentage of non smokers after 1 year was 20.1%, a result comparable with or better than other data in the literature (Bier 20%, Wu 16,6%) [13,26]. When TCM (sham or true) was combined with support group (groups A and B respectively), the percentages of smoking cessation are very high (33.1% and 34.9% respectively). Multimodal interventions are recommended by US and European guidelines for smoking cessation, because their effectiveness is higher than unimodal interventions. These results are in line with the data from other study, like for example Bier [13] who showed a 40% smoking cessation rate after 1 year with acupuncture and psychological treatment. Other authors have shown smaller percentages of success after a combination of pharmacological and psychological treatment: after 1 year of follow-up, Tonnesen showed that non smokers were 25% and had more side effects [27]. These results are consistent even if there is a non significant difference between true and sham TCM.

Injection of pharmacologic substances into acupuncture points have been shown to potentiate and prolong their effects up to 3 months after the end of the treatment series [45].

In our study the difference between true and sham treatment was not significant. This is in line with part of the literature, where many randomized controlled trials on smoking cessation do not report significant differences in efficacy between true and sham acupuncture [2,26,28–31].

In some cases the sham points were located in different parts of the body or of the ear [26], while in other cases the sham acupoints were very close to the true points [2].

It could be argued that when the sham acupoints are very close to the real acupoints the distance is not enough to stimulate a different effect, while when the sham acupoints are very distant from the real ones the blinding of the subject may not be very efficient. In fact for the first case, using sham acupuncture by needling at a distance of 5 mm from the real acupoint, one study has shown a difference between sham and true acupuncture [13] while another has not [2], thus making this a controversial area. Measuring the dimensions of the acupoints is a research area with very difficult technical issues, however one study has shown that the extension of the area of the acupoints is 4 mm, thus making the distance of 5 mm a safe one for sham acupuncture [32]. For the second case, needle insertion in different part of the body elicits different physiological responses, which may interfere with the results sought. In fact many researchers believe that placebo acupuncture is not inert, thus making sham acupuncture not a feasible placebo for acupuncture studies. In smoking cessation White et al. [33] concluded that there is no point-specificity in the ear acupuncture treatment, and that the true acupoint treatment may not be different from the treatment of sham acupoints.

However some authors have hypothesized that in some cases sham acupuncture procedures may not differ from true acupuncture interventions because the control procedure is not inert (for example see Ref. [34]). A recent Cochrane revision on placebo studies [35] has highlighted the fact that physical placebos, including sham acupuncture, have stronger effects when compared to a no-intervention control group rather than pharmacological placebos. This is confirmed by a metaanalysis of 37 trials with a total of 5754 patients, in which sham acupuncture showed large nonspecific effects [36]. It has been shown that interventions as small as light tough of the skin activate slow conducting unmyelinated (C) afferent fibers which eventually induce an emotional and hormonal response. These non-specific responses may be even bigger with stronger stimulations such as those used in sham acupuncture. Expectancy also may influence acupuncture control, and it also shares many pathways of the true acupuncture response, such as opioid and CCK system activation (for a review see Ref. [37]).

Thus sham acupuncture could make it difficult to identify additional specific effects and may generate false negative results [38], and other approaches, such as pragmatic designs, could be more appropriate.

However the response to sham acupuncture in our study is remarkable, in that it was higher than the response that has been reported to no treatment. An overview of 12 systematic reviews, including 11 Cochrane reviews, found that the response to no or minimal interventions was low, below 20%, and after 6 months the smoking cessation rate for placebo was 3% − 14%, with an overall average cessation rate of 8.4% in 57,867 participants on placebo [39].

Our treatment with TCM included interventions like pharmacopuncture which are a new evolution of typical TCM practices. Traditional medicines are now applied in a globalized world, and the exposition to different cultural contexts has led to modifications, for example innovations in techniques like pharmacopuncture [18]. It has been shown that the injection of various substances in the acupoints potentiates and prolongs their effects [40], and this integration between Western medicine and acupuncture has been shown to be effective in different pathologies [41–44]. For many years especially in the West local anesthetics have been injected into ear acupoints (including Shenmen) to treat various conditions, mainly psychological [45].

5. Conclusions

The aetiology of smoking is multifactorial, so smoking cessation could benefit from a multimodal programme. After an intervention with psychological support groups combined with TCM, about 30–33% of smokers quit smoking, in line with other studies which have shown that multimodal interventions are more effective for smoking cessation. Our multimodal intervention had the additional benefit of no side effects.

There was no difference between true and sham TCM. This could be due to the controversial use of sham acupuncture, which is not inert, or a lack of point specificity for smoking cessation treatments.

Further studies are needed to determine TCM efficacy compared to placebo, to explore its cost effectiveness, and to explore the reasons of treatment failure with qualitative studies.

Conflict of interest

Acknowledgements

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