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Motivational Intervention and Nicotine Replacement Therapies for Smokers: Results of a Randomized Clinical Trial

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1. Introduction

The World Health Organization (WHO, 2003, 2011) estimated that at international level approximately 1.3 million people currently smoke cigarettes or other products. Almost one billion men and 250 million women, and about 6 million people die each year from diseases related to smoking. Related diseases comprise different types of cancer (lung, larynx, oral cavity), cardiovascular (atherosclerosis, stroke), respiratory diseases (acute and chronic), alterations in the reproductive system, dental problems (leukoplakia, gingivitis, among others), peptic ulcer and some diseases of eye, diabetes.

In the last two decades different interventions have been developed for smoking cessation, resulting from the World Health Organization Framework Convention on Tobacco Control (abbreviated WHO FCTC), in which emphasize among other actions, the importance of scientific research to develop programs for smoking cessation and for the treatment of nicotine addiction (WHO, 2003). Such interventions include non-pharmacological (psychological) and pharmacological approaches (nicotinic and non-nicotine treatments). Some authors point out that the combination of a psychological intervention with any pharmacological intervention significantly increases the likelihood of success for quitting, however, the results are not conclusive (Ingersoll & Cohen 2005; Prochazca, 2000). In this sense, there have been different clinical trials with the purpose of evaluate systematically and empirically the effectiveness of the combination of these interventions.

2. Psychological interventions for smoking cessation

Different studies showed that psychological treatments, specifically those that employ behavioral and cognitive-behavioral techniques are effective for smoking cessation (Lancaster & Stead, 2011). These techniques include control of stimuli, cue exposure, the handling of contingencies, smoking fast, gradual reduction of ingestion of nicotine and tar (GRINT) technique, nicotine fading, self- control techniques and coping skills (prevention of relapses, skills training), solution of problems and social support (Dodgen, 2005; Fiore, et al., 2000; Foxx & Brown, 1979). Behavioral cognitive interventions focus on cognitive and

emotional processes associated to the consumption of tobacco. Recognizes the existence risk situations in which it is likely the person smokes, and identify them. These risk situations could include cognitive aspects, and/or emotional expectations, as well as places, friends or holidays. The identification of situations of risk provides training in coping skills, which can also be cognitive and emotional (cognitive dissonance, restructuring of thought, relaxation), and/or behavioral (avoidance of the situation, social skills, etc.).

3. Nicotine Replacement Therapies (NRT)

Nicotinic replacement therapies seek to reduce smoking and the withdrawal symptoms, consequently increase the probability of remaining abstinent. Reviews of various clinical trials indicate that all types of nicotine replacement therapy (nicotine gum, transdermal nicotine patch, nasal spray, inhaler, and sublingual tablets / pills) can help the people who try to quit smoking to increase the likelihood of maintaining abstinence and all are superior to placebo (Einsenberg, Filion & Yavin (2008)). Also remarks that the effectiveness of nicotine replacement therapy does not increase with the inclusion of some support program as a psychological intervention (Stead, et al., 2011). Some clinical trials in this regard, incorporate in experimental conditions the combination of a psychological intervention with some nicotine replacement therapy mainly with nicotine patch and gum with nicotine.

Richmond, Kehoe and Almeida (1997) analyzed different clinical trials showing that the combination of nicotine replacement therapy and cognitive behavior intervention is more effective. The purpose of the study was to determine the effectiveness of transdermal nicotine patch in combination with a cognitive-behavioral program. Participants (305) were randomly assigned to two groups: the active nicotine patch or the placebo patch group. The subjects of the active group received weekly patches until completing 10 weeks, 21 mg of nicotine / day for 6 weeks, followed by a dose of 14 mg/day for two weeks, and 7 mg of nicotine / day in the past two weeks. All subjects attended to a multicomponent cognitive behavioral program designed to promote the attitude and behavioral change in smokers, consisting in-group sessions of 2 hours/ week for five consecutive weeks. All measures (point prevalence, continuous and prolonged abstinence), abstinence rates at 12 months were consistently twice higher for those who wore nicotine patch compared with placebo.

Another clinical trial shows that telephone counselling in addition to NRT also increases abstinence rates. In this clinical trial 854 smokers were assigned to NRT (nicotine transdermal patches 21 mg, 14 and 7 mg for 10 weeks) alone or NRT and telephone counselling (5 sessions spaced according to a relapse-sensitive call schedule). Abstinence rates were significantly higher in participants receiving telephone counselling than among those not receiving telephone counselling at both 3 and 6 months. In addition, abstinence rates at 6 months were significantly higher for participants receiving counseling. The combination of telephone counselling and NRT was superior compared with NRT alone (in 28 continuous day abstinence at 3 months, 1.6% vs. 25.1%, and at 6 months 30.1% vs. 22.4%) and for 90 continuous day abstinence at 6 months 26.7% vs. 18.6 % (Macleod, Arnaldi & Adams, 2003).

Alterman, Gariti and Mulvaney (2001) evaluated the efficacy and cost of three levels of medical-behavioral treatment intensity in combination with NRT. A low-intensity group

received eight weeks of NRT and one advice and education session, a moderate-intensity group received NRT and four advice and education sessions, and a high-intensity group received the combination of NRT, four advice and education sessions, and 12 weeks of individualized cognitive-behavioral therapy. Abstinence rates confirmed biochemically at week 9, 26 and 52 after the beginning of the treatment, were higher for the treatment of high-intensity (45 %, 37 % and 35 %, respectively), followed by low-intensity (35 %, 30 % and 27 %, respectively) and moderate intensity (27 %, 12 %, 12 %, respectively). The cost calculated for the treatment of low-intensity was $308, for the moderate intensity $338 and for the high-intensity $582. The results showed that better abstinence rates confirmed biochemically after a year occurred in the groups that received the high and low intensity interventions. Similar results were obtained for African American smokers (Webb, et al., 2010). In such study, 154 smokers using transdermal nicotine patches for eight weeks (four weeks with 21 mg, two weeks with 14 mg, and 2 mg for seven weeks), were randomly assigned to one of two groups, either cognitive–behavioral therapy or general health education. Results showed that 7-day point prevalence abstinence was higher for cognitive behavioral therapy than for general health education, after the intervention (51% vs. 27%), at three (34% vs. 20%) and 6 months (31% vs. 14%).

However, different clinical trials have found negative results. In one study, the effectiveness of NRT alone and in combination with behavioral interventions was evaluated on a population of smokers from a New England Veterans Affairs Medical Center. Participants (2,054 smokers) were assigned to one of four conditions: stage-matched manuals (the manuals were consistent with their stage of readiness to change; NRT (16 hrs / 15 mg for 6 weeks) and manuals; expert system, NRT and manuals; and automated counselling, NRT, manuals, and expert system. The effectiveness at 30 months of stage-matched manuals was of 20.3%. Intervention did not increase with the addition of NRT (19.3%), nor expert system interventions (17.6%), or automated telephone counselling (19.9%) (Velicer et al., 2006), it is interesting to note that in this study the participants were ready to quit.

The effectiveness of cue exposure treatment in smoking relapse prevention in addition to other NRT, nicorette gum 2mg, and cognitive behavioral intervention was at evaluated 1, 3, 6 and 12 months. A sample of motivated smokers received a counselling session and was randomly assigned to one of the four treatments for the prevention of relapses: a) brief intervention; b) cognitive behavioral intervention and gum nicotine; c) cognitive behavioral intervention and cue exposure; and d) cognitive behavioral intervention, cue exposure and nicotine gum. The addition of NRT to the standard treatments did not increase abstinence rates; no differences were observed for the cue exposure conditions, however the same authors questioned the imaginal cue exposure paradigm used (Niaura et al., 1999).

4. Non nicotinic pharmacological therapies

Non nicotinic pharmacological treatments are one option for people who want to quit smoking and need medical prescription. One of the options for this type of treatment is the use of antidepressants, like bupropion, doxepin, fluoxetine, imipramine, moclobemide, nortriptyline, paroxetine, selegiline, sertraline, tryptophan and velanfaxine. Hughes, Stead and Lancaster (2011a) reviewed the results on the effectiveness to quit smoking with the administration of antidepressants finding that bupropion and nortriptyline have long-term

positive effects similar to nicotine replacement therapy, while fluoxetine, a selective serotonin reuptake inhibitor, had minor effects.

Different reviews coincide with the efficacy of the different non-nicotinic pharmacological treatments, being varenicline and bupropion the most effective to increase abstinence rates (Hughes, Stead & Lancaster, 2011a), and varenicline with higher effectiveness (Einsenberg, Filion & Yavin (2008)). Cytisine is an agonist of nicotinic receptors that has been used to treat tobacco dependence for 40 years in Eastern Europe (Etter, 2005) and varenicline is an analog of cytisine (Coe et al., 2005).

Varenicline (Chantix or Champix) is a partial nicotinic receptor agonist that also inhibits dopamine, and it was suggested for smoking cessation (Coe et al., 2005). Reviews of its effectiveness conclude that increases the chances of quitting successfully in the long term between two and three times in comparison with the attempts to quit smoking without pharmacological aid. In addition, varenicline seems to be more effective than bupropion, but the effectiveness compared with nicotine replacement therapy has not fully studied (Cahill, Stead & Lancaster, 2011). Bupropion (Zyban Wellbutrin, Zyban, Voxra, Budeprion) is a non-tricyclic antidepressant that inhibits norepinephrine and dopamine reuptake, and acts as a nicotinic acetylcholine receptor antagonist (Dwoskin et al., 2006; Richmond & Zwar, 2003). Clinical studies showed that bupropion was as effective as the standard antidepressants used at that time in the treatment of major depression, and it was helpful in patients resistant to typical antidepressants (James & Lippmann, 1991). Some reports demonstrated its efficacy in the treatment of smokers (Ferry & Burchette, 1994; Ferry et al., 1992). Bupropion has also been evaluated in combination with psychological interventions under the assumption that in combination with cognitive behavioral therapy abstinence rates are increased. Tonnesen et al. (2003) conducted a randomized, double blind, placebo-controlled study with 707 smokers, 527 smokers received bupropion 300 mg daily for 7 weeks and attended to a behavioral cognitive intervention, and 180 received placebo and a behavioral cognitive intervention. The results showed that abstinence rates were significantly higher for bupropion compared with placebo group. At 12 months continuous abstinence rates were 21% for bupropion and 11% for the placebo group. The authors conclude that bupropion in combination with counselling increases abstinence rates compared to placebo. In addition, McCarthy et al. (2008) conducted a clinical trial with 463 smokers who were randomly assigned to one of four groups: 1) placebo 2) placebo and counselling, 3) bupropion and 4) bupropion with counselling. Counselling sessions were focused in: a) preparation for quitting, b) cope abilities and problems solution (identification of triggers for relapse, analysis of past relapses and relapses in current attempts to quit smoking, and providing psycho education in relation to the distraction and coping), c) relapse prevention (planning long-term relapse) d) social support (empathy, support), e) keep the motivation to quit smoking by encouraging the participants to identify and record the reasons for quit smoking and developing strategies to remind themselves these reasons after they quit smoking. Prolonged abstinence rates obtained at the end of the treatment, at 6 and 12 months were for placebo group 25.1%, 16.8%, 14.2%; for bupropion (50%, 25% and 18.1%), and for bupropion and counselling (50%, 25% and 18.1%). The authors concluded that the group that received bupropion was more effective than the groups receiving placebo, and the inclusion of counselling plus bupropion did not increased abstinence rates significantly.

The combinations of bupropion with cognitive behavioral interventions of different intensity have been evaluated. In a randomized clinical trial, 1524 smokers were randomly assigned to one of four groups: 1) bupropion (150 mg) and moderate behavioral counselling (telephone program based on cessation strategies), 2) bupropion (150 mg) and minimal counselling (self-help mailed materials), 3) bupropion (300 mg) and moderate behavioral counselling, or 4) bupropion (300 mg) and minimal behavioral counselling. Three month follow up shows that groups of bupropion with doses of 300 mg and minimal and moderate behavioral counselling had higher abstinence rates (35% and 26.7% respectively) than the groups that received bupropion (150 mg) and minimal and moderate behavioral (24.4% y 24.2% respectively). At 12 months the abstinence rates changed mainly in the groups of moderate behavioral intervention; groups that used bupropion 150 and 300 mg with a moderate behavioral program had higher abstinence rates (31.4 % and 33.2 %, respectively) than with the bupropion 150 mg and 300 mg groups with a minimal behavioral program (23.4% and 25.7%, respectively) (Swan et al., 2003). The results show that there is an advantage associated with high doses of bupropion for smoking cessation in a three months period but not in 12 months, similarly to other clinical trials. In a similar study with 1524 participants using the same doses of bupropion in combination with behavioral interventions of minimal intensity (tailored mailings) or moderate intensity (proactive telephone calls), it was found that 150 mg of bupropion combined with either behavioral intervention was the most cost effective (Javitz et al., 2004).

Venlafaxine, a reuptake inhibitor of serotonin and norepinephrine (Redrobe, Bourin, Colombel & Baker (1998)) is another antidepressant used to quit smoking. In a study 147 participants were assigned to one of two groups, velanfaxine or placebo in combination with cognitive behavioral intervention (nine weekly sessions: six personally, three by phone) and nicotine patches (22 mg/day). The results showed that the inclusion of venlafaxine in a treatment program including behavioral intervention and nicotine replacement therapy does not improve rates of abstinence. Venlafaxine improves the abstinence of smokers who consume less than a packet, and has positive benefits on negative affect for all smokers 6 weeks after cessation, time in which there is a greater chance of having a relapse (Cinciripini et al., 2005).

Under the same logic, the search conducted identified two studies, which assessed the effectiveness of the combination with the antidepressant nortriptyline and behavioral intervention. Nortriptyline (Sensoval, Aventyl, Pamelor, Norpress, Allegron, Noritren and Nortrilen) is a second-generation tricyclic antidepressant that inhibits the reuptake of norepinephrine and serotonin with small effects on dopamine reuptake (Fuxe et al., 1977; Robinson et al., 2000).

In the first study, nortriptyline (12 weeks) was more effective than placebo increasing abstinence rates independently of depression history and alleviated a negative affect after smoking cessation; while cognitive behavioral therapy was more helpful in participants with a depression history. Participants were 199 smokers, stratified according depression history and number of cigarettes; participants were randomly assigned to cognitive behavioral treatment or health education program and one of two treatments, nortriptyline or placebo. Nortriptyline produced higher abstinence rates than placebo, independent of depression history. Cognitive behavioral therapy was more effective for participants with a history of depression. Nortriptyline alleviated the negative affect occurring after smoking

cessation (Hall et al., 1998). In the second study, the effect of long-term nortriptyline treatment (52 weeks) in combination with a psychological intervention was evaluated. One hundred sixty smokers were randomly assigned to four different conditions, brief nortriptyline (12 weeks) or extended treatment with their respective placebo groups; all participants received nicotine patches (4 weeks, 21 mg; 2 weeks 14 mg, 2 weeks, 7 mg) and five counselling sessions. Participants in extended treatment continued with drug or placebo until week 52 and 9 monthly additional counselling sessions. The abstinence rates were superior for extended treatment, and superior to placebo; the authors conclude that extended period in combination with psychological interventions induce high abstinence rates (Hall et al., 2004).

Other clinical trials assessed two types of antidepressants with behavioral interventions. The abstinence rates with 12 weeks of treatment with nortriptyline versus bupropion versus placebo, and the addition of behavior therapy intervention versus medical management involving (brief advice and counselling) was evaluated by Hall et al. (2002). In the study, 220 smokers were randomly assigned to one experimental condition: 1) placebo and medical management, 2) placebo and a psychological intervention, 3) nortriptyline and medical management, 4) nortriptyline and psychological intervention, 5) bupropion and medical management and 6) bupropion and psychological intervention. Bupropion and the nortriptyline were more effective than placebo after one year follow up; the effectiveness of bupropion and nortriptyline was similar (bupropion, nortriptyline and placebo with medical advice 29%, 23% and 13% respectively and bupropion, nortriptyline and psychological intervention 29%, 23% and 21%). The authors conclude that the inclusion of a psychological intervention or the increase of contact does not increase abstinence. Another study carried out with 220 cigarette smokers, comparing bupropion vs. nortriptyline vs. placebo in addition with two behavioral interventions; calculate the cost-effectiveness at 52 weeks. Nortriptyline costs was lower than bupropion, psychological intervention cost less than the two drug treatments; however in both cases the differences were not significant (Hall et al., 2005).

Fluoxetine (Prozac) is a specific serotonin reuptake inhibitor (SSRI) antidepressant also used in smoking cessation interventions (Cornelius et al., 1999). Niaura et al. (2002) explored the dose-effect of fluoxetine in smoking cessation. In a blind study, 989 smokers received nine sessions of a cognitive behavioral therapy and were assigned to one of three treatments: 1) fluoxetine 30 mg, 2) fluoxetine 60 mg, 3) placebo. Follow ups at four, 8, 16 and 26 weeks were conducted to identify abstinent participants. The rates of abstinence reached were of 13% for placebo, 12% for fluoxetine 30 mg, and 14 % for fluoxetine 60 mg, at the end of the treatment no significant differences were detected among groups, the authors suggest that there is not enough support to consider fluoxetine as either a first- or even a second-line treatment for smoking cessation.

In another clinical trial using fluoxetine, Saules et al. (2004) evaluated the combination of fluoxetine, the cognitive behavioral therapy and NRT to quit smoking in 150 people aged between 21 and 65 years. It was a double-blind, placebo controlled study, with three groups, a group receiving treatment with fluoxetine 20 mg, a second group 40 mg and a third group received placebo; all participants received 10 weeks of nicotine patch (20 or 40 mg/day) and six weeks of cognitive behavioral therapy. At the end of treatment abstinence rates obtained were of 35.4 % in the placebo group, 43.1% for the fluoxetine 20 mg group and 43.1 % for the

group fluoxetine 40 mg. The results suggest that fluoxetine can moderate withdrawal symptoms, but not improved abstinence rates. Thus, the results obtained by different studies show that behavioral interventions in combination with bupropion, nortriptyline and fluoxetine increase the probability of quitting, although the effectiveness of the first two compounds compared with placebo is substantially higher than fluoxetine.

Naltrexone (Narpan, Revia, Antaxona, Depade) and naloxone (Narcan), opioid receptor antagonists, employed mainly for of alcohol and opioid dependence are other compounds used for the treatment for smoking cessation. There are few studies with naloxone, with contradictory findings. For example, naloxone seems to increase craving (Krishnan-Sarin, Rosen & O´Malley, 1999), and no significant effects on nicotine withdrawal are described (Gorelick, Rose & Jarvik 1988; Wewers, Dhatt & Tejwani, 1998). Regarding the number of cigarettes smoked, a decline was observed with naloxone compared with placebo group (Gorelick et al., 1988; Karras & Kane, 1980), while also negative results are reported (Nemeth-Coslett & Griffiths, 1986). The results obtained with naltrexone are also ambiguous. Covey, Glassman & Stetner (1999), described significant abstinence rates at 3 and at 6 months (26.7% for naltrexone; 15.2% for placebo). The administration of naltrexone with NRT do not induce significant effects on smoking abstinence; 100 participants were given 12 weeks treatments: either placebo, naltrexone (50 mg daily), placebo with nicotine patches (21 mg/24-hour during first 8weeks, 14 mg/24-hour the last 4weeks), or naltrexone with nicotine patches (Wong et al., 1999). The use of naltrexone and nicotine patches in combination with cognitive behavioral treatment based on the community reinforcement approach (CRA) was evaluated in 25 abstinent smokers (smoking 15 cigarettes daily for at least 5 years, with 3 attempts to quit smoking in the last 5 years). The treatment lasted 8 weeks; the first week naltrexone from 5 mg to 25 mg was given orally, all participants received nicotine patches (21 mg/ 24 hrs to 7 mg /24hrs). On week 2, naltrexone doses were administered to four groups: 1) 25 mg of naltrexone, 2) 25 mg of naltrexone and CRA 3) naltrexone 50 mg, and 4) 50 mg of naltrexone and CRA. The craving decreases in each measurement and abstinence to the 3-month follow up rates were higher for groups who received the CRA and naltrexone compared with those that only received naltrexone (46 % and 25 %). In the 18-month follow up the abstinence rates were higher (17 % and 31 %) in the groups receiving the combination of treatments than that using only naltrexone (Roozen et al., 2006). The meaning of this study is questionable since the follow up was done just at 3 months, it is not a blind study and a placebo group was not included. However, since there are few studies of its effectiveness David et al. (2011) indicate that it cannot confirm or refute whether naltrexone helps people to quit smoking. In addition, the anxiolytics drugs do not have empirical evidence indicating that they are effective for smoking cessation (Hughes, Stead & Lancaster , 2011b).

5. Justification

The results of the literature support and justify the importance of conducting clinical randomized controlled trials, given that the results of this kind of studies derive from practice based-evidence, in other words, results show information about treatment options which allows clinical practice supported by scientific evidence (Nathan et al., 2000).

Specifically in México, in the national survey of addiction conducted in 2008, in the population among 12-65 years, 14 millions (18.5%) were active smokers, the 17.1%

ex-smokers and the 64.4% were not smokers (Secretaría de Salud [SS], 2008). The total number of annual deaths attributable to smoking by associated diseases is more than 60 thousand (daily killed 165 people). Specifically, 38% of these deaths (22 778 deaths) were from ischemic heart disease, 29% (17 390 deaths) due to emphysema, chronic bronchitis, and chronic obstructive pulmonary disease (COPD), 23 % (13, 751 deaths) from stroke and 10% by cancer of lung, bronchus and trachea (6,168 deaths) (Kuri-Morales et al., 2006).

The National Council Against Addictions (Consejo Nacional Contra las Adicciones [CONADIC], Spanish abbreviation), pointed out that in public health institutions the programs developed and currently in use are characterized by using different theoretical and methodological assumptions; the range include from rational emotive therapy, hypnosis, systemic therapy, therapy, cognitive behavioral interventions to NRT (SS, 2002).

So we propose that is necessary to consider aspects related to the effectiveness of treatments, such as: a) the systematic evaluation of interventions to stop smoking in order to know the real impact on the consumption pattern; b) the assessment of psychological interventions when combined with pharmacological treatments; c) the theoretical-methodological congruence of psychological treatments; d) evaluation of abstinence rates at the end of the treatment and follow up (for at least six months), that is, evaluate whether abstinence rates are maintained in the long term. Therefore, the hypothesis underlying this work is that the combination of a brief behavioral intervention with the NRT will induce abstinence rates higher at the end of treatment and follow up (6 months) than each one of the treatments.

5.1 Objective

Then the objective of present study was to assess the effectiveness of brief motivational intervention for smoking cessation applied alone and combined with nicotine replacement therapies.

5.2 Method

Participants: 71 smokers (38 man and 33 women), recruited via advertising and fliers which attended to the Communitarian Center and wanted to participate in the study.

Inclusion criteria: Being between 19 and 60 years; signed informed consent.

Exclusion criteria: Present specific medical condition (hypertension, ulcers, diabetes, some types of cancer, chest pain in the last month), pregnant women, and people who were taking any medication for the diagnosis of major depression, severe anxiety or any other psychiatric disorder.

Setting: Communitarian Center "Acasulco", Psychology Faculty, UNAM.

Instruments and assessment tools:

- Pre-selection questionnaire: consists of ten questions related to the criteria of inclusion and exclusion.
- Initial interview: To obtain socio demographic data, family and social history, work history and place of residence, history of alcohol and drugs (Ayala et al., 1998).

- Fagerström Test for Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker & Fagerström, 1991).
- Brief Questionnaire for Situational Confidence (BQSC) (Sobell et al., 1996; adapted by Ayala, et al., 1998).
- Beck Depression Inventory (BDI) (Beck et al., 1988; adapted by Jurado et al., 1998).
- Composite International Diagnostic Interview (CIDI), in this study only the B section that refers to "Disorders due to tobacco" was used (WHO, CIDI, 1990).
- Beck Anxiety Inventory (BAI) (Beck et al., 1988; adapted by Robles et al., 2001)
- The timeline follow-back (TLFB) (Sobell, Brown, Leo & Sobell, 1996; adapted by Lira, 2002).
- Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES8D), (Miller, 1999; adapted by Cuevas et al., 2005).

Material used in the brief motivational intervention for smoking (BMIS)

- Brochure No. 1 "Deciding to quit"
- Brochure No. 2 "Identifying my situations related to smoking"
- Brochure No. 3 "Plans of action to stop smoking"
- Registration form of cigarettes consumption.

Procedure:

Smokers attending to the Community Center had an admission session. In this in which several instruments were applied to select participants according to inclusion and exclusion criteria: pre-selection questionnaire, informed consent, initial interview, FTND, and CIDI.

Following the identification of the participants according to inclusion and exclusion criteria, all participants undergoing an initial assessment from the application of the following instruments: BQSC, BDI, BAI, TLFB, SOCRATES 8D.

Subsequent to the initial assessment participants were randomly assigned to one of five experimental conditions: 1) BMIS, 2) nicotine inhaler, 3) gum nicotine, 4) BMIS combined with nicotine inhaler, 5) BMIS combined with nicotine gum. At the end of the treatment and at 6 month follow up the initial assessment instruments were applied (see Figure 1).

Brief Motivational Intervention for smokers (BMIS)

The intervention is individual and consists of an admission session, an evaluation session, four sessions of treatment and six months follow up. In the program, the participants receive three booklets of work and self - reports of consumption (Lira-Mandujano et al., 2009). The BMIS is based in the social cognitive theory (Bandura, 1986), uses as main strategy the motivational interview (Miller, 1999; Miller & Rollnick, 1991), the relapse prevention approach (Carroll, 1999; Marlatt, Parks & Witkiewitz, 2002; Piasecki, 2006) and self-control techniques (Cooper, Heron & Heward, 2007; Muñoz, Labrador & Crusader, 2008).

Nicotine Inhalator (10 mg)

This kind of dose NRT was used by the people according to the level of dependency following the doses indicated by the manufacturer (Table 1). All participants were cited once a week to register the consumption pattern and know if they were having severe withdrawal symptoms and giving them, if necessary, more cartridges for the next week.

Dependence Level	Duration	Nicotine gum 2 mg	Inhalator 10 mg
	3 weeks	2mg / 1 -2 hr *	1 cartridge / 1 -2 hr **
Severe	3 weeks	2mg / 2- 4 hr	1 cartridge / 2- 4 hr
	2 weeks	2mg / 4 - 8 hr	1 cartridge / 4 - 8 hr
	3 weeks	2mg / 2 - 4 hrs	1 cartridge / 2 - 4 hrs
Low	3 weeks	2mg / 4 - 8 hr	1 cartridge / 4 - 8 hr
	2 weeks	2mg / 4 - 8 hr	1 cartridge / 4- 8 hr

* No more than 10 gums /day
** No more than 12 cartridges/day

Table 1. Doses for nicotine gum and inhalator

Nicotine Gum (2 mg)

The dose regimen of nicotine gum was according to the dependence level indicated by the manufacturer (Table 1). All participants were cited once a week to register the consumption pattern and know if you were having severe withdrawal symptoms and giving them, if necessary, more gum for the next week.

5.3 Results

The results showed in Figure 1, include all 71 participants (mean age = 43.5) assigned to one of each experimental conditions and with the initial evaluation; only 47 participants with 6 month follow up finished the treatment.

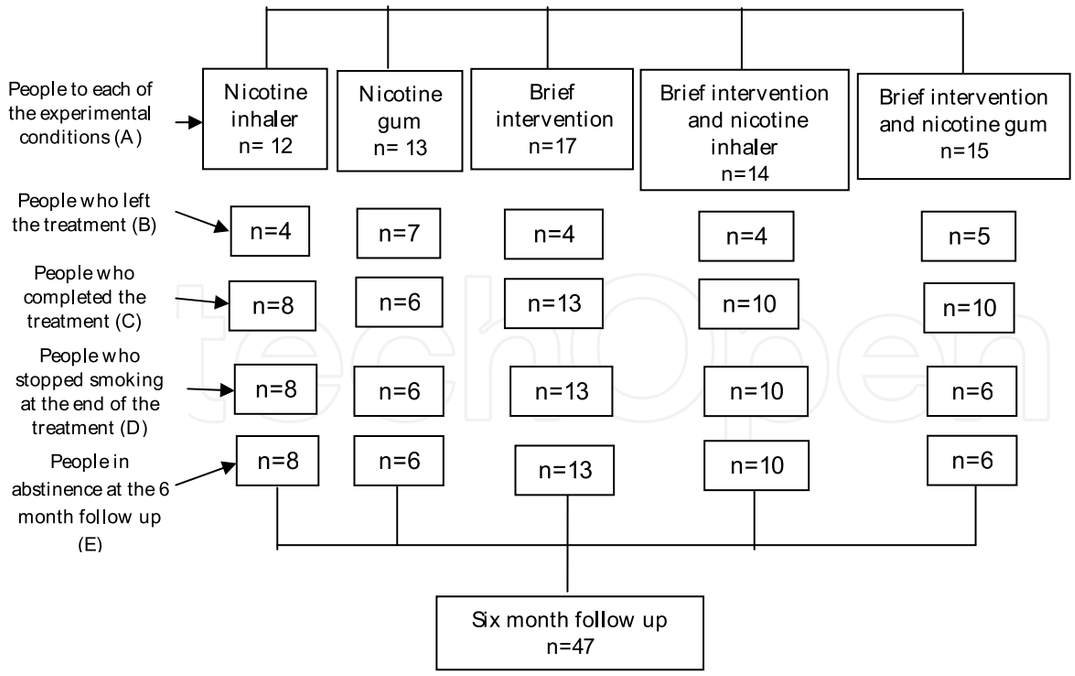

Fig. 1. Number of people in each experimental condition (A); number of persons who left the treatment (B); people who completed the treatment (C); people who stopped smoking at the end of the treatment (D) and people at six-month follow up (E).

In concordance analysis of results of smokers that finish the treatment, comprise:

Initial evaluation

Only the data of participants that finish the treatment and the 6 month follow up were included. Descriptive analysis of demographic variables contained in the initial interview and the corresponding tests were conducted to find out if the variables were homogeneous among groups.

Independent ANOVAS were carried for each variable, age, onset of consumption, number of years of regular smoking, as well as previous attempts to quit smoking. Significant statistically differences were detected for age variable ($F_{4, 62}$=2.55, p=0.048); post hoc test did not detect significant differences; a Kruskal Wallis detected significant differences for the academic level (H (4) = 3. 806, p < 0.001) in the inhaler group compared with the other groups.

Consumption Pattern

A second data obtained were abstinence rates (percentage of smokers that completed a specific treatment and self-declared smoking cessation) obtained at the end of each treatment and at six month follow up. Figure 2 shows that at the end of the treatment, the abstinence rates were higher for the BMIS plus the nicotine inhaler (30%, 40%). At the 6 month follow up a similar picture occurred, followed by BMIS (23% and 38.4 %), nicotine gum group (16.6% and 16.6%), BMIS plus nicotine gum (10% and 20%) and nicotine inhaler (0% and 25%).

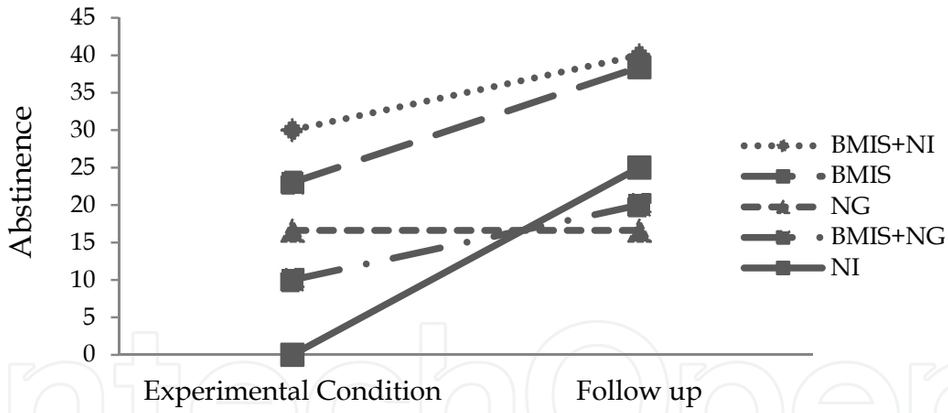

Fig. 2. Abstinence rates obtained in each of the experimental condition at the end of the treatment and 6-month follow up.

A repeated ANOVA (5 x 3; experimental condition x phase of treatment) detected significant differences (F [2.68] = 47. 429, p < 0.001) in consumption pattern for phase of treatment (Figure 3); however, no difference were found for the experimental condition (F [4.34] = 58. 78, p > 0.05). No differences were observed for the interaction experimental condition x phase of treatment (F [6.003, 51.024] = 2. 105, p > 0.05); for this parameter degrees of freedom correction was applied because the data violated the sphericity assumptions. Significant differences on consumption pattern were detected in between baseline, and treatment (p < 0.001) and with regard to the follow up (p < 0.001), but no significant differences between treatment and follow up (p > 0.05).

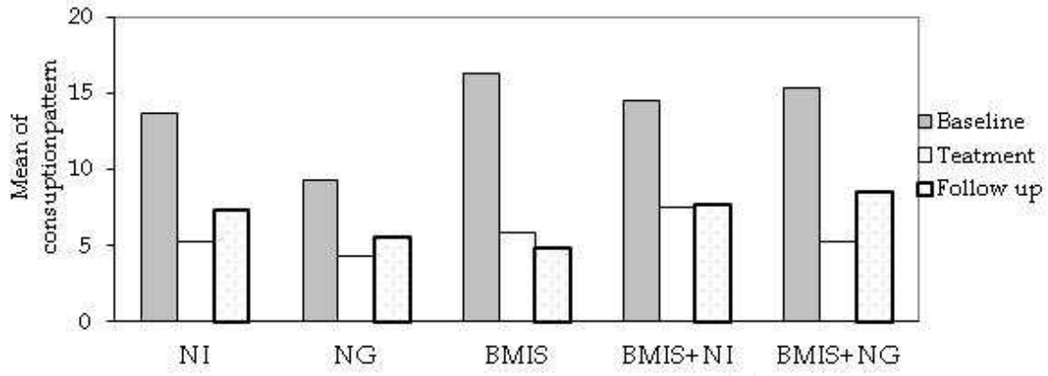

Fig. 3. Shows the mean of consumption pattern of each of the experimental groups (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up (n = 47).

Relationship between the observed variables, and the change in consumption pattern

To assess whether there was any relationship between the changes in consumption pattern, a regression analysis was conducted to see if there was a linear relationship between the change in consumption pattern during the treatment and follow up with regard to the variables. The variables proposed as predictors of change are demographic variables (e.g. sex, age, marital status, etc.), variables related to the initial pattern of consumption, level dependence and group to which he belonged during the study; psychological state related variables as depression and anxiety, and variables of readiness to change in recognition, ambivalence and taking steps.

Change in consumption pattern of during the treatment

This variable was calculated as the mean difference between the initial consumption pattern and during the treatment, regression model points out that the involved variables explain a 59.7% (R^2 corrected =. 597, Se = 5.14) variability in the pattern of consumption during the treatment, which is not a broad but quite acceptable percentage. In Table 2 the standardized partial regression coefficients, the probability that these coefficients were observed in the population and the coefficients confidence interval (95%) are presented. As we know, the standardized regression coefficients indicate the amount of change, in typical scores that will occur in the dependent variable for each change unit in the corresponding independent variable (keeping constant the rest of independent variables). Variables with more weight are more important as predictors of consumption pattern change. In order of importance the variables are: 1) initial consumption pattern (β =. 908), that is, when people had a high initial consumption, declined more his pattern of consumption; 2) level of depression (β =-.884), the sign of the coefficient indicates that when the level of depression was higher in initial evaluation, the change in the pattern of consumption was lower; (3) with respect to the level of readiness to change in recognition (β = 0. 542) when the initial evaluation was high, people decreased more their consumption pattern. The level of anxiety (β = 0. 276), the level of readiness to change in ambivalence (β = 0. 184), and the level of dependency (β = 0. 131) are similar but in much smaller proportion. It is important to mention that belonging to the experimental

condition variable was not significant to predict the improvement in consumption pattern, nor readiness to change in taking before treatment.

Model	No standardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence interval for B	
	B	Std. Error.	Beta			B	Std. Error
(Constant)	-17.381	5.620		-3.093	0.004	-28.874	-5.887
Experimental condition	0.325	0.654	**0.053**	0.497	0.062	-1.012	1.661
Dependence level	1.219	1.309	0.131	0.931	0.004	-1.459	3.896
Initial consumption pattern	0.817	0.127	0.908	6.428	0.000	0.557	1.077
Initial Anxiety	0.186	0.083	0.276	0.223	0.001	-0.152	0.189
Initial Depression	-0.656	0.098	-0.884	-0.670	0.005	-0.266	0.135
Readiness to change in initial recognition	0.545	1.134	0.542	0.480	0.006	-1.775	2.865
Readiness to change in initial ambivalence	1.885	1.126	0.184	1.674	0.001	-0.418	4.189
Readiness to change in initial taking steps	0.687	1.094	**0.697**	0.628	0.535	-1.549	2.924

Table 2. Regression coefficients (no standardized and standardized, significance levels, and confidence intervals), dependent variable is change of consumption during treatment.

Change of consumption pattern in follow up

This variable was calculated as the difference between the means of initial consumption pattern and the consumption in the follow up, regression model points out that the involved variables explain a 39.9% (R ^ 2 corrected =. 399, = 5.66) of the variability in consumption pattern during the treatment. This means, a missing of prediction with proposed variables between the treatments and the follow up, although the proportion explained by proposed variables is still appropriate, additionally the weight of independent variables differed from the previous analysis. Table 3 shows the standardized and no standardized regression and error estimation, the confidence interval and significance levels. The significant coefficients with more weight are: 1) initial consumption pattern (β = 0. 769), 2) level of readiness to change in taking steps before treatment (β=0,290), 3) level of readiness to change in ambivalence before treatment (β = 0, 229), 4) initial level of depression (β = 0, 220), 5) level of dependence (β = 0, 052), and 6) level of readiness to change in recognition before to treatment (β = 0, 038), the coefficients in this analysis are much smaller than previously. Both analyses met the assumptions of regression, both in independence as in the non-collinearity among the variables involved in the analysis.

Changes in anxiety, depression, and readiness to change by experimental condition

- **Anxiety scores**

The analysis of anxiety was carried out with global scores; however, the descriptive statistics was done account for each assessment period. Analysis of variance shows that there are

Coefficients(a)							
	No Standardized Coefficients		Standardized Coefficients	t	Sig.	95% Confidence interval for B	
	B	Std. Error	Beta			B	Std. Error
(Constant)	-12,191	6,184		-1,97	0,058	-24,838	0,457
Initial consumption pattern	0,624	0,140	0,769	4,457	0,000	0,337	0,910
Readiness to change in initial taking steps	2,398	1,159	0,290	2,069	0,048	0,028	4,768
Readiness to change in initial ambivalence	2,112	1,240	0,229	1,704	0,010	-0,423	4,647
Initial depression	-0,147	0,108	-0,220	-1,36	0,018	-0,368	0,073
Group	0,402	0,719	**0,073**	0,559	0,058	-1,069	1,873
Dependence level	0,435	1,441	0,052	0,302	0,008	-2,511	3,382
Readiness to change in initial recognition	0,342	1,248	0,038	0,274	0,008	-2,211	2,895
Readiness to change in initial taking steps	0,263	1,203	**0,030**	0,219	0,828	-2,198	2,724
Initial Anxiety	0,007	0,092	**0,012**	0,078	0,094	-0,181	0,195

Table 3. Regression coefficients (no standardized and standardized, significance levels, and confidence intervals), dependent variable is change of consumption during follow up.

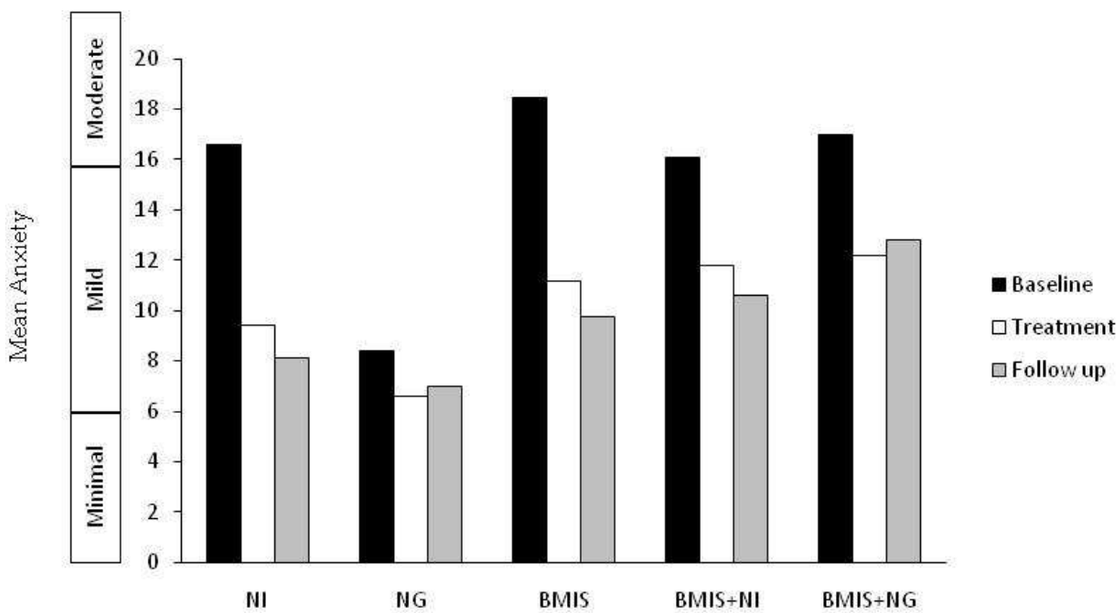

Fig. 4. Shows the mean of anxiety scores for each experimental condition (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up.

differences dependent on the assessed period (F [2.68] = 13. 54, p < 0.001), the Bonferroni test post hoc demonstrated that there are differences in the baseline with respect to the phase of treatment (p < 0.001) and on follow up (p < 0.001). No differences for experimental condition (F [4.34] = 0. 748, p > 0.05) or for the interaction between experimental condition and the phase of treatment (baseline, treatment and follow up) ([5.37, 45.66] F = 24. 85, p > 0.05) were detected (Figure 5).

- **Depression scores**

With the use of an ANOVA again significant differences were found for phase of assessment (F [2.68] = 12.59, p < 0.001), significant differences were detected in initial depression scores and phase of treatment (p < 0.05) and in the follow up (p < 0.05); but not between the phase of treatment with regard to the follow up. No difference for experimental conditions (F [4.34] = 0. 74, p > 0.05), and for the interaction of both factors ([6.06, 51.54] F = 0. 888, p > 0.05) (Figure 5).

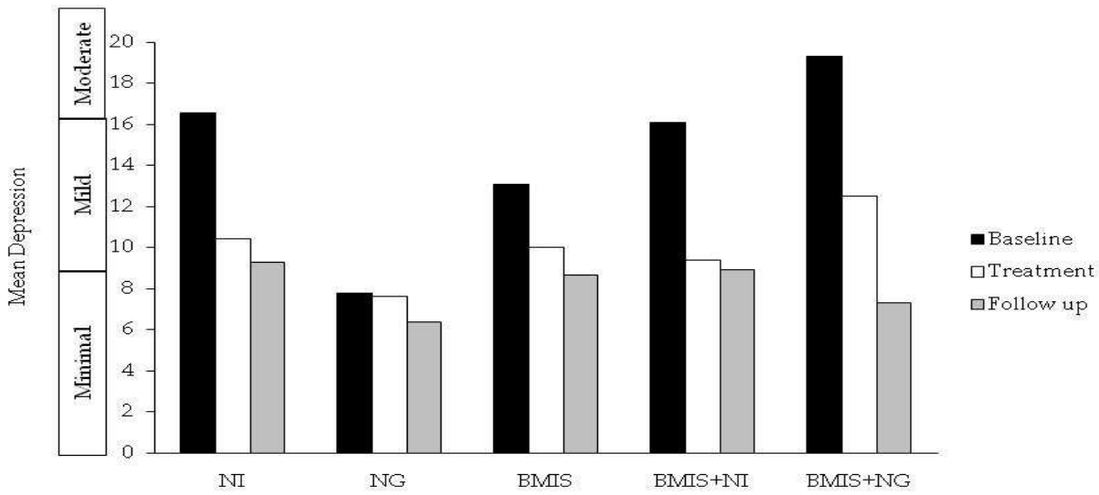

Fig. 5. Shows the mean of anxiety scores for each experimental condition (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up.

Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES 8D)

a. Readiness to change in recognition

According to Prochaska and DiCemente (1983) readiness to change in recognition refers to people who directly acknowledge that have problems related to the consumption of cigarettes, these people have a tendency to express a desire for change and perceive that the damage will continue if they do not do any changes. Analysis of variance did not detect significant differences for experimental condition (F [4.34] = 2.19, p > 0.05), changes in the level of readiness to change depending dependent on phase of evaluation ([1.68, 7.29] F = 1,196, p > 0.05), or for the interaction between the two factors.

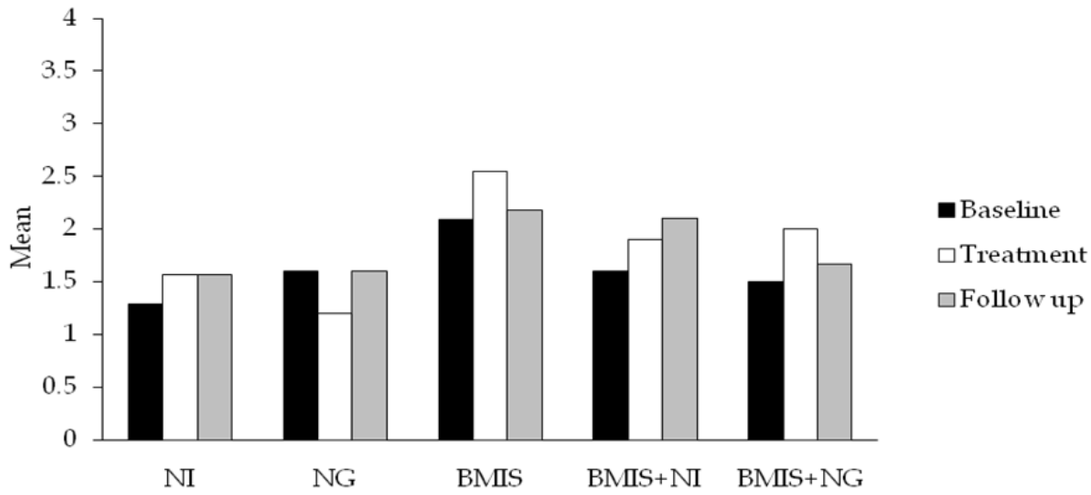

Fig. 6. Shows the mean of stages of change readiness and treatment eagerness scale scores for recognition in each experimental condition (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up.

b. Readiness to change in ambivalence

The ambivalence factor of readiness to change, according to the stages of change proposed by Prochaska and DiClemente (1983) refers to the person that is at a point in which knows that smoking can bring adverse consequences on their health, economy and social but find advantages for smoke. The analysis of variance showed differences for ambivalence relying on the time of evaluation, at the beginning, the the end of the treatment or follow up ([2.68] $F = 6.36$ $p < 0.05$); Bonferroni test was used to identify the differences in pairs of variables (Figure 7), differences were found between the baseline and the treatment ($p < 0.05$) as well

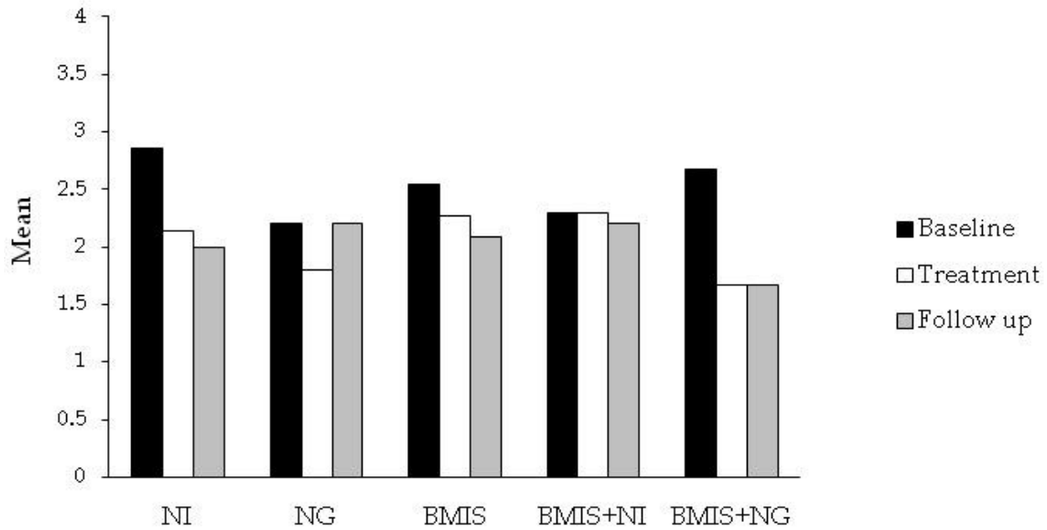

Fig. 7. Shows the mean of stages of change readiness scores for ambivalence factor in each experimental condition (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief

intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up.

as between the baseline and the follow up ($p < 0.05$), but there no differences between treatment and follow up; no differences were obtained for experimental condition ($F [4.34] =. 37.5$, $p > 0.05$), or fo the interaction between variables ($F [5.66,48.13] = 1.07$, $p > 0.05$).

c. Readiness to change in taking steps

Analysis of variance for the level of readiness to change in action showed that there are significant differences for the moment in which the instrument was applied ($F [2.68] = 8.36$, $p < 0.001$), Bonferroni test detected differences between the baseline with regard to treatment ($p < 0.05$) and six months follow up ($p < 0.05$), but not between the treatment and the the follow (Figure 8). No differences were found for groups ($F [4,348] = 0.765$, $p > 0.05$), or due to the interaction between variables ($F [5.95,50.59] = 0.23$, $p > 0.05$).

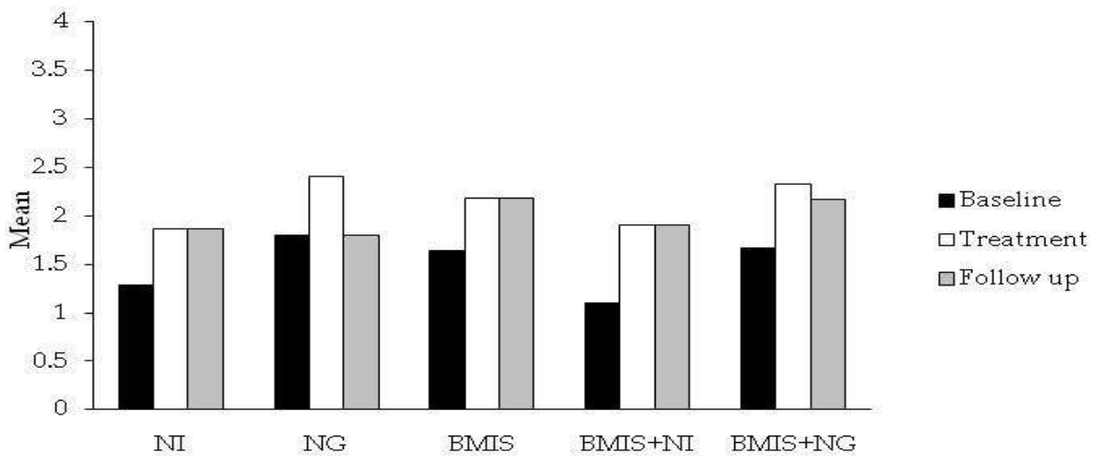

Fig. 8. Shows the mean of stages of change readiness scores for action factor in each experimental condition (NI = nicotine inhaler, NG = nicotine gum; BMIS = brief intervention, BMIS + NI= brief intervention plus inhaler, and BMIS + NG = brief intervention and nicotine gum) in baseline, treatment and 6 month follow up.

One of the specific purposes of the present investigation was to know if there was any relationship between the changes in the pattern of consumption during the treatment and follow up with regard to the observed variables (demographic, initial pattern of consumption, level dependence, group to which it belonged, depression, anxiety and willingness to change in recognition, ambivalence and action). The results obtained from regression analysis showed that no sociodemographic variable (age, sex, marital status) was predictive for reducing tobacco use. However, from a regression analysis, it was noted that the pattern of initial consumption, depression and anxiety as well as the readiness to change in recognition were good predictors to modify the consumption pattern but not to maintain it in the follow up, since their predictive power was lost. Variable with greater weight to change consumption from the baseline to treatment was the initial consumption pattern, i.e. when people had an initial high consumption, after treatment more decreased their consumption pattern.

5.4 Conclusions

Present study assessed the effectiveness of BMIS alone or combined with NRT in the consumption patterns of people who want to quit smoking. The results showed that abstinence rates (Hughes et al., 2003) for inhaler experimental condition combined with BMIS, was much higher at the end of the treatment and at 6 month follow up, followed by the BMIS experimental condition. This is consistent with a previous finding where BMIS has proven to be effective because the people learn a set of skills that allows addressing the specific factors that trigger the consumption of cigarettes (Lira-Mandujano et al., 2009). In the case of the inhaler, different studies have shown its effectiveness to relieve withdrawal symptoms because the absorption of nicotine depends on the administration route (Schneider et al., 2001). In other words, considering only abstinence rates, the hypothesis that increase abstinence rates when combined therapies (NRT and BMIS) are employed, can be accepted.

Clinical trials of last ten years combining NRT with a psychological intervention, show that nicotine patches in combination with a psychological intervention induce higher abstinence rates than the nicotine patch alone (Macleod et al., 2003) and when compared with a placebo group (Richmond et al., 1997). In present study significant differences were not observed between nicotine gum and inhalator in present study, results consistent with last Cochrane review that concludes that all NRT are equally effective and are better than no treatment (Stead et al., 2011).

The effectiveness of the BMIS observed in present study is similar to the reviews indicating the effectiveness of psychological interventions (Becoña, 2004). For all these reasons, the BMIS showed that is equally effective as the NRT. Then present study validates the technique previously used empirically and support the idea that the integrative model is useful for clinical and public health studies.

The brief motivational intervention for smokers initiate by obtaining baseline data related to the history of consumption, factors associated with the consumption of tobacco (depression, anxiety, and willingness to change consumption patterns). Subsequently, the results of such data are provided in order to give a personalized feedback that allows undertaking a decisional balance and thus choosing the technique that the user wants for abstinence. From the delivery of results and choice of technique to achieve abstinence, the user must register their daily consumption and withdrawal symptoms. Then, in the four treatment sessions, where the therapist applies motivational interviewing strategies (express empathy, show reflective listening, support and promote a sense of self-efficacy, develops discrepancy, avoid discussions and arguing) will work the following aspects:

1. Identify the three main triggers of the consumption of cigarettes (situations, states of mood, places, and people), the positive and negative consequences of the consumption of the user from a functional analysis of behavior.
2. With the three main triggers of the consumption, the user set up three strategies to implement them and to reach the abstinence. With the support of the therapist a viable and feasible strategy is selected to cope with the triggers.
3. The user develops an action plan that includes a specific description of how the strategy chosen is going to be applied prior to the trigger.

4. Later, the user must apply the action plan to evaluate the proposed strategies and in this form to apply them to other triggers or to change them to identify the strategies that turn out to be effective to stop smoking.

In the last session of treatment, information related to the consumption of tobacco is obtained to compare with the data obtained initially and a graph is presented where the daily consumption pattern from the baseline and during the treatment sessions to evaluate the advances reached at the end of the intervention and a follow up session is settled. In the session of follow up new information is obtained again with respect the application of strategies to new triggers, to the development of new strategies and for the identification of strategies that already were ineffective, and for the maintenance of the abstinence, for the lapses and relapses.

The analysis of present results suggests that is necessary to include new instruments in the BMIS. The factors inducing the smokers to quit the treatments, like the side effects (e. g. headache, dizziness, nervous, etc.) and the presence of withdrawal symptoms like irritability, anxiety, depression, etc. (Kenford et al., 2002) to different populations, need to be assessed. The literature only identifies seven scales in which the person registers the withdrawal symptoms: 1) *Cigarette Withdrawal Scale* (Etter, 2005), 2) *Mood & Physical Symptoms Scale* (West & Hajek, 2004), 3) *Profile of Mood States Manual* (McNair, Lorr & Droppelman, 1992), 4) *Shiffman Jarvik Withdrawal Scale* (Shiffman & Jarvik, 1976), 5) *Smoker Complaints Scale* (Schneider & Jarvik, 1984), 6) *Wisconsin Smoking Withdrawal Scale* (Welsch, Smith, Wetter, Jorenby, Fiore & Baker, 1999) and 7) *Scale to use on a hand-held computer* (Shiffman, Paty, Gnys, Kassel & Hickcox, 1996).

It is important to develop and instrument equivalent to the Drug Taking Confidence Questionnaire (DTCQ; Annis, Sklar & Turner, 1997) focused on the consumption of tobacco in the Mexican population. One of the components in the relapse prevention model is to identify risk situations and according to this to implement a personalized intervention to prevent relapse that allow maintaining long-term abstinence. That is, this kind of instrument may be included in the package of instruments of the initial component of the BMIS.

Another aspect to assess is the cost effectiveness of the BMIS and the NRT. It has been reported that psychological interventions are more expensive for the training cost and requires much time (Hall et al., 2005). Hall et al. (2005) showed that the psychological intervention was more cost-effective than the nortriptyline, bupropion, but the differences were not statistically significant. However in the case of BMIS, capacitating the personnel is inexpensive and the number of sessions require just 8 sessions. Therefore is important to perform a cost effectiveness analysis of BMIS in order to know which has better cost effectiveness between BMIS and pharmacological treatments. In a preliminary analysis considering only the cost of NRT for 8 weeks, and the material used, the BMIS showed a better cost-effectiveness ratio. It will be important to evaluate the cost effectiveness for new compounds like varenicline (Jorenby et al., 2006; Tonstad et al., 2006), in combination with behavioral interventions.

And finally, an aspect not analyzed but that would be necessary to include are the measurement of biological markers (carbon monoxide in expired air, cotinine concentration

in urine or plasma). This will increase the motivation respect of initial consumption, during and after the intervention and also will help to verify the pattern of consumption reported by the users (Benowitz et al., 2002).

A limitation of present study is the difference in the number of participants in each group at the end of the study, because two factors were not considered. The first factor was the use of a simple random assignment for allocate the participants. The second one was the number of people that abandoned the study. Based on the results obtained in present study, in future clinical trials it would be essential to pay attention in the method of randomization and as a consequence in the number of people assigned to each condition for of a clinical trial.

Lazcano Ponce et al. (2004) proposed the method of randomization of balanced blocks. In his method a series of blocks are assembled, consisting of a certain number of cells, which include the different types of treatment. The number of blocks is determined by the number of participants to be included in the study and the number of cells decided to be included in each block. "Each block will contain in each cell of treatment alternatives and within each block must be a balanced number of possible treatments" (p.569).

In present study data obtained in the initial assessment were used to match groups with regard to the level of dependency to nicotine, age, sex, previous attempts to quit smoking, the use of any NRT, so the groups were homogeneous in regard of these variables. An alternative is identified through the systematic or narrative literature review, in consultation with experts or of the same experience, those factors or variables that at any given time could modify the impact of the treatment on the outcome variable; depending on the feasibility of the size of the sample decide how many layers set up as a priori the allocation of the maneuver (Lazcano-Ponce et al., 2004) and to use the method of stratified randomization, which guarantees treatment balance on these known predictive variables, allowing easy interpretation of outcomes without adjustment.

Finally, an essential methodological aspect regarding the measure of abstinence is to explain the results in terms of: 1) prolonged abstinence (continuous abstinence after an initial grace period or the period of continuous abstinence in two follow ups) as a main measure; (2) the use of the term continuous abstinence only to refer to the prolonged abstinence without grace period; (3) not to use the term of sustained abstinence; (4) include the use of tobacco products other than cigarettes in the definition of failure; (5) do not include the use of nicotine (e.g. the use of NRT) in the definitions of failure and 6) present the results of the analysis of the history of survival (Hughes et al., 2003).

The variable group or experimental condition in relation to the treatment used to quit smoking, was not a good predictor, perhaps by the sample size or because it is interacting with all the other variables and this interaction interacting blur its action. The group CONSORT (Consolidated standards of reporting trials) indicates that would be important to address in the clinical trial the size of the sample, randomization, statistical methods, instrumentation, flow of participants, recruiting and reporting of results (Moher, Schulz & Altman, 2001).

Depression was found to be a predictive variable of change in consumption pattern during treatment, when the level of depression was higher in the initial assessment, the change in

the pattern of consumption was lower. In other words, there is a relationship between the presence of increased symptoms of depression and more difficult to reduce consumption or smoking cessation (Brody, Hamer & Haaga, 2005; Paperwalla, Levin, Weiner & Saravay, 2004; Vázquez, Becoña & Míguez, 2002). Vázquez and Becoña (1999) previously reported that subjects who continued smoking in 12 month follow up presented depressive symptoms in the initial assessment with the Beck Depression Inventory. In addition, Kinnunen et al. (1996) conducted a research with the idea of examine if smokers with high symptoms of depression were less likely to succeed in the treatment to quit smoking than smokers with minor symptoms of depression. The results showed that depressive symptoms were an obstacle to the success of abstinence from smoking.

Theoretically, this is in agreement with the assumption that smoking cessation induces depressive symptoms, since smoking modulates negative affection. People with depressive symptoms are more likely to smoke (this happens more often in women) and when smokers with depressive symptoms are trying to quit smoking have higher probability of not maintaining abstinence (Moreno-Coutiño & Medina- Mora, 2008). For this reason in present study, people with medical diagnosis of major depression where not included, however, some participants showed severe depression according to the BDI. Nevertheless in some cases they stopped smoking or decreased their consumption, therefore in forthcoming studies would be necessary to measure the depression during treatment and obtain abstinence data for more than six months.

A second particular aim of this study was to compare the level of anxiety, depression, and the readiness to change in the application of NRT and the brief intervention alone and combined. The results showed that there were no significant differences among treatments in these variables; only significant differences were detected for phases (baseline, treatment and follow up). Specifically in depression and anxiety significant differences were found between baseline and treatment and between baseline and follow up; in readiness for change in ambivalence existed changes from baseline to treatment and baseline and follow up, and readiness for taking steps action between baseline and treatment. Not any treatment resulted in a significant reduction in depression and anxiety. These results confirm that NRT do not lessen the symptoms of depression and anxiety by which have been used antidepressants and anxiolytics for smoking cessation (Hughes, Stead & Lancaster, 2005a; Hughes, Lancaster & Stead, 2005b; Hughes, Stead, Lancaster, 2008a; Hughes, Stead, Lancaster, 2008b).

Different reports show that there is a strong association between a history of depression and anxiety, and difficulty to smoke cessation (Becoña, 2003; Scheitrum & Akillas, 2002). Goldstein (2003) explains that for people with depression and anxiety antecedents that want to quit smoking and decide to use some NRT, it would be important to use an antidepressant or anxiolytic during the attempt to quit smoking, and for those who despite this combination fail in their attempt to quit would be advisable to combine bupropion with NRT or bupropion with other antidepressant; however, should be assessed its effectiveness (Hughes et al., 2005b; Hughes et al., 2008b).

In present study, the BAI was used to assess anxiety, however, would be important to use the instrument "Anxiety, trait and State" (Spielberger et al., 1998 in, Becoña, 2003) to know if

the people who want to quit smoking and present anxiety trait or state have higher rates of abstinence when they employ a NRT, when they attend to any psychological therapy or when treatments are combined. In addition it is important to investigate whether the anxiety trait or state is a predictor of treatment abandonment or relapse in the follow up. People who stopped using nicotine gum reported that the taste was unpleasant, that they did not feel better and that they continued with craving so they were not interested in continue using it; a possible explanation could be that 2 mg nicotine gum did not decrease withdrawal symptoms, perhaps with the use of nicotine gum of 4 mg effectiveness could increase.

Taken together, the results of this clinical trial including the BMIS and NRT show that the effectiveness for this program did not differ of the effectiveness of NRT, implying that it is just as effective to stop smoking with nicotine gum and nicotine inhaler. Present study is one of the first trials evaluating the effectiveness of the combination inhaler with a psychological intervention.

6. Acknowledgment

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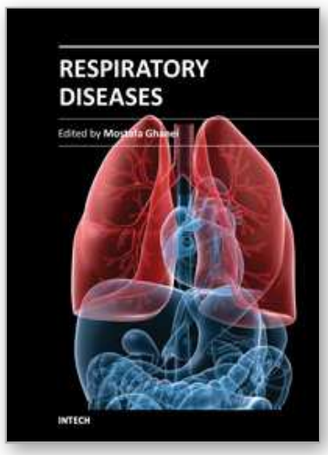

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Medicine is an ever-changing science. In this regard, Respiratory medicine is not an exception and has been evolving during recent years. As new research broadens our knowledge, advanced methods for diagnoses are better understood, providing genetic and underlying pathophysiology of diseases and new clinical experiences. Consequently, publications of new resources along with revisions of previous ones are required. The book Respiratory Diseases brings practical aspects of pulmonary diseases. It contains the result of years of experience through expert clinicians in this field from different scientific centers. The respiratory diseases are discussed according to epidemiology, pathology, diagnosis, treatment, and prognosis. It includes updated resources of the pathogenesis and some molecular aspects of the aforementioned diseases and is recommended reading for all clinicians and medical students, especially pulmonologists, to access highlighted respiratory diseases in this book.

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