

Mindfulness-based treatment for smoking cessation: a randomized controlled trial

Mariana Sponholz Araujo^{1,2}, Lucas Gabriel da Silva³, Gabriel Monteiro Alves Pereira³, Nanci Ferreira Pinto⁴, Fábio Marcelo Costa², Lucas Moreira², Daniella Porfírio Nunes², Mariane Goncalves Martynychen Canan², Maria Helena Santos de Oliveira⁵

- 1. Disciplina de Pneumologia, Departamento de Clínica Médica, Universidade Federal do Paraná, Curitiba (PR) Brasil.
- 2. Departamento de Cardiopneumologia, Hospital de Clínicas, Universidade Federal do Paraná, Curitiba (PR) Brasil.
- 3. Faculdade de Medicina, Universidade Federal do Paraná, Curitiba (PR) Brasil.
- 4. Núcleo de Estudos em Saúde Coletiva do Paraná, Curitiba (PR) Brasil.
- 5. Departamento de Bioestatística, Universidade Estadual de Maringá. Maringá (PR) Brasil.

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Study carried out in the Departamento de Cardiopneumologia, Hospital de Clínicas, Universidade Federal do Paraná, Curitiba (PR) Brasil.

ABSTRACT

Objective: To evaluate the efficacy of a mindfulness-based treatment (MBT) for smoking cessation or reduction and compare it with that of cognitive behavioral therapy (CBT). Methods: This was a single-center randomized controlled clinical trial including 113 patients divided into two groups: MBT (n = 54) and CBT (n = 59). The interventions comprised eight 90-min sessions. The primary outcome was smoking cessation at 16 weeks after program initiation. Secondary outcomes included reduction in the mean number of cigarettes smoked/day at 16 weeks after treatment initiation, as well as smoking cessation and reduction in the number of cigarettes smoked/day at the last program session. Participants had to attend ≥ 50% of the sessions to be included in the primary outcome analysis. An intention-to-treat analysis was also performed. Results: There was no difference between the groups regarding the primary outcome (30.4% in the MBT group vs. 31.6% in the CBT group, p = 0.68) or immediate abstinence rates (47.8% in the MBT group vs. 36.8% in the CBT group, p = 0.47). Both treatments were equally effective in reducing the number of cigarettes smoked/day at the last program session (a reduction of 93.33% [0-100%] in the MBT group and of 70% [33.3-100%] in the CBT group, p = 0.92) and at 16 weeks after program initiation (a reduction of 57.1% [0-100%] in the MBT group and of 70% [25-100%] in the CBT group, p = 0.49). Conclusions: MBT appears to be as effective as CBT for smoking cessation or reduction and can be an option for the treatment of tobacco use disorders in Brazil

(Brazilian Registry of Clinical Trials identifier: RBR-3w2scz [http://www.ensaiosclinicos.

Keywords: Mindfulness; Smoking cessation; Tobacco use disorder; Psychotherapy, group; Meditation; Cognitive behavioral therapy.

INTRODUCTION

Cigarette smoking is the leading cause of preventable death in the world, associated with approximately 8 million annual deaths.(1) In Brazil, 9.8% of adults are current smokers, (2) and it is estimated that 428 people die every day because of smoking-related diseases. (3) In addition, smoking costs the country 56.9 billion Brazilian reals in health care and productivity loss. (3) Although the majority of smokers claim that they want to quit smoking, only 1-5% will achieve long-term cessation without professional help.(4,5)

Most currently available treatments in Brazil are based on cognitive behavioral therapy (CBT), including the smoking cessation treatment provided by the Brazilian Unified Health Care System. Pharmacotherapies can be used in association with CBT, particularly when there is a high degree of nicotine dependence. Although this strategy has yielded positive outcomes in the short term, the cessation rates tend to decrease significantly in the long term. (6)

Mindfulness is defined as the ability to pay attention to the present moment, on purpose and nonjudgmentally.(7) Mindfulness-based treatments (MBTs) were originally targeted at stress and chronic pain disorders. (8) Later, they were successfully used in the treatment of depression, anxiety, (9) eating disorders, and addictions, (10) and only recently have they been adapted for smoking cessation. (11)

MBT targeted to smoke cessation uses meditation techniques in order to increase the awareness of thoughts, feelings, and sensations, especially those related to craving. The goal is to teach participants to step out of the "automatic pilot" that leads to smoking and to cope with cravings until they no longer occur. In contrast to CBT, the focus is not on avoiding triggers, and substitutes are not used. (11)

The efficacy of MBT for smoking cessation has been shown to be similar to or, regarding long-term abstinence maintenance, even greater than that of CBT.(11-13) In addition, MBT has been shown to be associated with mood improvement, reduction in the urge to smoke, and reduction in abstinence symptoms. (14-16)

Correspondence to:

Mariana Sponholz Araujo. Rua Marechal Deodoro, 51, Galeria Ritz, CEP 80020-310, Curitiba, PR, Brasil. Tel.: 55 41 3233-1492. E-mail: mari_sponholz@yahoo.com.br Financial support: None.



To our knowledge, there have been no studies evaluating MBT for smoking cessation in Brazil. The objective of the present study was to evaluate the efficacy of MBT in comparison with CBT for smoking reduction or cessation.

METHODS

This was an open, single-center, randomized controlled clinical trial conducted between May of 2019 and January of 2020 at the Federal University of Paraná *Hospital de Clínicas*, located in the city of Curitiba, Brazil. The study was approved by the local research ethics committee (Protocol no. CAAE 02984118.8.0000.0096) and registered with the Brazilian Registry of Clinical Trials (ReBEC; primary identifier: RBR-3w2scz [http://www.ensaiosclinicos.gov.br]). All participants gave written informed consent before inclusion in the study.

Sample size calculation was performed on the basis of the results of a previous study. (11) We sought to include a total of 120 participants. Given that both interventions required active participation in the sessions, we decided to divide the participants in three groups for each intervention in order to keep the groups sufficiently small (20 participants per group). Participants were recruited through television, radio, Internet, and newspaper advertisements, as well as posters and flyers offering nonpharmacological treatment for smoking cessation.

The eligibility criteria were as follows: being ≥ 18 years of age; being a current smoker with an average consumption of at least 5 cigarettes per day and fewer than 3 months of abstinence in the past year; and being motivated to quit smoking within the next 30 days. The exclusion criteria were as follows: active substance dependence, including alcohol dependence; schizophrenia or panic disorder, diagnosed in accordance with the criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition⁽¹⁷⁾; illiteracy; and use of medication for smoking cessation, including bupropion, varenicline, and nicotine in any form.

Participants were randomized to intervention (MBT) or control (CBT) after stratification based on age (\geq vs. < 40 years old), sex, cigarettes smoked/day (> vs. \leq 20), level of education (\geq complete high school education or < complete high school education), and Fagerström Test for Nicotine Dependence (FTND) scores (\geq 6 vs. < 6).

Both interventions comprised 90-min sessions twice weekly for four weeks. MBT sessions were based on a protocol used in a previous study. (11) The sessions covered theoretical concepts including associative learning, "automatic pilot," and the understanding of thoughts as such (and not as absolute truths). Guided meditations common to several mindfulness programs were used, including the following: the body scan, loving-kindness meditation, sitting meditation, and mindfulness in daily activities. A technique to

work with cravings "mindfully" (i.e., Recognize, Accept, Investigate, and Note what cravings feel like as they arise—RAIN) was also taught. Sessions were conducted by a qualified mindfulness instructor graduated from the Federal University of São Paulo Open Mind Center, located in the city of São Paulo, Brazil, a pulmonologist with experience in smoking cessation, and an undergraduate medical student. CBT was based on the Brazilian Unified Health Care System smoking cessation program, (18) also including exercises from the booklet Passos para uma Vida Livre do Tabaco (Steps to a Tobacco-Free Life)(19) and the American Lung Association Freedom from Smoking program. (20) The sessions were conducted by pulmonologists with experience in CBT for smoking cessation and an undergraduate medical student.

In addition to the in-person group sessions, home practice was suggested and additional materials were provided, including pamphlets, handouts, and recordings. Gradual reduction in cigarette consumption was encouraged, and the quit day was scheduled for the fourth session in both groups.

The primary outcome was smoking cessation at 16 weeks after program initiation. Secondary outcomes included reduction in the mean number of cigarettes smoked/day at 16 weeks after program initiation; smoking cessation and reduction in the mean number of cigarettes smoked/day at 4 weeks after program initiation (after the last session, i.e., immediate cessation); and correlation between attendance rates and percentage reduction in the mean number of cigarettes smoked/day.

Outcomes were assessed with standardized questionnaires administered by interviewers who were blinded to the intervention. Abstinence was confirmed by an exhaled carbon monoxide level of < 8 ppm.⁽²¹⁾

Only participants who attended at least 50% of the sessions were included in the primary analysis of the outcomes, because a minimum attendance rate was required for the learning process. An intention-to-treat analysis was performed, including all of the participants who attended at least the first session, as well as an analysis including only those who attended 75% of the sessions. Dropouts after randomization but before group assignment were excluded.

Participants who were lost to follow-up were considered nonabstinent. In accordance with standard practice in smoking cessation trials, a last-observation-carried-forward analysis was performed to quantify the number of cigarettes smoked/day. [22] In addition, attrition analysis was performed to assess systematic differences between participants with complete data and those lost to follow-up.

Data are reported as means \pm SD for variables with normal distribution or as median (IQR) for variables with non-normal distribution. The unpaired t-test or the Mann-Whitney U test was used to compare continuous variables. Categorical variables were compared by



Fisher's exact test or the chi-square test. The paired t-test or the Wilcoxon test was used for within-patient comparisons. Spearman's correlation coefficient was used to evaluate associations between variables. Differences were considered significant if p < 0.05. Data were analyzed with the R software, version 3.6.2 (The R Foundation for Statistical Computing, Vienna, Austria). Graphs and tables were created with GraphPad Prism software, version 9.2 (GraphPad Software Inc., San Diego, CA, USA).

RESULTS

Two hundred volunteers were assessed for inclusion in the study. Of those, 145 were considered eligible and randomized to MBT (n = 73) or CBT (n = 72). After randomization, 28 participants were excluded because they withdrew from the study before group assignment; 2 participants were excluded because of severe psychiatric disorders not reported during the screening phase (schizophrenia and panic disorder), and 2 were excluded because they were abstinent at the beginning of the trial. In total, 113 participants were included in the intention-to-treat analysis: 54 from the MBT group and 59 from the CBT group (Figure 1).

Both groups were well matched for sex, age, level of education, number of cigarettes smoked/day, and FTND scores. In the MBT group, the number of previous cessation attempts was higher, with 59% (vs. 32% in the CBT group) having tried to quit smoking three times or more. Most of the participants had previously undergone smoking cessation treatment, and previous use of varenicline was more common in the MBT group (Table 1).

Baseline characteristics including sex, age, number of cigarettes smoked/day, and FTND scores remained similar when we evaluated the subgroup of participants with \geq 50% attendance rates. Most (64%) of the participants were women, with a mean age of 51 ± 12 years, smoked > 20 cigarettes/day, and had a moderate degree of nicotine dependence (an FTND score of 5.3). There was a difference between the groups regarding the level of education (p = 0.037), the proportion of participants who had a college degree being higher in the MBT group than in the CBT group (65% vs. 34%; Table 2). Unlike what was observed in the intention-to-treat analysis, there were no differences between the groups regarding previous attempts to quit smoking and previous use of pharmacotherapy. In the MBT group, participants with attendance rates < 50% smoked more cigarettes/ day before the study (17.8 \pm 9 vs. 24.2 \pm 11.8, p = 0.03) and had higher FTND scores (6.4 \pm 2.4 vs. 5 ± 1.8 , p > 0.001).

There were no significant differences between participants who were lost to follow-up and those with complete data regarding baseline characteristics. There was no difference between the groups regarding the primary outcome (smoking cessation at 16 weeks

after program initiation) or immediate cessation rates (Figure 2).

Both treatments were effective (p < 0.001) in reducing the absolute number of cigarettes smoked/day at the end of treatment (a reduction of 19 cigarettes in the MBT group and of 15.5 cigarettes in the CBT group) and at 16 weeks after program initiation (a reduction of 14 cigarettes in the MBT group and of 10 cigarettes in the CBT group). There was no difference between the groups regarding this outcome (Figure 3). The relative reduction in the number of cigarettes smoked/day was = 93.3% (0-100%) in the MBT group vs. 70% (33.3-100%) in the CBT group at the end of treatment (p = 0.92) and 57.1% (0-100%) in the MBT group vs. 70% (25-100%) in the CBT group at 16 weeks after program initiation (p = 0.49).

In the intention-to-treat analysis, there were no differences between the groups regarding abstinence at 16 weeks after program initiation (12.9% in the MBT group vs. 20.3% in the CBT group, p = 0.29) and at the end of treatment (20.4% in the MBT group vs. 23.7% in the CBT group, p = 0.66). However, when we analyzed participants with \geq 50% attendance rates, both therapies were found to be more effective.

When we evaluated the participants who completed 75% of the programs (13 participants in the MBT group vs. 14 participants in the CBT group), cessation rates were found to be higher in both groups. The cessation rate was = 69% in the MBT group vs. 43% in the CBT group (p = 0.32) at the end of treatment and 38% in the MBT group vs. 43% in the CBT group (p = 0.85) at 16 weeks after program initiation.

There was a strong correlation between attendance at the sessions and the reduction in the proportion of cigarettes smoked/day at the last program session and at 16 weeks after program initiation (Figure 4).

DISCUSSION

To our knowledge, this is the first randomized clinical trial evaluating the efficacy of MBT in comparison with CBT in Brazil. This is also the first study to adapt an MBT protocol for smoking cessation in our country. The main findings of the study are as follows: 1. no significant differences between the groups regarding abstinence rates at the end of the programs and at 16 weeks after program initiation; 2. no significant differences between the groups regarding the reduction in cigarettes smoked/day at the end of the programs and at 16 weeks after program initiation; 3. treatment efficacy comparable to that reported in the literature for both treatments and the evaluated outcomes; and 4. a strong correlation between session attendance rates and reduction in cigarettes smoked/day.

Long-term abstinence rates of approximately 16% have been achieved with the use of CBT alone (i.e., without any medication). (4) In Brazil, there is a lack of studies with adequate methodology evaluating CBT as a stand-alone treatment for smoking cessation.



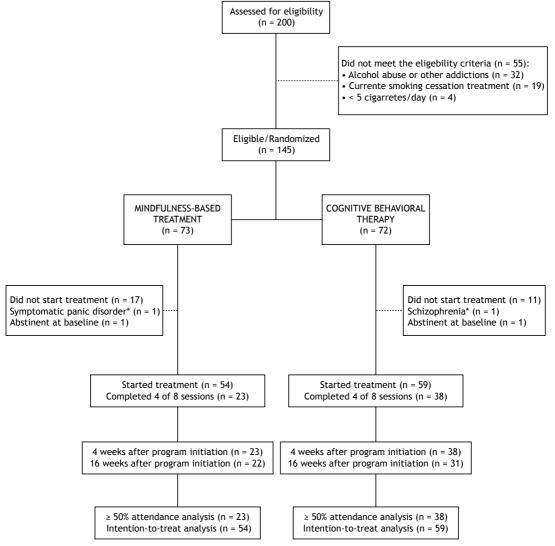


Figure 1. Flow chart of patient recruitment, enrollment, and follow-up. *Not reported at screening.

The available studies are small, are not randomized studies, are retrospective in nature, lack an objective verification of abstinence, or any combination of the four. Nevertheless, we chose to use CBT as a control intervention for several reasons: 1) It is the standard of care in our country; 2) It has demonstrated efficacy in epidemiological studies⁽²³⁾; 3) It has standardized materials; 4) Pulmonologists in Brazil are trained in administering CBT; and 5) The components of CBT are well matched to those of MBT, although the methods proposed for achieving cessation are different.

In a 2013 epidemiological study of CBT-based smoking cessation programs in the state of Paraná, Brazil, (23) 54% of the study participants attended the fourth (and last) treatment session; of those, 41% claimed to be abstinent (although this was not objectively determined). In addition, 61% were also receiving pharmacological treatment for smoking cessation. (23) In the present study, the MBT group

achieved an abstinence rate of 20.4% at the end of the program in the intention-to-treat analysis and an abstinence rate of 47.8% when only participants with \geq 50% attendance rates were evaluated. These results are comparable to those in the literature and are similar to those in the control group in our study.

In the present study, immediate cessation rates were = 47.8% in the MBT group and 36.8% in the CBT group (p = 0.25), whereas, in the study on which our MBT protocol was based, immediate cessation rates were = 36% in the MBT group and 15% in the CBT group (p = 0.063). With regard to long-term abstinence, cessation rates were = 30.4% in the MBT group and 31.6% in the CBT group (p = 0.68) in the present study, whereas, in the aforementioned study, they were = 31% in the MBT group and 6% in the CBT group (p = 0.012). Therefore, the results were comparable between the two MBT groups, whereas the CBT group in the present study performed better



Table 1. Participant baseline characteristics, by treatment group.^a

Characteristic	Overall sample (n = 113)	MBT (n = 54)	CBT (n = 59)	р
Female	69 (61.1)	32 (59.3)	37 (62.7)	
Male	44 (38.9)	22 (40.7)	22 (37.3)	
Age	50.3(11.6)	50.7(12.2)	49.9 (11.3)	0.71
Cigarettes/day	20.8 (9.2)	21.5(11.1)	20.2(7.2)	0.47
FTND score	5.7 (2.2)	5.8 (2.3)	5.7 (2.1)	0.84
Previous therapies	58 (51.3)	28 (51.8)	29 (50.8)	0.91
NRT	39 (34.5)	24 (37)	15 (32.2)	0.58
Bupropion hydrochloride	28 (24.7)	17 (24.1)	11 (25.4)	0.86
Varenicline	7 (6.1)	6 (11.1)	1 (1.7)	0.038
CBT	5 (4.4)	4 (3.7)	1 (5.1)	0.72
Level of education				0.22
< 9 years of schooling	7 (6.2)	4 (7.4)	3 (5.1)	
= 9 years of schooling	5 (4.4)	2 (3.7)	3 (5.1)	
High school (incomplete)	10 (8.8)	7 (13)	3 (5.1)	
High school (complete)	26 (23)	9 (16.7)	17 (28.8)	
College (incomplete)	16 (14.2)	5 (9.3)	11 (18.6)	
College (complete)	49 (43.4)	27 (50)	22 (37.3)	
Previous attempts to quit				0.04
None	14 (12.4)	5 (9.3)	9 (15.3)	
1 or 2	38 (33.6)	15 (27.8)	23 (39)	
3 or 4	36 (31.9)	18 (33.3)	18 (30.5)	
5 or more	18 (15.9)	14 (25.9)	4 (6.8)	
Attendance rate	3.9 (2.5)	3.6 (2.6)	4.2 (2.3)	0.2

MBT: mindfulness-based treatment; CBT: cognitive behavioral therapy; and NRT: nicotine replacement therapy. aData presented as n (%).

than did that in the aforementioned study.⁽¹¹⁾ In a larger clinical trial, in which either CBT or MBT was used in association with nicotine patches, immediate cessation rates were = 42.1% in the MBT group and 39.1% in the CBT group, and long-term cessation rates were = 19.4% in the MBT group and 23.8% in the CBT group.⁽¹²⁾ Similar to our study, no significant differences were found between the two interventions in that study.⁽¹²⁾ However, MBT showed benefits over CBT in promoting recovery from a lapse,⁽¹²⁾ an outcome that was not evaluated in the present study.

Adherence to the programs had a direct impact on the results. This was corroborated by a positive correlation between attendance rates and the reduction in the number of cigarettes smoked/day, as well as by higher quit rates in participants with attendance rates \geq 50% and 75%.

The main strength of our study lies in the fact that we were able to conduct a randomized controlled clinical trial with a diverse sample of smokers, including men and women of different age groups and levels of education. Another strength lies in the fact that the groups were matched for the duration of sessions and proposed home activities. In addition, assessing abstinence with a standardized questionnaire applied by an interviewer who was blinded to the intervention and performing exhaled carbon monoxide measurements made the outcomes more reliable.

We also believe that the statistical analysis based on the attendance rates led to a better understanding of the results.

Our study has limitations that need to be addressed. The high number of dropouts reduced the power of the study and did not allow a detailed subgroup analysis. Withdrawal from the study before intervention assignment was higher in the MBT group, meaning that the number of participants in the MBT group was lower from the outset. This difference was accentuated when the subgroups with a minimum attendance rate of 50% were evaluated. This can be partially explained by the fact that the number of individuals with multiple cessation attempts, previous use of antismoking drugs, or a combination of the two was higher in the MBT group, a difference that disappeared in the subgroup with attendance rates ≥ 50%. Another hypothesis is that MBT might be easier to apply in individuals with a higher level of education, given that knowledge about meditation is more widespread in this population. (24) In our study, groups were well matched for level of education in the intention-to-treat analysis. However, the MBT group showed a higher prevalence of individuals with a higher level of education when we analyzed the subgroup of patients with ≥ 50% attendance rates. In addition, dropouts were higher in MBT group individuals who smoked more and had higher



Table 2. Baseline characteristics of the participants with $\geq 50\%$ attendance rates, by treatment group.

Characteristic	Overall sample	MBT	СВТ	р
	(n = 61)	(n = 23)	(n = 38)	
Gender (%)				0.22
Female	39 (63.9)	12 (52.2)	27 (71.1)	
Male	22 (36.1)	11 (47.8)	11 (28.9)	
Age	50.7 (12.3)	53.7 (13)	48.9 (11.6)	0.15
Cigarettes/day	19.5 (7.9)	17.8 (9)	20.5 (7.2)	0.23
Fargeström	5.3 (2)	5 (1.8)	5.6 (2.1)	0.24
Previous therapies (%)	37 (60.6)	13 (56.5)	24 (63.2)	0.61
NRT	23 (37.7)	10 (43.5)	13 (34.2)	0.77
BUP	18 (29.5)	6 (26.1)	12 (31.6)	0.76
Varenicline	6 (9.8)	5 (21.7)	1 (2.6)	0.06
CBT	4 (6.5)	1 (4.3)	3 (7.9)	0.95
Education (%)				0.037
Incomplete Elementary School	4 (6.6)	1 (4.3)	3 (7.9)	
Complete Elementary School	1 (1.6)	0 (0)	1 (2.6)	
Incomplete High School	4 (6.6)	3 (13)	1 (2.6)	
Complete High School	14 (22.9)	2 (8.7)	12 (31.6)	
Incomplete College	10 (16.4)	2 (8.7)	8 (21.1)	
Complete College	28 (45.9)	15 (65.2)	13 (34.2)	
Previous attempts (%)				0.1
None	8 (13.1)	2 (8.7)	6 (15.8)	
1 or 2	21 (34.4)	5 (21.7)	16 (42.1)	
3 or 4	23 (37.7)	11 (47.8)	12 (31.6)	
5 or more	7 (11.4)	5 (21.7)	2 (5.3)	
Attendances	5.7 (1.7)	6.2 (1.7)	5.4 (1.7)	0.07

MBT: mindfulnes-based treatment; CBT: cognitive behavioral therapy; NRP: nicotine replacement therapy; and BUP: bupropion hydrochloride.

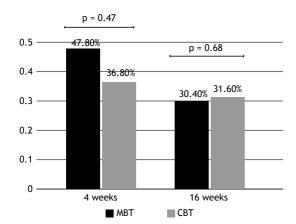


Figure 2. Abstinence rates by treatment group at 4 weeks after program initiation and at 16 weeks after program initiation (subgroup of patients with ≥ 50% attendance rates). MBT: mindfulness-based treatment; and CBT: cognitive behavioral therapy.

FTND scores, situations in which the association of pharmacotherapy is usually recommended. (25)

Missing data rates as a result of loss to follow-up in the long term were higher in the CBT group than in the MBT group (18% vs. 4%). Given that recurrence is common in this scenario, we believe that using the last-observation-carried-forward analysis might have underestimated the number of cigarettes consumed by some of those participants, therefore favoring the CBT group.

Another potential limitation is that the MBT instructors had little experience with the therapy applied. Although we had a certified mindfulness instructor and a pulmonologist with experience in smoking cessation, this was our first experience implementing a mindfulness-based protocol for smoking cessation. Professionals with more experience and maintenance sessions might have achieved even greater results.

In conclusion, the results of the present study indicate that MBT is as effective as CBT in promoting smoking cessation or reduction. If we consider that nicotine dependence is a very difficult-to-treat disease affecting millions of people of different socioeconomic, educational, and cultural backgrounds, we can understand how important it is to have different treatment options. Because MBT uses a strategy that is significantly different from CBT, it might become an interesting alternative, especially in individuals who have been unable to quit by using standard treatment.



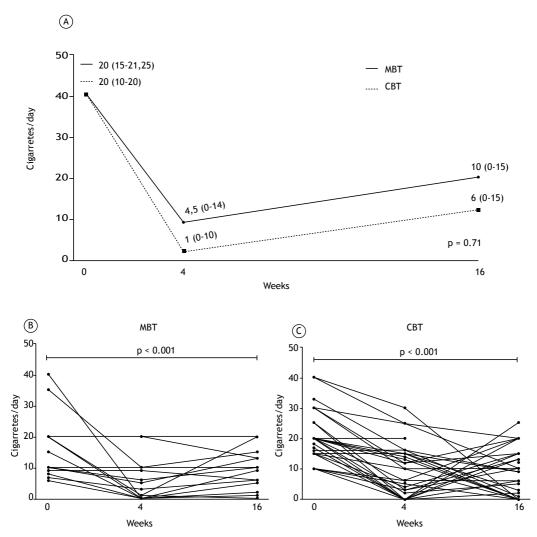


Figure 3. Smoking reduction at the end of mindfulness-based treatment (MBT) or cognitive behavioral therapy (CBT). In A, median number of cigarettes smoked/day in the MBT and CBT groups at 4 weeks after program initiation and at 16 weeks after program initiation. In B, variation in the number of cigarettes smoked/day for each participant in the MBT group (n = 23). In C, variation in the number of cigarettes smoked/day for each participant in the CBT group (n = 38).

Multicenter studies with larger samples are warranted to understand fully the potential of MBT for smoking cessation. Such studies will also be important in identifying the subsets of patients who will most likely benefit from this intervention, as well as in investigating the use of MBT in association with pharmacotherapy.

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AUTHOR CONTRIBUTIONS

MSA, LGS, and GMAP: conception and planning of the study; interpretation of evidence; drafting and revision of preliminary and final versions; and approval of the final version. NFP: conception and planning of the study; drafting and revision of preliminary and final versions; and approval of the final version. FMC, LM, DPN, and MC: planning of the study; revision of the final version; and approval of the final version. MHSO: interpretation of evidence; revision of the final version; and approval of the final version.

CONFLICT OF INTEREST

None declared.



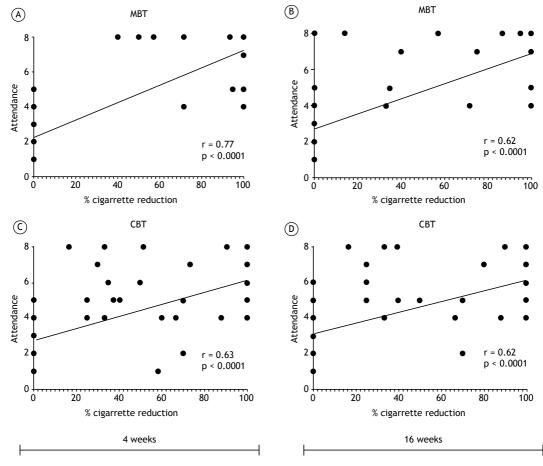


Figure 4. Correlation between smoking cessation program attendance and the percentage of reduction in the number of cigarettes smoked/day at 4 weeks after program initiation (in A and C) and at 16 weeks after program initiation (in B and D) in the mindfulness-based treatment (MBT) group and in the cognitive behavioral therapy (CBT) group.

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