A Randomized Controlled Trial of Mindfulness Based Cognitive Therapy for Treating Tinnitus

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Abstract

We conducted a randomized clinical trial to examine the relative effectiveness of two psychological interventions for treating tinnitus. Tinnitus sufferers were initially offered a single session of psychoeducation about tinnitus, followed two months later, by either 6 weekly sessions of mindfulness or relaxation training. Results indicated benefits from psychoeducation in reducing negative emotions, rumination and the psychological difficulties of living with tinnitus. These effects were maintained or enhanced by mindfulness training that also emphasized acceptance, while they eroded in the relaxation condition over the follow up. Mediating processes are discussed and suggestions for refining clinical interventions for this population are offered.

A Randomized Controlled Trial of Mindfulness Based Cognitive Therapy for Treating

Tinnitus

Tinnitus is defined as an auditory perception without any external stimulation. In most cases, it results from dysfunctional neural activity (Peignard, 2003) that can originate from diverse medical conditions, such as presbyacousy, ear infection, Menière syndrome. Tinnitus varies in terms of the nature of the sounds that constitute it, their frequency, intensity, localization and complexity (Henry & Wilson, 2002). In some cases, the medical cause of tinnitus can be cured. However, in most cases there is no medical treatment, and the individual suffering from chronic tinnitus has to learn to live with and accept tinnitus (Schéry-Croze, 2003). Davis and Rafaie (2000) have estimated that 10 to 14% of the population suffers from prolonged spontaneous tinnitus and that 1 to 2% will develop clinically significant psychological difficulties as a result. The psychological difficulties triggered by tinnitus encompass a large array of emotional symptoms related to depression, irritability and anxiety.

Different psychosocial interventions have been developed to relieve psychological difficulties resulting from chronic tinnitus, with each sharing a common focus on reducing psychological distress, rather than eliminating tinnitus itself. Psychoeducation is featured in most forms of psychological interventions for tinnitus (Clauw, Falise, Hayward, & Philippot, 2006; Dineen, Doyle & Bench, 1997; Henry & Wilson, 2002) and consists of informing clients about the nature of tinnitus, the processes that lead to psychological distress consecutive to tinnitus, and the best ways to cope with tinnitus (including the facts that avoiding and attempting to suppress tinnitus are ineffective strategies). In some cases, psychoeducation is sufficient to restore a normal quality of life in tinnitus suffers (Dineen, Doyle & Bench, 1997; Henry & Wilson, 2002). However, if no significant improvement is

observed within two months, additional treatment is required (Kröner-Herwig, Frenzel, Fritsche, Schilkowsky & Esser, 2003; Zachriat & Kröner-Herwig, 2004).

One such approach is relaxation training. Progressive Muscular Relaxation (PMR; Jacobson,1957) has been extensively studied as a treatment for tinnitus (e.g. Andersson & Lyttkens, 1999; Kirsh, Blanchard & Parnes, 1989; Lindberg, Scott, Melin, & Lyttkens, 1987, 1989; Scott, Lindberg, Lyttkens, & Melin, 1985). The general conclusion of this research is that relaxation is an effective treatment if it is combined with psychoeducation (Coles & Hallam, 1987; Kirsh, et al., 1989; Wilson & Henry, 2000). Biofeedback has also been studied, but research is less conclusive regarding its benefits (Young, 2000).

Other interventions have combined psychoeducation and relaxation with aspects of cognitive behavior therapy (Henry & Wilson, 2002). The behavioral component consists in preventing avoidance of tinnitus or of activities and situations in which tinnitus is feared (Sweetow, 1986). The cognitive component consists of cognitive restructuring targeting dysfunctional beliefs about tinnitus (Henry & Wilson, 2002). Research has established the efficacy of such combined interventions (e.g. Andersson & Lyttkens, 1999; Jakes, Hallam, Rachman, & Hinchcliffe, 1986; Kröner-Herwig, Hebing, Van Rijn-Kalkmann, Frenzel, Schilkowski, & Esser, 1994; Wise, Rief, & Goebel, 1998; for a review see Martinez Devesa, Waddell, Perera, & Theodoulou, 2007). In particular, these combined interventions have been proven more effective than other types of monotherapies (psychoeducation, relaxation, yoga, hypnosis). Observed outcomes have pointed to reductions in negative affect and sleep disturbances resulting from tinnitus. Reviewing studies conducted between 1982 and 1998, Peignard (2003) has estimated that combined interventions including cognitive and behavioral components reduce psychological difficulties resulting from tinnitus by 50% in 74% of the cases. Similarly, a recent Cochrane Collaboration review has concluded that cognitive and behavioral therapy is effective in improving the quality of life of tinnitus sufferers (effect size

is .70) but that there is no evidence of efficacy in reducing tinnitus intensity or depression (Martinez Devesa, Waddell, Perera, & Theodoulou, 2007). Although psychological treatments are effective, there is still ample room for improvement.

The aim of the present study is to examine whether mindfulness training, a new form of psychological intervention that encourages acceptance as the first response to distressing experiences, can reduce psychological difficulties resulting from tinnitus. Mindfulness training is a manualized intervention that teaches participants to maintain their attention on present experience, without judging or analytically processing it (Kabat-Zinn, 1982). Weekly training sessions consist of meditative exercises and group discussion and patients are expected to supplement group sessions with daily homework (40 mins). Baer (2003) has identified possible therapeutic mechanisms including: relaxation, cognitive change, acceptance, exposure, and self-regulation. As argued above, these are precisely the components that are required by psychological intervention in tinnitus. In addition, mindfulness training has also been proven effective for treating chronic pain (e.g. Kabat-Zinn, Lipworth, Burney, & Sellers, 1987; Randolf, Caldera, Tacone, & Greak, 1999), a condition that shares many similarities with the psychological consequences of tinnitus. Further, preliminary data from an ongoing study suggest that acceptance plays an important role in the reduction of the negative emotional impact of tinnitus (Hesser, Westin, Hayes, & Andersson, 2009). Thus, in light of its putative active components and its proven effectiveness in a related condition, mindfulness training offers promise as a psychological intervention for tinnitus.

In the present study, we used a stepped-care design in which tinnitus sufferers were randomly allocated to one of two combined-treatment groups. Both groups first received psychoeducation about tinnitus. Two months latter, one group received 6-weeks of PMR training, while the other group received 6-weeks of mindfulness training. The delay of two months between psychoeducation and training is recommended by the clinical literature

(Dineen, Doyle & Bench, 1997; Henry & Wilson, 2002), this time-lag being necessary to apply effectively and practice what is learnt during psychoeducation. Participants were evaluated before psychoeducation, pre- and post-training (PMR versus mindfulness), and at a 3-month follow-up.

<div style="text-align:center">Method</div>

Participants

The study was advertised in local newspapers as a controlled clinical trial aimed at reducing the psychological distress resulting from tinnitus. Approximately 300 people who responded to this advertisement were informed of the study procedure, of the inclusion and exclusion criteria, and of the ethical considerations relevant to the present study.

Inclusion criteria were (a) tinnitus experienced within the past six months, (b) a medical check-up by a physician specialized in hearing disorders, (c) sufficient hearing capacity to follow instructions delivered during group sessions, and (d) significant psychological distress and impairment in everyday activities resulting from tinnitus. This last aspect was evaluated by the Tinnitus Psychological Impact Questionnaire (QIPA, Philippot, Clauw, & de Romerée, 2010) described bellow; specifically, to be included, participants' mean evaluations of the negative emotions and deteriorated quality of life resulting from the tinnitus had to be greater that 3 (on a scale from 1 to 7) and their quality of life had to be . Exclusion criteria were (a) tinnitus resulting from an organic condition that could benefit from a medical intervention, (b) use of a tinnitus masking apparatus, (c) other psychotherapy or psychological intervention during the study, and (d) borderline or anti-social personality disorder.

Eligible participants were invited to a screening interview which consisted of an anamnesis of the tinnitus and of resulting psychological difficulties, a full diagnosis on the Axis I of the DSM IV (American Psychiatric Association, 1994) as determined in a semi-

structured interview conducted by a clinical psychologist (MINI, Lecrubier, Weiller, Bonora, Amorin, & Lépine, 1994; Sheehan, Lecrubier, Harnett-Sheehan, & al., 1998), the State Trait Anxiety Inventory (STAI, Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), Beck Depression Inventory (BDI, Beck & Steer, 1987), and the psychological impact questionnaire (QIPA, Philippot, & al., 2010).

Thirty participants (18 men) met the inclusion criteria. The most common exclusion reasons were insufficient psychological distress and the fact that the applicant was following another psychological treatment. Selected participants were randomly allocated to the mindfulness training condition or to the relaxation training condition with the restriction that there were equal numbers and gender proportions in each group: Within gender, an equal number of participants was randomly allocated to each condition. Two participants dropped out at the first training session (one was much younger (25) than the average sample), and three were dropped from the analyses, because they missed three training sessions; of these five participants, two were in the mindfulness training condition and three in the relaxation training condition. At debriefing, it was ascertained that none of the participants started a new treatment during the trial. All analyses were conducted on the 25 participants who completed the entire protocol. Participants (mean age : 60, s.d. : 11.53, range : 35-79) were all well educated (22 with a higher education degree). There were no differences in terms of age, gender, educational or clinical status, depression, or anxiety between groups. Demographic characteristics are displayed in Table 1.

Insert about here Table 1.

Tinnitus psychological impact questionnaire (QIPA)

The 42 item QIPA[1] is a recently created questionnaire that has the advantage of evaluating different dimensions of the psychological responses to tinnitus : emotional

reaction, everyday life handicaps, coping modes, and the evaluation of their efficacy (Philippot & al., 2010). It combines a selection of original items and items from Tinnitus Reaction Questionnaire (Wilson, Henry, Bowen & Haralambous, 1991) that evaluates the psychological distress consecutive to the tinnitus, the Tinnitus Handicap Questionnaire (Kuk, Tyler, Russell & Jordan, 1990) that evaluates the handicap induced by the tinnitus, and the Tinnitus Coping Style Questionnaire (Budd & Pugh, 1996) that assesses the coping strategies initiated to alleviate tinnitus distress. Specifically, the QIPA assesses six dimensions of tinnitus experience during the past week. The first dimension measures the amount of time the tinnitus was present on a single item, from 1 ("without any interruption") to 7 ("time to time a day without tinnitus"). The second dimension evaluates the extent to which the tinnitus triggered negative emotions (2 factors, "negative affect", Cronbach's $\alpha = .74$, and "frustration", Cronbach's $\alpha = .94$). A third dimension targets the negative rumination triggered by the tinnitus, Cronbach's $\alpha = .84$, and a fourth dimension, the difficulties in everyday life resulting from the tinnitus (2 factors: "social and professional difficulties", Cronbach's $\alpha = .91$, and "personal difficulties" Cronbach's $\alpha = .78$). The fifth dimension evaluates the coping strategies used (4 main factors: cognitive control, Cronbach's $\alpha = .91$, distraction, Cronbach's $\alpha = .62$, avoidance and acceptance, the two latter being measured by a single item). Finally, the questionnaire meausres the feeling of self-efficacy for the coping strategies used, Cronbach's $\alpha = .73$.

Procedure

Psychoeducation was delivered in single group sessions offered to multiple groups (about 10 participants in each group) during which two psychologists informed the participants about the nature and characteristics of tinnitus, its epidemiology, etiology, as well as adaptive and ineffective coping strategies. The session material was based on a written manual. An independent observer ensured that the information presented was consistent with

the manual's content. At the end of the session, which lasted about 2 jours, participants received a booklet outlining the information provided during the session as well as a two-page self-observation report sheet on which to record their emotions, thoughts and behaviors associated with tinnitus.

Relaxation and mindfulness training started two and an half months following psychoeducation. The training consisted of six weekly group sessions. The two groups were trained in parallel, exactly at the same time, in similar, adjacent rooms of a university psychology department. The groups were instructed by two PhD level psychotherapists, with at least 3 years of practice in mindfulness and in relaxation training, and with a formal training in MBCT. To avoid therapist effects, each instructor alternated in teaching the relaxation or the mindfulness session. Thus, each treatment group received the same amount of training from both instructors.

A manual was constructed for each training condition. To ensure treatment integrity, an observer was present in each group with the task of rating the extent to which the manual content and treatment procedures were adhered to. Weekly briefing sessions gathered observers and instructors to coordinate the intervention and ensure treatment homogeneity and integrity. Before the first training session and after the last one, all participants filled in the QIPA, the BDI, and the STAI. Mid-way between the end of the training and the follow-up, participants received a letter reminding them of the importance of practicing the exercises.

For the follow-up, three months after the end of the training, participants received a letter requesting them to fill in and send back within the week three attached questionnaires: the QIPA, BDI and STAI. This request for the mailing was followed-up by a phone call if required. Finally, 3 months later, participants were invited to a debriefing session. The results of the study were presented, they were fully debriefed and thanked for their participation.

Training manual

Instructors' manuals were created for the mindfulness and the relaxation training intervention. The sessions were organized around similar frames in each treatment condition: They lasted exactly the same amount of time (2 hours and 15 minutes per session); they started with a long exercise (30 minutes), continued with the review of the previous week's homework, before presenting and discussing the specific theme of the session. Finally, all sessions ended with an experiential exercise.

For mindfulness training, the manual was derived from Segal, Williams & Teasdale (2002). The original manual, designed for the prevention of depressive relapse, was adapted in the following ways. First, the content relative to psychoeducation of depression relapse was deleted, as the present treatment target was the psychological consequences of tinnitus. This deletion concerns mostly the content from sessions 4 and 5 of the original program. Second, the number of session was reduced from 8 to 6. The first four sessions were very similar to the original program: They comprised exactly the same exercises, but (a) referred to dealing with the adversity of tinnitus rather than with depression relapse and (b) did not present the psychoeducative part of session 4. The fifth session of the program merged aspects of session 5 and 6 of the original program, focusing mostly on the theme that thoughts are not facts. The main exercise consisted in a 40 min. sitting meditation with a sequential focus on breath, body, thoughts and finally the introduction of a difficult thought in the meditation. The sixth session of the program merged aspects of session 7 and 8 of the original program dealing with how to take care of oneself (relapse prevention) and evaluating the program. The main exercise consisted in a 40 min bodyscan.

For relaxation training, the manual followed the progressive relation training of Jacobson (1957) adapted by Van Rillaer (1997). The first session consisted of breathing training, the second session taught Jacobson relaxation and divided in 13 body parts, the third

session into 8 body parts, the fourth into 4 body parts, and the fifth on 2 body parts. The sixth session focused on mini-relaxation and on maintenance of relaxation competence.

Results

Analysis strategy

Each variable was analyzed with 2 X 2 ANOVAs, with treatment group (mindfulness versus relaxation) as a between-subjects factor and time of measurement as a repeated measure. The first analysis examined the overall effect of treatment by comparing the means at baseline (intake: Time 0) and the 3-months follow-up (Time 3). Then, to assess the specific effect of the psycho-educative component of the treatment, ANOVAs compared the means at baseline and just before mindfulness or relaxation training (Time 1, i.e. two months and an half after psychoeducation). Then, ANOVAs evaluated the impact of the mindfulness or relaxation training by comparing means between pre- (Time 1) and post-training (Time 2), and between Time 1 and the 3-month follow-up (Time 3). All post-hoc analyses used the Bonferroni correction to adjust p values to multiple comparisons. It should be noted that, as will appear in full details in the following analyses, no group differences were observed at baseline on the outcome measures.

Effects on tinnitus presence

The comparison baseline/follow-up on the presence of the tinnitus revealed an effect of time, $F(1,23) = 5.47$, $p < .03$, partial $\eta^2 = .19$, the tinnitus being more present at follow-up (*mean* : 2.40, *s.d.* : 2.16) than at baseline (*mean* : 1.72, *s.d.* : 1.54). No effects were observed in the other comparisons. Similarly, no effects reached significance in any analysis conducted on the amount of hours a day the tinnitus was perceived as tolerable. It should be noted that the treatment did not aim at reducing the tinnitus itself. The increase in tinnitus presence might be a consequence of the greater attention allocated to tinnitus during treatment.

Effects on affectivity

The QIPA distinguished two dimensions in the emotional responses to tinnitus: overall negative affect and frustration. Analyses were first conducted on the overall negative affect scores. The baseline/follow-up comparison revealed a clear effect of time, $F(1,23) = 16.02$, $p < .001$, partial $\eta^2 = .41$, moderated by a Time X Group interaction, $F(1,23) = 8.36$, $p < .01$, partial $\eta^2 = .27$. As shown in Table 2, negative emotion significantly decreased in the mindfulness group (Cohen $d = 1.44$) but not in the relaxation group (Cohen $d = .22$). The baseline/pre-training comparison showed that psychoeducation clearly had a positive impact on negative affectivity, $F(1,23) = 9.56$, $p < .005$, partial $\eta^2 = .29$, Cohen $d = .60$, with no effect nor interaction with group. The pre-/post-training comparison revealed no significant effect, but the pre-training/follow-up comparison showed a significant Group X Time interaction, $F(1,23) = 6.11$, $p < .02$, partial $\eta^2 = .21$, negative affectivity decreased from pre-training to follow-up in the mindfulness group (Cohen $d = .75$), while it tended (non significantly) to increase in the relaxation group (Cohen $d = .34$). In sum, in terms of affectivity, while both groups benefited from the psychoeducation, the mindfulness group continued to show reductions at follow-up, whereas the relaxation group did not. Indeed, post-hoc tests, using the Bonferroni procedure showed that, in the mindfulness group, mean negative affectivity at follow-up was significantly lower than both at baseline and at pre-training. However, in the relaxation group, mean negative affectivity at follow-up did not differ from the mean at any other time of measurement.

Insert about here Table 2.

Regarding frustration, the baseline/follow-up comparisons evidenced effects of time, $F(1,23) = 5.98$, $p < .03$, partial $\eta^2 = .21$, moderated tendencially by a Time X Group interaction, $F(1,23) = 4.03$, $p < .06$, partial $\eta^2 = .15$ (mindfulness group Cohen $d = .98$,

relaxation group Cohen d = .11), as well as a tendencial effect of group, $F(1,23)$ = 3.32, $p <$ .09, partial η^2= .13. As can been seen in Table 2, no difference was observed at baseline. At follow-up however, feelings of frustration decreased in the mindfulness group but not in the relaxation group. The baseline/pre-training comparison showed that, similarly to what was observed for negative affectivity, psychoeducation diminished frustration, $F(1,23)$ = 8.00, $p <$ .01, partial η^2= .26, Cohen d = .48, with no effect nor interaction with group. The pre-/post-training comparison revealed no significant effect, but the pre-training/follow-up comparison showed a main effect of group, $F(1,23)$ = 5.05, $p < $.04, partial η^2= .18, the mindfulness group reporting less frustration than the relaxation group (Cohen d = .75). Overall, it appears that psychoeducation diminished the feelings of frustration engendered by the tinnitus. The mindfulness or relaxation interventions did not have a direct effect on this variable. However, the effects of psychoeducation were maintained in the mindfulness group but they were eroded in the relaxation group.

Effects on rumination

The baseline/follow-up comparison of the rumination scores revealed an effect of time, $F(1,23)$ = 22.89, $p < $.000, partial η^2= .50, moderated by a Time X Group interaction, $F(1,23)$ = 5.72, $p < $.03, partial η^2= .20. As shown in Table 2, rumination decreased more in the mindfulness group (Cohen d = 1.56) than in the relaxation group (Cohen d = .44). The baseline/pre-training comparison showed that psychoeducation clearly decreased rumination, $F(1,23)$ = 8.21, $p < $.009, partial η^2= .26, Cohen d = .10. The pre-/post-training and pre-training/follow-up comparisons revealed no significant effects. In sum, psychoeducation reduced rumination in both groups. However the mindfulness group continued to capitalize on this benefit up to follow-up, while the initial benefit of psychoeducation was just maintained in the relaxation group.

Effect on daily difficulties

The QIPA distinguishes between the difficulties generated by the tinnitus at the social and professional level, e.g. problem to attend social events (social difficulties) and at the personal level, e.g. sleep problems (personal difficulties). Regarding social difficulties, the baseline/follow-up comparison only revealed an effect of time, $F(1,23) = 17.24$, $p < .001$, partial $\eta^2 = .43$, Cohen $d = .82$. As shown in Table 2, the social difficulties generated by tinnitus significantly decreased from baseline to follow-up. The baseline/pre-training comparison showed that psychoeducation had a positive impact on the difficulties, $F(1,23) = 26.87$, $p < .001$, partial $\eta^2 = .54$, Cohen $d = .72$. No effects were significant for the pre-/post-training, and for the pre-training / follow-up comparisons.

Regarding personal difficulties, the baseline/follow-up comparison showed main effects of group, $F(1,23) = 6.40$, $p < .02$, partial $\eta^2 = .22$, and a tendency for time, $F(1,23) = 3.78$, $p < .07$, partial $\eta^2 = .14$. As shown in Table 2, the mindfulness group reported less personal difficulties, on the average, than the relaxation group. No effects were significant for any of the other comparisons. In sum, it seems that no aspects of the treatment did modulate this variable.

Effect on coping strategies

The QIPA differentiate four coping strategies: cognitive control, distraction, avoidance and acceptance. Regarding cognitive control, the pre-training / follow-up comparison revealed a tendential Time X Group interaction, $F(1,23) = 3.85$, $p < .07$, partial $\eta^2 = .14$. As shown in Table 2, cognitive control attempts tended to decrease more in the mindfulness group while the reverse is observed in the relaxation group. No effects were significant for any of the other comparisons.

Regarding distraction, the only significant effect in all comparison is a Time X Group interaction between pre-treatment and follow-up, $F(1,23) = 4.46$, $p < .05$, partial $\eta^2 = .16$. The

relaxation group tended to increase their use of distraction, Cohen $d = .63$, while no change was observed in the mindfulness group, Cohen $d = .07$.

No effects were observed for the avoidant coping comparisons.

Finally, regarding acceptance, no effect of time or of Time X Group interaction reached significance. However, group effects were observed for the baseline / follow-up comparison, $F(1,23) = 11.50$, $p < .003$, partial $\eta^2 = .33$, and for the pre-training / follow-up comparison, $F(1,23) = 11.25$, $p < .003$, partial $\eta^2 = .33$, the mindfulness group reporting more acceptance than the relaxation group. To understand this pattern of results, between-groups comparisons were computed for the four measurement times. Only the follow-up comparison yielded a significant difference, $t(23) = 4.11$, $p < .000$, Cohen $d = 1.71$, indicating more acceptance in the mindfulness group than in the relaxation group, at follow-up only.

Effects on efficacy beliefs

The baseline/follow-up comparison of efficacy ratings for the strategies used to cope with tinnitus revealed two statistical tendencies, one of time, $F(1,23) = 4.15$, $p < .06$, partial $\eta^2 = .15$, one of the Time X Group interaction, $F(1,23) = 3.88$, $p < .06$, partial $\eta^2 = .14$. As shown in Table 2, efficacy judgments tended to increase in the mindfulness group but not in the relaxation group. The baseline/pre-training comparison showed that psychoeducation clearly had a positive impact in both group, $F(1,23) = 9.33$, $p < .006$, partial $\eta^2 = .20$. The pre-/post-training comparison revealed no significant effect, but the pre-training/follow-up comparison evidenced a tendency for the Time X Group interaction, $F(1,23) = 2.96$, $p < .10$, partial $\eta^2 = .11$. The overall pattern suggests that efficacy beliefs increased in both groups following psychoeducation. However, these beliefs decreased at follow up in the relaxation group, while they were maintained in the mindfulness group.

Effects on depression and anxiety

Finally, the analyses on the scores of depression (BDI) and anxiety (STAI) revealed no effects of time or treatment conditions. This observation is congruent with the meta-analysis of Martinez Devesa et al. (2007).

Discussion

Confirming previous reports (e.g. Dineen, Doyle & Bench, 1997; Henry & Wilson, 2002), a clear positive effect of psychoeducation was observed in the present study, specifically in terms of reduction of negative affectivity, rumination, and of the difficulties experienced as a consequence of tinnitus. This effect is particularly marked for rumination and negative affectivity. This supports the clinical recommendation of offering psychoeducation as a first line intervention in tinnitus treatment. It should be noted that, in the present study, the large positive effect of psychoeducation was still observed two to three months after its delivery. As suggested by previous accounts (e.g. Henry & Wilson, 2002), it is assumed that tinnitus sufferers need sufficient time (often estimated around two months) to integrate this information their daily lives and to practice what is taught during psychoeducation.

The mindfulness and relaxation trainings did not bring immediate improvement, as the comparison pre- and post-treatment did not reveal significant differences. This might be in part due to the large effect already yielded by psychoeducation. The only one exception here was cognitive control coping, which in the present study indexed reflecting on the causes and consequences of the tinnitus. This unhealthy mode of coping tended to decrease in the mindfulness group between pre- and post-training. Such change was not observed in the relaxation group. It is to be noted that mindfulness training specifically targets disengagement from maladaptive repetitive patterns of analytical thinking, of which reflecting

on the causes and consequences is a prototype (Watkins, 2004). This interpretation has to be taken cautiously as the effect is only tendential in the present data.

If, for most variables, mindfulness or relaxation trainings did not have an immediate effect, a clear differential impact was observed at follow-up: Mindfulness training appears to have brought either postponed improvements or a better maintenance of the benefits of psychoeducation as compared to relaxation training. This was seen on measures of negative affectivity, frustration, rumination, and self-efficacy beliefs. Specifically, in the mindfulness condition, participants reported less negative emotion, irritability, and rumination at follow-up than they reported at pre-training, i.e. after psychoeducation. These effects are particularly significant as they concern the central psychological complaints of tinnitus sufferers (Peignard, 2003). This pattern was not observed in the relaxation condition. The benefits of mindfulness might thus depend on a long term practice and might only appear after several months. It should be noted that the mindfulness training in the present study was concentrated on six weeks while the typical program lasts eight weeks. During debriefing many participants in the mindfulness condition (but not of the relaxation condition) reported that they would have preferred a longer training, supporting the conjecture that extended practice is necessary for obtaining the full benefits of this intervention. It should also be noted that, in the relaxation condition, for most variables, the benefits of psychoeducation tended to erode at follow-up. This is especially true for negative affectivity for which no differences are observed between baseline and follow-up in the relaxation condition.

The impact of the intervention on acceptance of tinnitus followed a different dynamic in time. Clearly, it remained unaffected by psychoeducation. Mindfulness training had a positive impact of this variable, but it only appeared at follow-up, manifested by a significant difference as compared to relaxation training. This pattern of results again suggests that the benefits of mindfulness training require several months of practice to appear.

Overall, the present results are congruent with the notion that a reduction in analytical rumination and the development of acceptance are among the most active processes in mindfulness intervention (Baer, 2003). Our interpretation is that, in the present mindfulness intervention, the decrease in negative emotionality and in psychological difficulties resulting from tinnitus might be mediated by these two processes: decrease in rumination and development of acceptance. Future studies with larger samples should be designed to conduct mediational analyses on these variables.

As a first exploration of the usefulness of mindfulness training in tinnitus treatment, the present study suffers from several limitations. First, the samples were small. On the one hand, the fact that clearly significant effects were observed with a limited sample size indicates that the effects are large. On the other hand, it calls for caution in generalizing these results. The small sample size also precludes the possibility of mediational analyses. It should also be noted that the average level of education in the present sample is higher than in the general population. The present study should be replicated with a less educated sample, especially given that having a manual occupation with noise exposure has been shown to yield higher prevalence for tinnitus. Another limitation is that mindfulness training comprised only six sessions while the standard training includes eight sessions and one or two booster sessions (e.g. Segal, Williams & Teasdale, 2002; Teasdale, Segal, Williams, Ridgeway, Lau & Soulsby, 2000). Given the feedback of the participants at debriefing, we suggests that the standard version of the training (eight sessions plus booster sessions) is preferable.

To conclude, our results support the use of psychological interventions for people suffering from tinnitus. In line with previous research, it suggests that the first line intervention should consist of psychoeducation. It further suggests that the benefits of psychoeducation are maintained and either enhanced by mindfulness training. Relaxation training seems to be less effective in this context and mindfulness training may be preferred.

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Footnote

[1] Ihe QIPA can be obtained by email, from the authors, on simple request.

Table 1.

Participants' Demographic Characteristics by Group Assignment (Standard Deviations in Parentheses)

	Mindfulness Treatment Group	Relaxation Treatment Group
Age	60.92 (11.09)	59.75 (12.46)
Years of Education	14.61 (2.60)	14.58 (2.71)
BDI	9.00 (5.65)	13.08 (9.80)
STAI	39.84 (9.76)	43.83 (6.63)

Notes: BDI is Beck Depression Inventory, STAI is State and Trait Anxiety Inventory

Table 2 :
Outcome Variables Means as a Function of Treatment Group and Time of Measurement (Standard Deviation in Parenthesis).

Dependent Measure	Mindfulness Group				Relaxation Group			
	Baseline	Pre-Training	Post-Training	Follow-up	Baseline	Pre-Training	Post-Training	Follow-up
Neg. Emotion	3.65 (1.31)	2.98 (1.59)	2.59 (1.37)	2.03 (.98)	3.49 (1.19)	2.84 (1.12)	2.90 (1.48)	3.23 (1.32)
Irritability	4.58 (1.81)	3.46 (1.66)	3.00 (1.40)	2.88 (1.79)	4.83 (1.50)	4.37 (1.87)	3.96 (2.00)	4.67 (1.61)
Rumination	4.38 (1.08)	3.61 (1.62)	3.26 (1.52)	2.72 (1.14)	4.28 (1.18)	3.66 (1.64)	3.42 (1.61)	3.72 (1.48)
Social Diff.	4.26 (1.21)	3.50 (1.17)	3.14 (1.25)	2.84 (1.00)	3.95 (1.17)	3.12 (1.06)	3.19 (1.24)	3.13 (1.37)
Personal Diff.	1.99 (.37)	2.08 (.75)	1.62 (.57)	1.70 (.53)	2.91 (1.37)	2.29 (.89)	2.12 (1.27)	2.21 (1.20)
Cognitive Control	3.69 (1.43)	3.21 (1.80)	3.06 (.78)	3.08 (1.10)	3.47 (.82)	3.24 (1.11)	3.50 (1.30)	3.63 (.99)
Distraction	4.08 (1.20)	4.35 (1.52)	4.46 (1.77)	4.23 (1.76)	4.95 (.93)	3.68 (1.76)	4.46 (1.36)	4.75 (1.10)
Avoidance	1.96 (1.27)	2.83 (1.95)	2.80 (2.28)	2.61 (1.44)	3.13 (1.81)	2.90 (1.73)	4.08 (1.97)	3.08 (2.11)
Acceptance	4.61 (1.88)	4.73 (1.39)	4.84 (1.21)	5.31 (1.05)	3.42 (1.82)	3.71 (1.29)	4.17 (1.85)	3.46 (1.20)
Efficacy	2.14 (1.15)	2.82 (1.30)	3.15 (1.30)	3.13 (1.28)	2.54 (.75)	3.03 (1.13)	2.54 (.78)	2.56 (1.13)
BDI	9.00 (5.66)	12.28 (8.39)	8.84 (9.43)	9.38 (10.44)	13.08 (9.80)	15.20 (7.74)	12.83 (5.36)	11.92 (7.23)
STAI	39.84 (9.76)	45.13 (12.54)	42.85 (12.77)	40.46 (12.37)	43.83 (6.63)	44.22 (10.72)	45.75 (7.72)	45.73 (10.47)

Notes : Neg. = Negative; Diff. = Difficulties, BDI = Beck Depression Inventory, STAI = Spielberger State and Trait Anxiety Inventory.

CONSORT Statement 2001 - Checklist
Items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	6
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3-5
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	7-8
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	7-9
Objectives	5	Specific objectives and hypotheses.	5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	7; 8
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	5-6
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	6
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	6
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	5-6
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	Not done
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	11

RESULTS Participant flow	13	[Flow of participants through each stage](#) (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. [Describe protocol deviations from study as planned, together with reasons](#).	See Flowchart
Recruitment	14	[Dates defining the periods of recruitment and follow-up](#).	7-8
Baseline data	15	[Baseline demographic and clinical characteristics of each group](#).	6-7
Numbers analyzed	16	[Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat"](#). State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	6
Outcomes and estimation	17	[For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision](#) (*e.g.*, 95% confidence interval).	11-16
Ancillary analyses	18	[Address multiplicity by reporting any other analyses performed](#), including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	n.a.
Adverse events	19	[All important adverse events or side effects in each intervention group](#).	n.a.
DISCUSSION Interpretation	20	[Interpretation of the results](#), taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	16-18
Generalizability	21	[Generalizability (external validity) of the trial findings](#).	18
Overall evidence	22	[General interpretation of the results in the context of current evidence](#).	18

www.consort-statement.org

The Consort E-Flowchart Aug. 2005

Assessed for eligibility
(n= 300)

Enrollment

Randomized
allocation

Excluded (n= 270)

  Not meeting inclusion criteria
                (n= 205)
  Refused to participate
                (n= 0)
  Other reasons (living too far away,
absence forecasted during the trial,
etc.) (n= 65)

Allocated to intervention "Relaxation"
                (n= 15)
Received allocated intervention
                (n= 13)
Did not receive allocated intervention
                (n= 2)
Reasons : one participant got ill;
another dropped out –he was much
younger than the other participants)

Allocation

Allocated to intervention
"Mindfulness"
                (n= 15)
Received allocated intervention
                (n= 15)
Did not receive allocated intervention
                (n= 0)

Lost to follow-up (n= 0)

Discontinued intervention
    (n= 0)

Follow-Up

Lost to follow-up (n= 0)

Discontinued intervention
    (n= 0)

Analyzed (n= 12)

Excluded from analysis (n= 1)
Reasons : missed more than 2
sessions

Analysis

Analyzed (n= 13)

Excluded from analysis (n= 2)
Reasons : one missed more than 2
sessions, the other did not hand
back questionnaires several times