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ORIGINAL PAPER



Metacognitive Therapy in Patients with Tinnitus: a Single Group Study

Laura Ferraro¹ · Daniele La Barbera¹ · Aldo Messina² · Simona Galioto¹ · Anna Maria Marinaro¹ · Chiara Caruso¹ · Rosalinda Rizzo¹ · Caterina La Cascia¹

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Abstract

Tinnitus is often in comorbidity with anxiety and depression, and several authors have proposed a reduced efficiency of the top-down executive control in its perception. This single-group study describes a novel application of the metacognitive therapy (MCT), which works on a top-down engagement of proactive attentional control mechanisms on a group of patients with tinnitus, to see its impact on the perception of tinnitus and its anxiety and depression correlates. Eight metacognitive therapy group-sessions were proposed to a group of nine patients, as part of a regional project conducted at the University General Hospital "Paolo Giaccone" of Palermo. The last was a follow-up session, proposed three months after the seventh. The Tinnitus Handicap Inventory (THI) and the Hospital Anxiety and Depression Scale (HADS) were administered during the first, the seventh and the follow-up group session. The distress perceived by tinnitus (THI), lowered at a tolerable level at re-test, by maintaining this result up to 3 months after the conclusion of the experience (F(2) = 13.1, p = 0.001; effect size = 0.731). Distress scores (HADS) (F(2) = 8.3, p = 0.016; effect size = 0.462) and anxiety sub-scores (F(2) = 12.06, p = 0.001; effect size = 0.670) improved at the end of the experience, and the benefits stayed stable over the course of the follow-up, while depression scores did not change (p = 0.549). The use of MCT appears to offer promise in reducing the perception of the tinnitus and reduces the significance of annoying thinking. Further studies are necessary to test its efficacy and replicability in a controlled trial.

Keywords Distress · Anxiety · Depression · Tinnitus · Metacognitive therapy

Introduction

Tinnitus is an auditory conscious perception without a corresponding external stimulus with a prevalence of 10-15% in the adult population. The origins of tinnitus are complex (Baguley et al. 2013).

A recent review and meta-analysis (Trevis et al. 2018) have addressed the general role of psychological processes as contributors to both the ongoing awareness and failing in habituation process and severity of tinnitus (McKenna et al. 2014). Authors identified two core themes: (i) increased

anxiety and (ii) increase in depressive symptoms, in people with chronic tinnitus (> 3 months) compared to healthy controls, both having a moderate effect size, and comparatively limited replication of other psychological effects. They also identified a moderately strong positive correlation between depressive and anxiety symptoms and the impact of chronic tinnitus (Trevis et al. 2018). This relationship (see also Bhatt et al. 2017) could be due to common underpinning mechanisms.

It was proposed that tinnitus is intrinsically related to attention disorders (Heeren et al. 2014) which prevent the habituation process (Roberts et al. 2013) and do not inhibits "phantom" auditory perception from reaching awareness (Andersson et al. 2000; Jastreboff and Jastreboff 2000; Posner and Rothbart 2007).

Relatively consistent evidence was found among 16 studies for impaired selective and divided attention processing in chronic tinnitus, compared to healthy controls, with slower reaction times and biased information processing (Trevis et al. 2018). Araneda et al. (2015a, b) have recently proposed

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that reduced efficiency of the top-down executive control in tinnitus could play a role in attention resources (Das et al. 2012).

Further investigations are required aimed at determining if impaired cognitive functioning actively maintains awareness of tinnitus by failing to re-direct cognitive resources or if it is a result of the tinnitus, which acts as a distracting source. In both cases, a failure in top-down cognitive control and attentional shifting, in favour of a self-directed attention, may be symptomatic of a "default-mode network" (Buckner et al. 2008), which is associated with salience, emotional regulation in mental diseases (Broyd et al. 2009), rumination and anxiety (Derryberry and Reed 2002), depressive symptoms (Rayner et al. 2016) and phantom perceptions (Bushnell et al. 2013; De Ridder et al. 2011).

Findings on psychological correlates of tinnitus suggest that affected people could likely benefit from psychological interventions to reduce anxiety and depression, which may decrease the impact and potentially awareness of tinnitus in everyday activities.

Treatment focused on attention, and top-down regulation could also be appropriate to treat tinnitus (Makar et al. 2017). One of the first treatments designed for tinnitus was the Tinnitus Retraining Therapy (TRT), an habituation-based technique that derives from a combination of educational counselling and sound-therapy (Jastreboff and Azell 1993), which results more efficient than masking alone in reducing time aware of, and annoyed by, tinnitus (Henry et al. 2006).

Cognitive-Behavioural Therapy (CBT) is currently considered one of the best treatment to reduce tinnitus perception and its anxiety and depression associated symptoms (Hesser et al. 2011; Makar et al. 2017). The reason for this effect could be explained through the cognitive model of tinnitus, by McKenna et al. (2014). It describes tinnitus perception as a "vicious circle", in which the sound increases distress and arousal by overly negative or catastrophizing thoughts about it. It motivates maintaining factors such as selective attention, monitoring, and counterproductive safety behaviours, by leading to greater detection of tinnitus and further distress.

More recent updates of CBT have been adapted and experimented in tinnitus to enhance the ability to control its perception, such as Tinnitus Coping Technique (TCT) (Kröner-Herwig et al. 2003), a group therapy including education on tinnitus, relaxation, attention and habituation training. Acceptance and commitment therapy (ACT) was also experimented with tinnitus, with beneficial effects in reducing tinnitus distress compared to TRT, but similar effects as CBT (Molander et al. 2018; Westin et al. 2011).

Metacognitive therapy (MCT) is a novel CBT-derived model (Wells and Mattews 1994), focused on metacognitive beliefs, experiences, and strategies that generate specific patterns of dysfunctional thoughts and repetitive negative thinking (rumination). Rumination is, in turn, responsible for many psychological disorders (Wells 2002) and has been linked to chronic conditions such as fatigue (Fernie et al. 2016), chronic pain (Schütze et al. 2017; Yoshida et al. 2012) or fibromyalgia (Kollmann et al. 2016).

MCT focuses on removing rumination, by raising awareness of this process, developing new responses to negative thoughts and by improving the selective attention control. MCT works on a top-down engagement of proactive metacognitive control mechanisms and by a cognitive work on dysfunctional ideas. It resulted effective in reducing anxiety (Wells et al. 2010) and depression (Hagen et al. 2017), but it has not been yet proposed to people with chronic tinnitus.

This single group study is aimed to test the impact of MCT on the perception of tinnitus and its anxiety and depression correlates.

Methods

Participants

267 people were referred to the IPRAC project (*Interventi Psicologici e Riabilitativi nei Reparti ad Alta Criticità*— Psychological and Rehabilitation Interventions in High-Risk Units) at the University General Hospital "Paolo Giaccone" of Palermo, from January 2013 to October 2014 by their doctors or asked for psychological help by themselves. Psychologists working into the project administered the *Hospital Anxiety and Depression Scale* (HADS) to evaluate the mental health and the effects of the existing clinical practice on this group, as described elsewhere (Ferraro and Sartorio 2016).

20% of them (N = 53; 18 males and 35 females; aged 23–79 years, M = 51.2; SD = 12.9) were subjects with tinnitus, afferent to the Tinnitus Centre of the Audiology Unit. They had over the average cut-off scores of distress (HADS: M = 14.88; SD = 9.11) and anxiety (HADS-A: M = 8.70; SD = 4.8), but not for depression (HADS-D: M = 6.19; SD = 4.9). They all were administered with *Tinnitus Handicap Inventory* (THI) as part of the baseline assessment of tinnitus, and the mean score was 47.2 (SD = 27.6), i.e. moderate tinnitus.

Twelve people participated in the first session, nine of them concluded the whole experience: five males and four females (age M = 49.1; SD = 4.7). Two of them were single, and the remaining seven were married. Five of them achieved a diploma; the remaining four had a compulsory school education. One was unemployed, and one was retired, while others were occupied. Two of them had a history of prior pharmacological treatment for a psychiatric disorder. No one was taking medications or doing any psychological treatment during the experience.

Design

The study employed a repeated measure design in a single group study, as part of the IPRAC project. It took place at the Psychiatric Unit of "Paolo Giaccone" University General Hospital "Paolo Giaccone" of Palermo, which coordinated the project and offered psychological support to people afferent from other Units.

Measures

Tinnitus Handicap Inventory (THI) (Newman et al. 1996)

It is a 25-item self-report instrument grouped into subscales: the functional (11 items), the emotional (9 items) and catastrophic responses to tinnitus (5 items) scale.

The total score range from 0 to 100 with a higher score indicating higher handicap, as follow: slight (0-16), tinnitus only heard in quiet environments; mild (18-36), easily masked by environmental sounds and easily forgotten with activities; moderate (38-56), noticed in the presence of background noise, daily activities can still be performed; severe (56-76), almost always heard, leads to disturbed sleep patterns and can interfere with daily activities; catastrophic (78-100), always heard, disturbed sleep patterns, difficulty with any activities.

It was used in the Italian version, that showed a robust reliability (alpha=0.91), and a good construct validity with statistically significant correlations with distress (anxiety r = 0.281, p < 0.005 and depression r = 0.274, p = 0.006) and quality of life (item-factor correlation ranging between r = 0.52 and 0.77, p < 0.05). The catastrophic subscale showed unacceptable internal consistency reliability (alpha=0.63), probably due to its shortness (Monzani et al. 2008; Passi et al. 2008). Thus we used the overall score.

Hospital Anxiety and Depression Scale (HADS), (Zigmond and Snaith 1983)

It is a self-assessment scale reliable to detect states of depression and anxiety amongst people treated for a variety of medical problems. It comprises fourteen questions fulfilled on a four-point Likert scale (0–3), so the scores array from 0 to 21 for each scale, with higher scores indicating higher distress (cut-off > 7) (Whelan-Goodinson et al. 2009). It does not include physical signs that can confound anxiety or depression symptoms in medical conditions. In its Italian version, it was validated with cancer patients, by showing good internal reliability (alpha ranging between 0.80 and 0.85). The comparison of the areas under the curve (AUC) between the two scales did not show any difference in identifying either anxiety or depressive disorders, while the 14-item total scale showed a high internal consistency

(alpha = 0.89 and 0.88) and a high discriminating power for all the psychiatric disorders (AUC = 0.89; 95% CI 0.83-0.94) at a cut-off point of 10 (Costantini et al. 1999). So, the total score was also used as the primary measure of emotional distress in this study.

Metacognitive Questionnaire (MCQ-30) (Wells and Cartwright-Hatton 2004)

It consists of 30 items and has a five-factor structure: positive beliefs about worry (POS); negative beliefs about the controllability of thoughts and corresponding danger (NEG); cognitive confidence (CC); negative beliefs about ideas in general/need to control thoughts (NC); cognitive self-consciousness (CSC); responses are scored on a four-point scale ranging from 1 (do not agree) to 4 (agree very much); higher scores indicate higher levels of unhelpful metacognitions. It was used in its brief Italian version, that showed a very good internal consistency (alpha ranging from 0.71 to 0.87), re-test coefficients for the total score of 0.86 (p < 0.005), ranging from 0.62 to 0.89 for the subscales and a convergent validity with pathological worry (r=0.61; p < 0.01), stateanxiety (r=0.61; p < 0.01), and obsessions–compulsions (r=0.57; p < 0.01) (Quattropani et al. 2014).

Procedure

The audiologist proposed a first group meeting to subjects with chronic tinnitus who were not into an individual psychotherapy setting, suffering from bilateral neuro-sensory moderate deafness, without any implants and free from dizziness. They were invited to attend an informative seminar on the psychological aspects of tinnitus. Researchers proposed eight group sessions of MCT, conducted by four trained psychotherapists, lasting an hour and a half each.

Treatment

Tinnitus was presented and treated as an intrusive and annoying though, able to pathologically draw the attention of the subject and boosting its perception. Tinnitus was also considered as a trigger for a chain of bad thoughts capable of arousing anxiety, sadness, and helplessness about tinnitus and in everyday activities. The two main techniques used were the attention training technique (ATT) and the detached mindfulness (DM).

ATT consists of 12 min of actively listening and focusing attention in the context of contemporary sounds presented at different loudness and spatial locations, to learn how to maintain awareness of thoughts as a passive observer (Wells 2002). A subjective rating scale of attention precedes and follows every ATT session to establish how much of one's attention is focused inward or outward (Wells and Melli 2012).

With the term "detachment" is meant to stop or disconnect any response to a thought, and to experience oneself as separate from an idea. With the term "mindfulness" is meant the awareness of thoughts and the ability to distinguish a negative thought from a subsequent ruminative response to that thought (Wells and Mattews 1994; Wells and Melli 2012).

The last step of the intervention usually focuses on metacognitive believes that sustain and enhance rumination (Wells and Mattews 1994; Wells and Melli 2012).

Eight sessions took place every two weeks, between March and December 2015. The follow-up session was in March 2016 (3 months later the seventh session). The therapeutic plan is fully described in Table 1.

Statistical Analysis

SPSS (version 23) was used to perform statistical analyses. Given the paucity of the sample (nine subjects), nonparametric tests were used for all the analyses. The characteristics of this sample were compared to those available from the original IPRAC sample of people with tinnitus by using t-test and Exact Fisher Test (Ex-F) for quantitative and categorical variables respectively. To test the relationship between clinical scores and the persistence of the tinnitus measured in months, non-parametric correlation statistics (Spearman's Rho) were applied between THI, HADS scores and moths of tinnitus, while Pearson's correlation was used for the whole original sample. Non-parametric two-tailed ANOVA test for repeated measures (i.e. Friedman Test) was used to see if there were a statistically significant difference across the periods. Kendall's W test was used to indicate effect sizes (ranging from 0 to 1). Finally, post-hoc pairwise comparisons were conducted using a Wilcoxon test and controlling for the Type I errors across these comparisons at

Table 1 Therapeutic plan

the 0.05 level, using the LSD procedure (Green and Salkind 2008).

Results

Representativeness of The Sample

The final group was comparable to the remaining subjects from the original IPRAC sample in terms of age (t(49)=-0.94, p=0.348), gender (Ex-F (1)=2.2, p=0.245), marital status (Ex-F (3)=2.1, p=0.533), school achievement (Ex-F (3)=5.5, p=0.136), occupational status (Ex-F (2)=3.4, p=0.198) and in terms of past psychopathology in the anamnesis (yes/no) (Ex-F(1)=1.2, p=0.574).

The clinical characteristics of this group at baseline were also comparable with the remaining part regarding anxiety (HADS-A: t(51) = -0.17, p = 0.815), depression (HADS-D: t(51) = -0.78, p = 0.436) and tinnitus severity (THI: t(51) = -0.51, p = 0.608).

Baseline Scores

The nine subjects presented a long history of tinnitus, ranging between 6 and 360 months (M = 150.3; SD = 130.9). HADS mean scores exceeded the cut-off at baseline (M = 13.4; SD = 6.9) particularly for anxiety sub-score (M = 8.4; SD = 3.1), while HADS-D means score was standard (M = 5; SD = 4.2). THI scores ranged from 22 to 80, and the mean score indicated a moderate perception of tinnitus (M = 42.8, SD = 23.3). The MCQ-30 resulted in highly variable scores between subjects (M = 67.4; SD = 12.7) (Table 2).

There were no correlations between the persistence of the tinnitus in months and THI and HADS, both general and subscale scores (all p > 0.05). Higher scores of THI were related to higher ratings of HADS (Rho=0.890 p<0.001) for both anxiety (Rho=0.856; p=0.003) and depression

1st Session	Participants introduced themselves. The therapists explained the therapeutic rationale and the methods
2nd Session	Subjects were pre-tested by HADS and THI. Clinical notes collection
3rd Session	Presentation of the ATT followed by two ATT sessions, (including the subjective rating scale). Homework: to repeat one-two times a day the ATT exercise
4th Session	Homework discussion, followed by two ATT sessions. Homework: to repeat one-two times a day the ATT exercise
5th Session	An introduction to the DM, through metaphors and metacognitive orientation, MCQ-30 administration. Metacognitive exercises (for example the tiger exercise by Wells et al. 2012). Homework: to find new metaphors and to repeat DM and ATT exercise one-two times a day
6th Session	Homework discussion, new metaphors on thoughts and metacognitive exercises. Homework: ATT and DM exercises
7th Session	Discussion about group sessions and techniques used. HADS, THI and MCQ-30 re-administration
8th Session	HADS, THI and MCQ-30 follow-up re-administration. Discussion about techniques used and their utility in the everyday activities

HADS Hospital Anxiety and Depression Scale, THI Tinnitus Handicap Inventory, ATT attention training technique, DM detached mindfulness, MCQ-30 Metacognitive Questionnaire

Table 2 Change of clinical scores after the treatment and at following	ow-up
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	Pre-test	Post-test	Follow-up	F (df) ^a
THI, mean (SD)	42.8 (23.3)	29.3 (18.9)	28 (18.5)	13.1 (2)**
HADS, mean (SD)	13.4 (6.9)	10.6 (6.2)	10.1 (6.4)	8.3 (2)*
Anxiety, mean (SD)	8.4 (3.1)	6.3 (2.3)	5.7 (2.6)	12.1 (2)**
Depression, mean (SD)	5 (4.2)	4.3 (4.3)	4.3 (4.3)	1.2 (2)
MCQ-30, mean (SD)	67.4 (12.7)	58.8 (14.7)	62.6 (10.4)	3.8 (2)
POS, mean (SD)	8.2 (2.8)	7.2 (1.9)	7.7 (2.7)	8.2 (2)
NEG, mean (SD)	16.1 (3.9)	13.8 (2.8)	14.4 (2.2)	4.8 (2)
CC, mean (SD)	12.2 (4.1)	10.7 (4.5)	11.2 (3.4)	1.3 (2)
NC, mean (SD)	15.5 (5.1)	12.6 (4.6)	13.6 (4.4)	6.8 (2)*
CSC, mean (SD)	15.3 (2.1)	14.6 (3.8)	15.5 (2.7)	0.4 (2)

THI Tinnitus Handicap Inventory, *HADS* Hospital Anxiety and Depression Scale, *HADS-A* Hospital Anxiety and Depression Scale-Anxiety, *HADS-D* Hospital Anxiety and Depression Scale-Depression, *MCQ-30* Metacognitive Questionnaire, *POS* positive beliefs about worry, *NEG* negative beliefs about the controllability of thoughts and corresponding danger, *CC* cognitive confidence, *NC* negative beliefs about ideas in general/need to control thoughts, *CSC* cognitive self-consciousness

^aFriedman's Test statistics; * p<0.05; **p<0.01

(Rho=0.762; p=0.017). The same correlations were found in the remaining original sample (all Spearman's test had p < 0.001) (data not shown in tables).

Repeated Measures

At the end of the last group session and follow-up THI resulted "mild" or "slight" for the majority of the subjects. The change was significant [F(2)=13.1, p=0.001] and Kendall's W=0.731, indicated a substantial difference among the three times (Kendall and Babington Smith 1939). Posthoc tests indicated significantly lower scores at the end of the last session than at baseline (Z=-2.692, p=0.007), as it was at follow-up (Z=-2.524, p=0.012) but these two times did not differ significantly each other (p=0.350).

Compared with baseline, a lower distress was registered, with a moderate effect [F(2) = 8.3, p = 0.016; Kendall's W=0.462], at re-test (Z=2.254, p=0.024) and at the follow-up (Z=2.316, p=0.021) as compared to the pre-test and no differences between these two times (p=0.395). Anxiety sub-score decreased with a good effect size [F(2)=12.06, p=0.001; Kendall's W=0.670] while decreasing in depression sub-score was not significant (p=0.549).

There were no differences in MCQ-30 total score over time (p=0.148). NC_MCQ subscale was the only scale which decreased, with a moderate effect size [F(2)=6.897,

p = 0.032; Kendall's W = 0.383], while other subscales did not significantly improve (all p > 0.05) (Table 2).

Discussion

Psychological Correlates of Tinnitus

As expected, subjects with tinnitus referred to the IPRAC project, and those who adhered to the group therapy had general distress and anxiety scores above the cut-off (Trevis et al. 2018), while this was not true for depression scores, which resulted in a reasonable level at HADS-D subscale, apparently in a contrasting finding. However, looking at previous studies (Araneda et al. 2015a; Mannarelli et al. 2017; Waechter and Brännström 2015), the impact of depression is not always detected in subjects suffering from tinnitus. Trevis et al. (2018) report in their meta-analysis that effect sizes for depression range from minimal negative effects to large positive effects, thus suggesting a diversity within the tinnitus population in depressive symptoms, as compared to controls, and a more substantial impact for anxiety.

There was no correlation between the perceived severity of the tinnitus and the duration of it in months (Gül et al. 2015), but we found a positive correlation with both anxiety and depression scores. It was proposed that a score at THI higher than 36 is an indicator for psychiatric diseases (Salviati et al. 2013) and it was also the case in our little group.

Therapy Effect

The therapy had a good effect in reducing distress and perception of tinnitus, and results were maintained over time. In particular, anxiety sub-scores improved, and the benefits stayed stable throughout the follow-up, while depression scores did not change. These results are in line with Hesser et al. (2011), who included CBT, ACT, enhanced TRT and TCT in their meta-analysis and observed a more significant effect of these therapies on tinnitus distress but a more substantial heterogeneity and a non-significant random impact on anxiety and depression scores, combined in a single index. The two subscales in the Italian version of the HADS, have a weak discriminative power. Additionally, HADS-D was not pathological at the baseline; thus an effect on it was not a goal of the therapy. Finally, an inner work on metacognitive believes is required to fight depressive thoughts, when they are present (Wells and Melli 2012).

The MCQ-30 scores improved from session 5 to session 7, by indicating a reduction of dysfunctional metacognitive believes of participants, especially of negative thoughts; this is not surprising, as we know that negative metacognitive beliefs are particularly important in the development of anxiety (Ryum et al. 2017). However, the overall result was not

stable over time, probably because less time was spent on this part of the work.

The therapy had a good result on participant's abilities to focus and pay attention to several stimuli at the same time, by engaging selective attention control and moving tinnitus on the "background landscape" of awareness. They reported being able to develop new responses to negative thoughts, triggered by tinnitus, and to be less ruminative about tinnitus and in their everyday life. Those who had troubles in falling asleep declared to have successfully used ATT techniques, lying in their beds, through a metacognitive attention control on tinnitus and lower self-directed attention. They were also more conscious of an active role in their mental health. Thus, the therapy resulted effective on levels of distress through the top-down engagement of proactive metacognitive control mechanisms and, secondly, by a cognitive work on dysfunctional ideas.

During the sessions, participants could benefit from a group setting to share their experiences and thoughts about tinnitus. For example, one subject, whose anxiety and depression levels were significantly high, found in the group the right setting to share his suffering and found-out an individual psychotherapeutic help at the end of the experience. As already indicated by Seydel et al. (2008), emotional support and learning from other examples can improve internalising coping strategies.

Limitations and Strengths

This was a little single-group study, settled to answer patient's request of assistance into the IPRAC project; thus it has several limitations, but it could be used to inform the design of a subsequent study with an internal comparison group or a clinical trial. It would be interesting to structure a specific treatment plan for tinnitus by comparing different approaches of MCT in parallel groups, by choosing which techniques are prevalently effective, in which order to present them and for how many sessions. A quantitative and qualitative comparison with CBT results and the therapeutic process could also be informative.

About instruments, it is useful to add a second test for the attentional changes, other than the subjective rating scale of attention, administered during ATT, that is part of the therapeutic tool.

Even if results are encouraging, the IPRAC-patients who did not adhere to the therapeutic group could embody lesscompliant people, who are generally more likely to have a worse outcome over time.

One strength of the study is the representativeness of the sample, as compared to the remaining part and our patients did not present higher scores in psychological symptoms compared to non-help-seekers counterparts, opposite to Scott and Lindberg (2000) findings. Additionally, the group

is an instrument that could be economic and replicable, able to reduce the number of psychologists involved in interventions in an audiological unit, especially in a general public hospital.

Conclusions

The use of MCT appears to offer promise in reducing the perception of the tinnitus and the anxiety of participants and reduces the significance of annoying thinking, rumination and dysfunctional belief about the uncontrollability of thought. Further studies are necessary to test its efficacy and replicability in a controlled trial.

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Compliance with Ethical Standards

Conflict of interest Laura Ferraro, Daniele La Barbera, Aldo Messina, Simona Galioto, Anna Maria Marinaro, Chiara Caruso, Rosalinda Rizzo, and Caterina La Cascia declares that they have no conflict of interest.

Ethical Approval All procedures performed in this study, involving human participants, were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Informed Consent People who asked to be included in the group, signed an informed consent form before to be engaged in the therapeutic experience and they were informed that they could leave the experience at any time.

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