Effectiveness of a structured group relaxation-training program based on sophrology's dynamic relaxation techniques for primary care patients with moderate and high anxiety levels.

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Abstract

Objective. The aim of this study is to determine the effectiveness of an intensive *four-week* structured group relaxation-training program (sophrology's dynamic relaxation) on anxiety and depression symptoms in primary care patients with moderate and high anxiety levels. **Method.** Seventy patients, according to the Hospital Anxiety Depression Scale - Anxiety subscale (HADS-A), cut-off \geq 8, were randomized to the sophrology or a control program based on physical and mental health recommendations (PMHR). Hospital Anxiety and Depression Scale (HADS) and the State-trait Anxiety Inventory (STAI) ratings were obtained before and after 12 one-hour sessions for 4 consecutive weeks. **Results.** Sixty-five patients completed the study. The dropout rate was 2,9 % (N=1) for the intervention and 11,4% (N=4) for the control group. Sophrology showed statistically significant improvements in all HADS and STAI subscales for RM-ANOVA with-in group effect (p<0,001) and for the interaction effect rates (p=0,001 to 0.046), regardless of gender or age. The pre-post effect sizes (Cohen's d) for anxiety and depression symptoms were large for sophrology (ES=0,84 to 1,36) and small to moderate for the control (ES=0,28 to 0,49). **Conclusion:** An intensive four-

week structured group relaxation-training program by sophrology is highly effective in reducing anxiety and depression symptoms in primary care patients with moderate and high anxiety levels.

Key Words. Well-being, Caycedian sophrology, dynamic relaxation, anxiety, depression, primary care

Introduction.

Mood and anxiety disorders are becoming one of the main health problems of the industrialized society (Kessler et al., 2005; Haro et al., 2006). Studies have persistently shown that anxiety disorders cause morbidity, increase use of health care services, decrease work productivity, work absence and possibly will be one of the leading causes of disability in the twenty-first century (Alonso et al., 2004). Recent worldwide estimates for the 1-year and lifetime prevalence of any anxiety disorder are 10,6% and 16,6% respectively with a ratio indicating that a large number of people experience anxiety on a continuous or recurring basis. Prevalence is twice among women with overall age-specific rates relatively stable or increasing across the lifespan (Somers, Goldner, Waraich, Hsu, 2006). From a socio-economic point of view, the annual costs associated with anxiety disorder are in general high (Greenberg et al., 1999).

In the treatment of anxiety disorders, psychopharmacological interventions with benzodiazepines and selective serotonin reuptake inhibitors (SSRI) have shown their efficacy (Offidani, Guidi, Tomba, Fava, 2013). A meta-analysis realized by Bandelow (Bandelow et al., 2015). compared the efficacy of pharmacological, psychological and combined treatments in three anxiety disorders. This analysis showed the superiority for pharmacological treatments but they conclude that the final decision remains in the hands of the patients, as drugs may have side effects, interactions and contraindications Long-term SSRI medication might show important adverse effects including sexual dysfunction, weight gain, and sleep disturbance (Ferguson, 2001) and benzodiazepines might cause dependency, drowsiness, and impaired cognition amongst others (Uzun, Kozumplik, Jakovljevic, Sedic, 2010).

Non-pharmacologic interventions may be proposed as an alternative option, with the aim to reduce perceived anxiety and stress and to increase the sense of well being in the general population and relaxation – meditation techniques represent one of the most important alternatives in anxiety intervention worldwide (Kanji & Ernst,

2000). A meta-analysis by Manzoni shows the consistent and significant efficacy of relaxation training in reducing anxiety (Manzoni, Pagnini, Castelnuovo, Molinar, 2008). In our present study, we propose to analyse one among these training programmes, which is sophrology (Caycedo, 1972). Sophrology is a well-known body-mind discipline in French speaking European countries. Its aim is to study human conscience in harmony by means of a descriptive research method based on Husserl's phenomenology. It consists of a structured training program using dynamic relaxation, contemplation and meditation techniques. Its character is strictly non-political and non-confessional. Sophrology training claims to improve concentration, calmness, to reduce or prevent somatisations and chronic stress. On the other hand it develops positive attitudes, psychosocial capacities and personal values (Caycedo, A., 1973; Caycedo, A., 1974; Caycedo, A., 1975).

Similar effects claim some other disciplines like the autogenic training (Schultz & Luthe, 1969), progressive relaxation (Jacobson, 1938 and 1980), Yoga, Zen Meditation (Arias, Steinberg, Banga & Trestman, 2006) and others emerging as Mindfulness (Kabat-Zinn, et al., 1992, Hoffman, Sawyer, Witt & Oh, 2010; Chiesa & Serreti, 2011;). Within this spectrum, sophrology is positioned as a discipline that is not only interested in the episodic therapeutic benefit but also its permanence in time.

The aim of the present study is to determine the effectiveness of an intensive **four-week** structured group relaxation-training program (sophrology's dynamic relaxation) on anxiety and depression symptoms in primary care patients with moderate and high anxiety levels.

Methodology

A. Participants selection

During two consecutive days 388 patients, visiting the Cerdanyola's Medical Health Care Centre (Spain), were asked to participate in this study and to answer the self-rating HADS to establish the baseline anxiety level. The University Review Board approved the study and written informed consent was obtained from all participants.

Inclusion criteria: From this initial sample 70 patients were selected. The inclusion criteria were the following: a) *A cut-off* \geq 8 for the HADS anxiety subscale, b) being between 18 and 70 years of age, c) have

formally expressed their desire to participate in this research study, (d) do not submit any of the exclusion criteria (detailed in the following section), (e) have read and signed an informed consent document.

Exclusion criteria: Were excluded from the study those patients who; a) initiated or changed pharmacological, behavioural or any other therapy during the program, b) presented uncontrolled mental illness, c) had planned to participate in other therapies or similar programs such as Yoga, Mindfulness, meditation, acupuncture, or others, d) during the program suffered from important stressful life events, that could produce bias in the ratings of the study, e) were not able to participate for linguistic, cultural or physical problems, f) could not attend the sessions in a regular way.

These patients were randomly assigned in two groups of 35 participants each; an intervention group and a control group. The intervention group followed the sophrology program named "wellbeing and sophrology" (Rangelrooij van, Caycedo, Dallest, 2014) and the control group a cognitive program based on physical and mental health recommendations (PMHR).

Finally, 65 patients completed the study. The dropout rate was 2,9 % (N=1) for the sophrology and 11, 4% (N=4) for the PMHR control group. The gender distribution for the female sex was 82.9% in the sophrology group and 80.6% in the control group. The mean age was 47.06 for the intervention group (SD = 11.50) and 50.03 years for the control group (SD=10.49).

B. Instruments

Two self-ratings of short duration (15-20 min) were used: The Hospital Anxiety Depression Scale (HADS) (Zigmon & Snaiht, 1983) and the State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983; Spielberg, Gorsuch & Lushsene, 1994). Both questionnaires were used at the beginning of the first and the last session of the training program.

The HADS-Anxiety subscale was used as a screening test to select the participant. The HADS questionnaire is widely used to detect anxiety and depression symptoms in a clinical setting or the general population. It is brief, easy to apply and consists of simple questions. In the dynamic environment of a Medical Health Care

Centre, it permits in a very short time to measure anxiety (and depression) symptoms in a large number of patients.

It consists of 14 items and assesses anxiety (7 items) and depression (7 items) symptoms. The cut-off points are the following: normal range between 0 and 7 points, medium risk for anxiety or depression disorders between 8 and 10 points, and high risk for anxiety or depression between 11-21 points.

The concurrent validity of each of the two subscales, HADS-anxiety subscale and the HADS-depression subscale has been demonstrated in different populations, amongst others primary care population, and different countries (Roberge et al., 2013; Hinz, & Brähler, 2011. The studies concerning the accuracy of these thresholds all show them to be reliable (Bjelland, Dahl, Haug, Neckelmann, 2002; Bocéréan & Dupret, 2014). This questionnaire is translated to different languages and has demonstrated its validity and reliability in different Spanish studies (Terol, Cabrera and Martín 2015; Vallejo, Rivera, Esteve-Vives Rodriguez-Muñoz, 2012; Terol et al., 2007; Herrero et al., 2003). In spite of the international acceptation and extensive use, the controversy behind HADS factorial structure still sustains from the beginning (Coyne & van Sonderen, 2012; Norton et al., 2013; Burns et al., 2014; Stott, Orrell, Charlesworth, 2017. Further research might contribute to appropriate conclusions over this long standing debate regarding the instrument.

STAI: State-Trait Anxiety Inventory (STAI). The STAI has positioned itself as a simple, brief and useful test for the assessment of symptoms of anxiety in clinical and non-clinical populations. The STAI has been cited in more than 14,000 documents and there exists more than 60 adaptations in the world. It is translated to the Spanish language (Spielberger et al., 2011) and has shown to be reliable for patients with anxiety disorders (Guillén & Buela, 2014).

C. Intervention

Both programs covered a total of 12 one-hour sessions during only 4 weeks (3 sessions a week). Two physicians, two nurses and a psychologist of the Medical Health Care Centre guided both the sophrology intervention and the PMHR control program. Previously they had followed an intensive training in sophrology's dynamic relaxation techniques and the sophrology program on one hand and the PMHR program on the other hand.

The Hospital Anxiety and Depression Scale (HADS) and the State-trait Anxiety Inventory (STAI) were applied at the beginning and the end the study for both the sophrology and the PMHR control group.

Each sophrology session was divided in 50% theory and 50% practice. The theory overlapped with the PMHR program and consisted in stress management in daily life, somatizations, adequate sleep hygiene, positive thinking, relaxation in daily life, etc. The practical part consisted of a selection of short sophrology techniques (10 to 20min.) such as diaphragmatic breathing, dynamic relaxation, imaging and mental programming techniques. At the end of each session, the sophrology group patients were provided with a summary and a digital recording of the applied sophrology technique. Patients were motivated to practice daily and to apply the treated theoretical concepts in everyday life.

The control group sessions consisted of a cognitive intervention program based on physical and mental health recommendations (PMHR). Some of the treated subjects were: stress management in daily life, somatizations, physical exercise and wellbeing, a balanced diet, adequate sleep hygiene, positive thinking, and relaxation in daily life, etc. In the interactive part patients attended conferences and watched videos related to healthcare. The same professionals of the Medical Health Care Centre guided the control group sessions. Special attention was given to the application of the PMHR in everyday life.

D. Statistical Analysis

Statistical analyses were performed using SPSS 18.0 version (IBM Corp.). Descriptive statistics including mean and standard deviation of the HADS and STAI scores for the sophrology and control group were used to describe the different variables used in this study (Table 1). Repeated measures for the analysis of variance (RM-ANOVA) were used to compare pre and post intervention scores for the sophrology and control group (group and intervention effect). Student t test was used to compare the basal scores for both groups and to detect possible initial differences between both groups. Pre-post Cohen's (d) effect sizes (ES) were used to measure the effect size in the sophrology and control group (Cohen, 1977); *P*-value under 0.05 was considered statistically significant for all data analysis.

Table 1. Study of the evolution of variables depression (HAD-D) and anxiety (HAD-A) measures with HADS and the STAI-state variables (State/Trait) and range measures according to the intervention or control group. Cohen's d effect size measures the impact of the effect.

		V	isit	P-value ^b	Differences in mean change in groups Cohen e.s. (95% CI)	P-value ^c Interaction effect
Variable	Group	Baseline n mean (SD)	Final mean (SD)			
HAD-D	Control	7,68 (5,16)	5,84 (4,61)	0,010	0.49 (0.08, 0.66)	0.046
	Intervention	7,59 (3,39)	4,06 (3,41)	<0,001	1.19 (0.65, 1.42)	
	P-value ^a	0.994				
HAD-A	Control	10,5 (4,86)	9,23 (4,59)	0,113	0,29 (-0.06, 0.58)	0.003
	Intervention	12,1 (3,36)	7,85 (3,47)	<0,001	1,16 (0.77, 1.72)	
	P-value ^a	0.08				
STAI-S	Control	28,1 (12,3)	24,4 (12,8)	0,134	0,28 (-0.09, 0.67)	0.032
	Intervention	27,9 (13,8)	17,3 (9,17)	<0,001	0,84 (0.47, 1.32)	
	P-value ^a	0.955				
STAI-T	Control	31,2 (12,5)	27,2 (13,0)	0,029	0,41 (0.03,0.58)	0.001
	Intervention	34,6 (9,15)	22,9 (9,60)	<0,001	1,36 (0.78, 1.61)	
	P-value ^a	0.199				

^a Statistical significant (p < 0.05). Comparison of baseline values between sophrology and control group (**) *p*-values from an analysis of variance for repeated measures (RM-ANOVA) with-in group analysis (***) within group Cohen's d effect size with 95% CI

(****) *p*-values from an analysis of variance for repeated measures (RM-ANOVA) for interaction between Sophrology and control (checks whether the evolution in time is different according to the group)

I. Results

A. Sample Study

According to the HAD-Anxiety cut-off score ≥ 8 , seventy patients were finally selected for the study. Five of them, one belonging to the intervention and four to the control group, left the study for personal reasons (two for labour reasons and three for family issues), therefore, have been excluded from the data analysis.

B. Effects on the questionnaire HADS

B1. Effects on the questionnaire HADS-Anxiety subscale

In the sophrology group, the mean anxiety level reduced from 12,1 at baseline to 7,9 at the final visit. Pre-post intervention assessments by repeated measures ANOVA, showed a high statistically significant reduction for *the HAD-Anxiety subscale* (p<0.001). The control group did not show any statistically significant reduction (p=0.113). The RM-ANOVA *interaction effect* between the Sophrology and PMHR group showed a highly significant reduction (p=0.003) for the Sophrology group.

Pre-post Cohen's d effect size value on anxiety symptoms suggested a large effect for the Sophrology program (ES=1,16; 95% CI = 0.77 to 1.72) and a small effect (ES =0,29; 95%CI = -0.06 to 0.58) for the PMHR group (see Figure 1 and Table 1).

B2. Effects on the questionnaire HADS-Depression subscale

In the sophrology group, the mean depression level reduced from 7,6 at baseline to 4,1 at the final visit. Prepost intervention assessments with RM-ANOVA showed a high statistically significant reduction for the *HAD-Depression subscale* (p<0.001). The control group also showed a statistically significant reduction in depression symptoms (p=0.010). However, RM-ANOVA *interaction effect* between the Sophrology and control group showed a statistically significant reduction (p=0.046) for sophrology.

Pre-post Cohen's d effect size value on depression symptoms suggests a large effect (ES=1,19; 95%CI=0.65-1.42) for the sophrology and a moderate effect (ES=0,49; 95%CI=0.08-0.66) for the control program (see Figure 1 and Table 1).

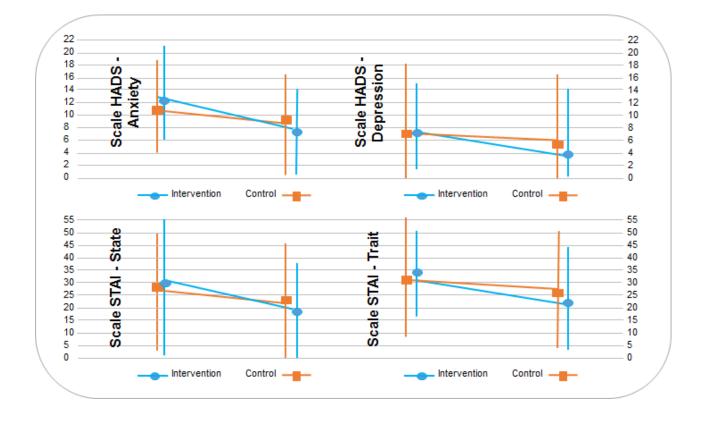


Figure 1. Baseline and final values for HAD-Anxiety, HAD-Depression, STAI-State Anxiety and STAI-Trait Anxiety for the intervention (Sophrology) and control (PMHR) group.

C. Effects on the STAI questionnaire

C1. Effects on the STAI - State Anxiety questionnaire

Pre-post intervention assessments with RM-ANOVA revealed a high statistically significant reduction for *STAI-State anxiety* (p<0.001) in the sophrology group. The control group did not show any statistically

significant reduction (p=0.134). RM-ANOVA *interaction effect* between the intervention and control group showed a statistically significant improvement (p=0.032) for the Sophrology program.

Pre-post effect size value (Cohen's d) on *state anxiety* symptoms suggests a large effect (ES=0,84; 95%CI=0.47-1.32) for the sophrology and a small effect (ES=0,28; 95%CI= -0.09-0.67) for the control program (see Figure 1 and Table 1).

C2. Effects on the STAI - Trait Anxiety questionnaire

In the sophrology group, pre-post intervention assessments with RM-ANOVA, showed a high statistically significant reduction for STAI-Trait Anxiety (p<0.001) and a small statistically significant reduction in the control group (p=0.029). However, the RM-ANOVA *interaction effect* between the intervention and control group *s*how a statistically significant improvement (p=0.001) for the Sophrology program.

Pre-post effect sizes (Cohen's d) value on *trait anxiety* (ES=1,36; 95%CI=0.78-1.61) suggests a large effect for the sophrology and a small to moderate effect (ES=0,41; 95%CI=0.03-0.58) for the control program (see Figure 1 and Table1).

It deserves to be mentioned that the sophrology group patients reported a variety of positive effects of the dynamic relaxation training particularly in relation to psychosomatic symptoms such as relieve of headaches, neck pains, lumbar or digestive problems and improvement of sleep, mood and joy.

II. Discussion

The aim of this study was to determine the effects of dynamic relaxation techniques (sophrology) on anxiety and mood in primary care patients and, as far as we know, this is the first randomized prospective controlled study. Seventy patients with moderate and high anxiety levels, according to the HADS-Anxiety subscale questionnaire (cut-off \geq 8), were randomly distributed to sophrology (wellbeing and sophrology program) or a physical and mental health recommendations (PMHR) program. At the end of the four weeks intensive group-training sessions, RM-ANOVA for sophrology showed statistically significant improvements in all HADS and STAI subscales for the with-in group effect. Compared to the control group, the interaction effect rates were all statistically significant for sophrology, regardless of gender or age. The pre-post effect sizes (Cohen's d) for anxiety and depression symptoms were large for sophrology and moderate to small for the control. In general we can conclude that a short (four weeks) and intensive (3 times per week) sophrology group-training intervention has important therapeutic and preventive benefits on anxiety and depression symptoms in primary care patients with medium and high anxiety levels.

The patient's selection criteria were based on their level of anxiety according to the HAD-Anxiety sub scale (cut-off \geq 8) and not limited to the classification of a specific anxiety disorder. This way of selection has certain advantages in primary care service. It is quick, brief, easy to apply and cheap, on the other hand it allows intervening not only in patients with one or more anxiety disorders *but also in those at risk*. As far as we know, no studies have used the HADS-anxiety subscale (cut-off \geq 8) as a selection criterion for group-treatment intervention in patients with moderate and high anxiety levels.

Concerning the intervention program's mode of action, it is difficult to analyse in what measure the theoretical part (physical and mental health information) on one hand and the dynamic relaxation training on the other hand, is responsible for the effect on anxiety and depression symptoms. However, the small to moderate effect size of the PMHR program on anxiety and depression symptoms, receiving similar theoretical information and recommendations, shows the superiority of the combination with dynamic relaxation training, compared to physical and mental health recommendations only.

According to Cabello & Brugada (2003), the dynamic relaxation training program, does not only reduce anxiety levels but also reduces medical care consumption by anxiety patients. Future studies are required to measure the impact of the sophrology program on medical health care use, including psychopharmacological consumption and frequentation of the Medical Health Care Centre.

Sophrology training might be a choice for those patients with medium or high anxiety levels, suffering from important psychopharmacological side effects or intolerance but also for those patients at medium risk for anxiety disorders, interested in developing healthy psychophysical habits, personal resources and coping strategies.

Although in general, a greater number of women show interest for well-being programs, as also can be seen in this study, it is important to state that our results demonstrate that the sophrology program is equally effective in persons of any age and gender.

Limitations

Our study sample was *limited in time*, and some cautions should be observed in generalizing these results in medium and long term. But in a primary care context it results not easy to motivate participants to participate in this kind of intensive group intervention studies (three times a week) for more than one month. Future studies have to show the effectiveness of sophrology training on anxiety and depression, its effectiveness in the medium and long term, using 6 and 12 months follow-ups for the psychometric questionnaires.

The patient's selection criteria based on their level of anxiety according to the HAD-Anxiety sub scale (cutoff \geq 8) and not on classification of a specific anxiety disorder also might be interpreted as a weakness of this study. Future studies are planned to study sophrology effectiveness on anxiety disorders.

This study shows an important inequality in gender participants. In general, a greater number of women show interest for well-being programs, and this is also seen in this study.

Conclusion

In conclusion, these findings demonstrate that a four week structured dynamic relaxation training program (well-being and sophrology) is effective to reduce anxiety and depression symptoms in primary care patients with moderate and high levels of anxiety according to the STAI and HADS questionnaires.

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