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# Effectiveness of a 4-week sophrology program for primary care patients with moderate to high anxiety levels: a randomised controlled trial

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## ABSTRACT

**Background.** 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.** In an experimental study, seventy patients, according to the Hospital Anxiety Depression Scale - Anxiety subscale (HADS-A), cut-off≥8, were randomized to the "well-being and 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 group and 11.4% (N=4) for the control group. Sophrology showed statistically significant improvements in all HADS and STAI subscales for with-in group (p<0.001) and between groups analysis (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 "well-being and sophrology" is highly effective in reducing anxiety and depression symptoms in primary care patients with moderate and high anxiety levels.

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

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## RESUMEN

**Objetivo.** Valorar la efectividad del programa estructurado Bienestar y Sofrología para reducir los síntomas de ansiedad y depresión en pacientes con un nivel medio o alto de ansiedad que acuden a un centro de asistencia sanitaria CAP.

**Método.** Estudio prospectivo controlado de 70 pacientes, con una puntuación HAD-A ≥ 8 (Escala de Ansiedad y Depresión Hospitalaria), que fueron distribuidos de forma aleatoria en 2 grupos; el grupo de intervención (N = 35) con el programa Bienestar y Sofrología y el grupo control (N = 35) con el programa Hábitos Saludables a nivel Psicocorporal. El HADS y el Inventario de Ansiedad Estado-Rasgo (STAI) fueron aplicados al inicio y al final de las 12 sesiones de una hora, asignadas en 3 sesiones a la semana durante 4 semanas seguidas.

**Resultados.** Finalizaron el estudio 66 participantes. El abandono fue 2,9 % para el grupo de intervención (N = 1) y 11,4 % para el grupo control (N = 4). El grupo de intervención mostró mejora estadísticamente significativa a nivel intragrupo (p < 0,001) e intergrupal (p = 0,001 a 0,046), en todos los parámetros del HADS y STAI, independientemente del género y edad. El tamaño del efecto, según la (d) de Cohen para la ansiedad y depresión, fue grande para el grupo de intervención (TE = 0,84 a 1,36) y entre pequeño y medio para el grupo control (TE = 0,28 a 0,49). **Conclusión.** El programa estructurado e intensivo de 4 semanas de duración Bienestar y Sofrología ha mostrado eficacia para reducir los síntomas de ansiedad y depresión en pacientes de asistencia primaria con niveles medio o alto de ansiedad.

**Palabras clave.** Bienestar, Sofrología, Relajación Dinámica de Caycedo, Ansiedad, Depresión, Asistencia Primaria

## BACKGROUND

Anxiety disorders are considered the most prevalent mental disorders around the world and are associated with significant comorbidity and morbidity[1]. Anxiety disorders often co-occur with other anxiety disorders, major depression, somatic symptom disorders, personality disorders, and substance abuse disorders[2]. According to diagnosis, anxiety disorders are often underrecognized and undertreated in primary health care. Women are 1.5 to two times more likely than men to receive a diagnosis of anxiety disorder[3].

Systematic reviews and meta-regressions have confirmed differences in prevalence of anxiety disorders around the globe. There is considerable uncertainty around estimates, and have suggested a current global prevalence of anxiety disorders of 7.3% (4.8% to 10.9%) and 10.4% (7.0-15.5%) in Euro/Anglo cultures[4,5].

The Global Burden of Disease study found that in 2010, anxiety disorders were the sixth leading cause of disability in terms of years of life lived with disability in both high-income and in low- and middle-income countries[6]. The current conceptualization of the etiology of anxiety disorders includes an interaction of psychosocial factors, e.g., childhood adversity, stress, or trauma, and a genetic vulnerability, which manifests in neurobiological and neuropsychological dysfunctions. From a socio-economic point of view, the annual costs associated with anxiety disorder are in general high[7].

In the treatment of anxiety disorders, psychopharmacological interventions with benzodiazepines and selective serotonin reuptake inhibitors (SSRI) have shown their efficacy[8]. A meta-analysis carried out by Bandelow[9], compared the efficacy of pharmacological, psychological and combined treatments in three anxiety disorders. This analysis showed superiority for pharmacological treatments. 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 and benzodiazepines might cause, for example, dependency, drowsiness, and impaired cognition[10].

Several non-pharmacologic interventions have been proposed as an alternative to pharmacotherapy with the aim to reduce perceived anxiety and stress and to increase the sense of well-being. Cognitive Behavioural Therapy (CBT) is one of them and several randomized clinical trials have shown its effectiveness in anxiety and depression disorders[11,12]. In a recent study with GAD patients, three CBT protocols were compared (a) Cognitive Therapy/Borkovec's treatment package; (b) Rational Emotive Behavior Therapy, and (c) Acceptance and Commitment Therapy/Acceptance-based behavioral therapy. All of them were similar effective and associated with large pre-post intervention reductions in GAD symptoms. No significant differences were found between groups[13].

The relaxation – meditation techniques represent another important alternative in anxiety intervention[14]. Several meta-analytic studies show the consistent and significant efficacy of relaxation training in reducing anxiety[15,16].

In this study, sophrology is proposed as a new alternative. 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. What is more, it develops positive attitudes, psychosocial capacities and personal values[17].

Similar effects have been claimed by some other disciplines like progressive relaxation[18], autogenic relaxation[19,20], yoga[21,22], meditation[14,23] and other emerging techniques such as mindfulness[24,25]. Within this spectrum, sophrology is positioned as a discipline that is not only interested in episodic therapeutic benefit but also in 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.

## METHODS

### Participants selection

During three consecutive days 388 patients, visiting the Cerdanyola Medical Health Care Centre (Spain), were asked by the Medical Health Care team to participate in this study independent of gender, age, academic level or professional occupation. To establish their baseline anxiety level, they

were asked to answer the self-rating HADS. Out of them, 86 patients (22.2%) met the HADS-anxiety selection criteria (HADS-Anxiety cut-off score *≥8).*

- *Inclusion criteria:* From this initial sample 70 patients (81.4%) met the inclusion criteria: a) *A cut-off ≥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:* Excluded from the study were those patients who: a) initiated or changed pharmacological, behavioural or any other therapy during the program, b) Acute state of a severe mental disorder (mayor depression, bipolar disorder and schizophrenia, etc.), 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, which could produce bias in the ratings of the study, e) were not able to participate for linguistic, cultural or physical problems.

## Randomisation

These patients were randomly assigned into two groups of 35 participants following simple randomisation. Following the list of selected patients (N=86), every multiple of seven was called by telephone (patient 7,14, 21, etc.) and alternately assigned to the intervention group or the control group until the number of 35 participants was reached for each group. The sample size was based on medical and statistical considerations.

The intervention group followed the sophrology program called "well-being and sophrology" 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 group 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).

The Ethics Committee approved the study and written informed consent was obtained from all participants.

## Instruments

Two self-ratings of short duration (15-20 min) were used: The Hospital Anxiety Depression Scale (HADS)[26] and the State-Trait Anxiety Inventory (STAI)[27]. Both questionnaires were used at the beginning of the first and the last session of the training program.

*HADS: Hospital Anxiety Depression Scale (HADS).* The HADS-Anxiety subscale was used as a screening test to select the participants. 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 the measure of 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[28,29]. The studies concerning the accuracy of these thresholds all show them to be reliable[30,31].

This questionnaire is translated into different languages and has demonstrated its validity and reliability in different Spanish studies[32,33]. In spite of international acceptance and extensive use, the controversy behind HADS factorial structure still exists, as it has right from the beginning[34,35]. 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 into the Spanish language[36] and has shown to be reliable for patients with anxiety disorders[37].

## 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 from 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 of the study for both the sophrology and the PMHR control group.

Each sophrology session was divided into 50% theory and 50% practice. The theory overlapped with the PMHR program and consisted of stress management in daily life, somatizations, adequate sleep hygiene, positive thinking, relaxation in daily life, etc. The practical part consisted of a selection of 20-minute sophrology techniques, such as diaphragmatic breathing, dynamic relaxation exercises, imaging and mental programming techniques, and a 10-minute feedback related to the personal experiences. 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 to everyday life.

The control group sessions were also divided into a theoretical (50%) and interactive part (50%). Theory consisted of a cognitive intervention program based on physical and mental health recommendations (PMHR) based on WHO recommendations[38]. Some of the treated subjects were: stress management in daily life, somatizations, physical exercise and well-being, a balanced diet, adequate sleep hygiene, positive thinking, and relaxation in daily life, etc. During the interactive part patients attended conferences and watched videos related to healthcare. The same professionals from the Medical Health Care Centre guided the control group sessions. Special attention was given to the application of the PMHR to everyday life.

## Statistical Analysis

Statistical analyses were performed using SPSS 23th 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 (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 the two groups. Pre-post Cohen's (d) effect sizes (ES) were used to measure the effect size in the sophrology and control groups[39]; *P*- value under 0.05 was considered statistically significant for all data analysis.

**Table 1** 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.

| Scale | *N Control* | Baseline mean | (SD) | Final mean | (SD) | *P*-value[b] | Cohen ES[c] (95% CI) | *N Sophrologie* | Baseline mean | (SD) | Final mean | (SD) | *P*-value[b] | Cohen ES[c] (95% CI) | *P*-value[a] *between groups* | *P*-value[d] *between groups* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| HAD-D | 31 | 7,68 | 5,16 | 5,84 | 4,61 | 0,01 | 0.49 (0.08, 0.66) | 34 | 7,59 | 3,39 | 4,06 | 3,41 | <0,001 | 1.19 (0.65, 1.42) | 0.994 | 0.046 |
| HAD-A | 31 | 10.5 | 4.86 | 9.23 | 4.59 | 0.113 | 0,29 (-0.06, 0.58) | 34 | 12.1 | 3.36 | 7.85 | 3.47 | <0,001 | 1,16 (0.77, 1.72) | 0.08 | 0.003 |
| STAI-S | 31 | 28.1 | 12.3 | 24.4 | 12.8 | 0.134 | 0,28 (-0.09, 0.67) | 34 | 27.9 | 13.8 | 17.3 | 9.17 | <0,001 | 0,84 (0.47, 1.32) | 0.955 | 0.032 |
| STAI-T | 31 | 31.2 | 12.5 | 27.2 | 13.0 | 0.029 | 0,41 (0.03,0.58) | 34 | 34.6 | 9.15 | 22.9 | 9.60 | <0,001 | 1,36 (0.78, 1.61) | 0.199 | 0.001 |

[a] p-values. Comparison of baseline values between sophrology and control group
[b] *p*-values from an analysis of variance for repeated measures (ANOVA) for with-in group analysis
[c] within group Cohen's d effect size with 95% CI
[d] *p*-values from an analysis of variance for repeated measures (ANOVA) for between groups analysis

## RESULTS

### 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, they have been excluded from the data analysis.

### Effects on the questionnaire HADS-Anxiety subscale.

- *Between groups analysis*: The ANOVA interaction effect between the Sophrology and PMHR group was statistically significant for the Sophrology group (p=0.003).

- *Within group analysis:* 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).

- *Effect sizes:* 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).

### Effects on the questionnaire HADS-Depression subscale.

- *Between groups analysis*: ANOVA interaction effect between the Sophrology and control group showed a statistically significant reduction for sophrology (p=0.046).

- *Within group analysis:* In the sophrology group, the mean depression level reduced from 7.6 at baseline to 4.1 at the final visit. Pre-post intervention assessments with 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=0.01).

- *Effect sizes:* 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).

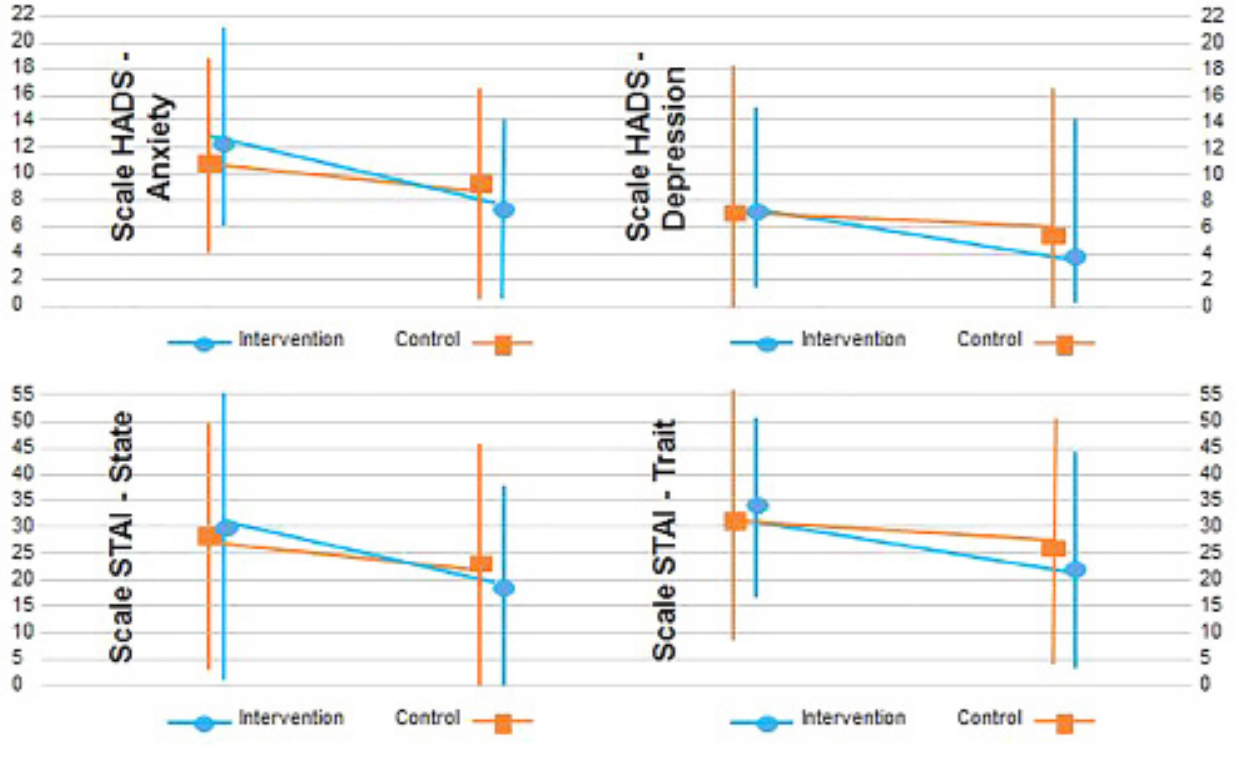


*Figure 1* — *Baseline and final values for HAD-Anxiety, HAD-Depression, STAI-State Anxiety and STAI-Trait Anxiety for the intervention (Sophrology) and control (PMHR) group.*

### Effects on the STAI – State Anxiety questionnaire.

- *Between groups analysis*: The ANOVA interaction effect between the intervention and control group showed a statistically significant improvement for the Sophrology program (p=0.032).

- *Within group analysis:* Pre-post intervention assessments with ANOVA revealed a high statistically significant reduction for *STAI-State anxiety* in the sophrology group (p<0.001). The control group did not show any statistically significant reduction (p=0.134).

- *Effect sizes:* 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).

### Effects on the STAI – Trait Anxiety questionnaire.

- *Between groups analysis*: The ANOVA interaction effect between the intervention and control group showed a statistically significant improvement (p=0.001) for the Sophrology program.

- *Within group analysis:* In the sophrology group, pre-post intervention assessments with ANOVA, showed a high statistically significant reduction for STAI-Trait Anxiety (p<0.001) and a small statistically significant reduction for the control group (p=0.029).

- *Effect sizes:* 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 Table 1).

It should 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 relief from headaches, neck pains, lumbar or digestive problems and improvement in sleep, mood and joy.

## DISCUSSION

The aim of this study was to determine the effects of sophrology's dynamic relaxation techniques on anxiety and mood in primary care patients and, as far as we know, this is the first experimental study. Seventy patients with moderate and high anxiety levels, according to the HADS-Anxiety subscale questionnaire (cut-off ≥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-week intensive group-training sessions, the with-in group analysis (ANOVA) for the sophrology group showed statistically significant improvements in all HADS and STAI subscales. The between groups analysis was statistically significant in all HADS and STAI subscales in favour of the sophrology group, 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 group.

A remarkable finding is the STAI-trait subscale improvement in the sophrology group after only the 4-week sophrology program. However, the findings of several studies using factor analytic procedures have offered good support for the notion that the STAI-trait scale assesses depression as well as anxiety symptoms[40,41,42]. The important improvement of the HAD-Depression scale in the sophrology group might explain the surprising good results for the STAI-trait scale.

We conclude that a short (four weeks) and intensive (3 times per week) sophrology group-training intervention is effective in reducing 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≥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, it also allows intervention 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 ≥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 sophrology 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 sophrology, compared to physical and mental health recommendations only.

According to Cabello & Brugada[43], 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. In this clinical study it was not easy to motivate the PMHR control group to finish their intensive 4-week control program (three times a week). For ethical reasons, once ended the intensive PMHR control program, the control group was offered several sophrology sessions, which made a scientific follow-up impossible.

Future studies have to show the effectiveness of sophrology training on anxiety and depression, its effectiveness in the medium and long term, using 3-, 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 (cut-off≥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 line with other observations, a greater number of women suffer from anxiety symptoms[3] and, in general, show more interest for well-being programs.

## 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.

## ABBREVIATIONS:

- STAI: State-Trait Anxiety inquiry
- HADS: Hospital Anxiety Depression Scale
- PMHR: Physical and Mental Health Recommendations
- SSRI: Selective Serotonin Reuptake Inhibitors

## DECLARATION

### Ethics approval and consent to participate

Approval was obtained from the ethics committee and informed consent was obtained from all participants before the beginning of this clinical trial.

Ethics committee "Investigación Clínica Parc de Salut MAR", Barcelona, Spain. Secretary: Ma Teresa Navarra Alcrudo. Clinical Investigation Project: 2015/6141/I .

### Availability of data and material

The datasets obtained and analyzed during the current study are available from the corresponding author on reasonable request

### Competing Interests

The author and three co-authors collaborate with Sofrocay, Academy for Caycedian sophrology, Barcelona, Spain.

*Funding:* This is a low budget study. The author (PhD student), the co-authors and the medical health care team declare that they have participated in this study without any financial compensation.

### Authors' contributions

KR contributed to the concept and study design, the development of the protocol, the literature search, the interpretation of the results and wrote the first and the final version of the manuscript. RSB contributed to the concept and design, the development of the protocol (control group), the literature search and the interpretation of the results. MJFG contributed to the interpretation of the results and the development of the final version. NCD contributed to the development of the protocol (intervention group), the interpretation of the results and the development of the final version. RS contributed to the data extraction, inputting the data to the statistical software, the data analysis and the development of the final draft. AB contributed to the concept and design, the interpretation of the results, critically revised and approved the final manuscript. All authors contributed to the interpretation of the results, read and approved the final manuscript.

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