

Anti-anxiety efficacy of Sudarshan Kriya Yoga in General Anxiety Disorder: a multicomponent, yoga based, breath intervention program for patients suffering from generalized anxiety disorder with or without comorbidities.

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1. Introduction

An estimated third of the total European population suffers from mental disorders (Wittchen, 2005). Among these, depression and anxiety are two of the most common psychiatric disorders affecting adults, young adults and adolescents of both sexes (Da Silva, 2009; Alonso, 2004; Cassano, 2002; Wittchen, 1999, 2002b, 2005, 2010). Psychiatric disorders are the prominent cost of disability adjusted life years world-wide (Balasubramaniam, 2012). The personal, social and occupational functions of an individual, as well as their physical health, can be dramatically affected by these disorders, which, in turn, produce a negative impact on society, in terms of both the elevated cost of health care resources, and the subsequent reduction in worker productivity (Frye et al., 2006; Wittchen, 2005; Wang, 2009).

Regarding treatment strategies, recent studies have revealed an issue of particular relevance concerning the difference in access and propensity to psychiatric care in relation to gender. Women result as demonstrating a higher propensity to acknowledge psychological discomfort, and subsequently, to request aid, given that they are primarily affected by internalization-related disturbances (Depression and Anxiety). On the contrary, men result as being much more likely to repress their psychological discomfort, and are characterized by a general refusal to ask for assistance, opting, instead, to isolate themselves, given that they are primarily affected by externalization-related disturbances (antisocial behavior, drug addiction, etc.) (Kessler et al, 1993,1994; Eaton et al, 2011). To this regard, in order to facilitate equal access and compliance to psychiatric care for both genders, it is necessary to develop strategies in communication, diagnosis and care specifically designed for the different needs and characteristics of male and female psychological disorders.

Furthermore, in order to achieve effective, long-term results in therapeutic treatment, it is also essential to take into account the tendency of mood and anxiety disorders to be not only chronic and highly comorbid, but by their very nature, prone to exacerbate other forms of psychiatric illnesses (Andrews et al., 2002; Wittchen et al., 1998, 2005).

Generalized Anxiety Disorder (GAD), has the potential to cause serious interference with a person's daily life (Wittchen et al., 2002a, 2005). By definition, GAD is characterized by excessive anxiety and worry that lasts for at least six months and is associated with three or more of the following symptoms: restlessness, becoming easily fatigued, difficulty concentrating, irritability, muscle tension, and sleep disturbance. Excessive and uncontrollable worrying is a core feature of GAD, often concerning the individual's health and that of their significant others, their personal finances and their future (American Psychiatric Association, 1994). This disorder also exhibits a high degree of chronicity, with women more likely to be diagnosed than men. (Wittchen et al., 2002) It is often complicated by a high prevalence (45-91%) of comorbidity with other psychiatric and/or medical conditions including panic disorders and major depressive disorders (Massion,1993; Olfson, 1997; Wittchen, 2005) as well as a variety of cardiovascular, gastrointestinal and respiratory diseases (Wittchen et al., 2002). Relapse rates are fairly high for people suffering with GAD with two thirds of patients suffering a recurrence within one-year (Brawman-Mintzer, 1996).

Current pharmacotherapeutic options for GAD include antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRI), e.g. venlafaxine, O-desmethyl-venlafaxine, duloxetine, milnacipran, buspirone, hydroxyzine, and benzodiazepines, low-dose anti-psychotics, and pregabalin (Ballenger, 1991) (Montgomery, 2006). Nevertheless, all pharmacological treatments for GAD can cause troublesome side effects, including nausea, sexual dysfunction, and weight gain for the antidepressants (Kennedy, 1999; 2001), and anterograde memory impairment, sedation and the risk of dependence with benzodiazepines; therefore, they are not recommended for long-term use (Michellini, 1996). Response to these treatments tends to be highly variable, ranging from 40% to 70% (Baldwin, 2005; Gelenberg, 2000; Pollack, 2001; Rickels, 1993). Furthermore, limits in terms of efficacy and tolerability often result in poor patient adherence to medication and thus, long-term remission is often difficult to achieve (Katzman, 2008). On average, only a third of GAD patients achieve remission within a year of follow-up, while patients who do achieve an initial response often relapse (Andrews, 2000).

Depressive disorder is another well-known chronic, recurrent and disabling mental disease with high direct and indirect costs to society in both western and eastern cultures (Hwu, 1996; Cassano, 2002; Lu, 2008). Depressive disorder is also associated with a considerable disability burden in

terms of number of work days lost (Wittchen, 2005). Although a large number of novel antidepressants have been introduced over the past few decades, at least 40% of depressed patients show only partial or no response to initial or even multiple antidepressant medication (Fava, 1996; Golden, 2002). Thus, novel, effective therapies for anxiety and depression are currently needed.

Sudarshan Kriya Yoga (SKY) is a comprehensive program derived from yoga that includes bodily postures, powerful breathing exercises, meditation, and cognitive/behavioral procedures. From the biomedical point of view, it is a set of techniques with demonstrable effects on brain function (Meti and Desiraju, 1984; Meti and Raju, 1993). Previous studies have suggested that SKY is an effective tool in relieving clinical and non-clinical anxiety and depression. There is sufficient evidence to consider SKY to be a beneficial, low-risk, low-cost adjunct to the treatment of stress, anxiety and depression (Brown, 2005; Katzman, 2012; Zope, 2013). Thus SKY represents a potentially valuable adjunct to standard pharmacotherapy in patients with GAD or treatment-resistant GAD patients, and warrants further investigation. The objective of the current study was to evaluate the possible efficacy of SKY in relieving anxiety and depression symptoms, at the same time improving the general psychological condition of a population of Caucasian adult outpatients.

2. Methods

2.1. Patients

The study was made up of 69 consenting outpatient adults (between 25-64 years) with a primary diagnosis of DSM-IV Mood and/or Anxiety disorders (American Psychiatric Association, 1994). Thirty-nine consenting outpatients presented a primary diagnosis of DSM-IV Anxiety disorders, 18 consenting outpatients presented a primary diagnosis of DSM-IV Mood disorder (patients with major depression, dysthymic disorder, or other depressive disorders) with 12 patients presenting both diagnoses. The 39 patients suffering from Anxiety were diagnosed with Generalized Anxiety Disorder ; all 18 patients suffering from Depression were diagnosed with Dysthymic Disorder or Depressive Disorders not otherwise specified. The remaining 12 patients were diagnosed with both dysthymic disorder and generalized anxiety disorder. All patients, 28 men and 41 women, signed informed consent forms for participation in the study. The majority of women in the study reflects two principle factors: a gender breakdown in prevalence of anxiety and depression (Breslau, 1995; Eaton et al. 2011), and the fact that the prevalence of yoga practitioners are more likely to be female (Birdee 2008; Ding 2014). The sample has been divided in to two groups, both groups undergoing SKY treatment and participating in self-help weekly groups. Prior to initiating the study, patients belonging to Group 1 had undergone a minimum of six months of standard pharmacological

treatment with a fixed dosage of antidepressant and/or anxiolytic and were diagnosed as stable. Inclusion in Group 1 was based on a clinical psychiatric evaluation and uninterrupted assumption of their fixed pharmaceutical treatment. Participants in Group 2 had undergone at least six months of participation in self-help groups and were also diagnosed as being in stable condition; inclusion in this group was based on three factors: a clinical psychiatric evaluation, low efficacy of the psychotropic drug on the specific patient and the personal decision of the patient to not assume their prescribed medication.

2.2 Treatments

2.2.1 SKY

The application of the SKY procedure has been previously documented (Janakiramaiah et al., 1998; Kjellgren et al., 2008) in environments where SKY was taught by trained, certified facilitators. In the current study, the selected sample group participated in an intense SKY workshop consisting of 10 sessions over the course of two weeks, followed by weekly SKY follow-up classes for a period of six months. Each individual session lasted approximately two hours.

The sequence of SKY, adapted to clinical purposes, consists of five sequential breathing exercises separated by 30-second periods of normal breathing.

The sequence is performed as follows: Ujjayi, slow breathing 3-4 cycles per minute; Nadi Shodana, alternate nostril breathing, Kapalabati, fast diaphragmatic breathing; Bhastrika, rapid exhalation at 20-30 cycles per minute; and Sudarshan Kriya, rhythmic, cyclical breathing in slow, medium and fast cycles. A brief interlude of chanting is introduced between the Bhastrika and the Sudarshan Kriya cycles. These variations of rhythmic breathing are practiced while sitting with the eyes closed and the awareness focused on the breath. A relaxed state is reached by the end of the cyclical breathing and the process culminates with a ten-minute rest in a tranquil supine position. There is a "long version" of the protocol which must be practiced in the presence of a trained facilitator and a "short version" that the patients can practice alone; all patients were instructed on how to perform the simplified home version of the protocol autonomously. The home sessions are prescribed as: once a day in the morning, six days a week. The group sessions with the trainer includes the practice of a simple classical yoga stretching sequence.

2.3 Assessments

Assessments were carried out by a psychiatrist and a psychologist, external to patients ongoing treatment protocol, in a quiet ambulatory environment: at the time of recruitment, after two weeks, after three months, and six months after recruitment. . The severity of anxiety was assessed using the Hamilton Rating Scale for anxiety (HRSA) (Hamilton, 1959) and the Zung Self-Rating Anxiety Scale Inventory (ZASI) (Zung, 1971). The severity of depression was assessed using the Hamilton Rating Scale for Depression (HRSD) (Hamilton, 1960) and the Zung Self-Rating Depression Scale Inventory (ZDSI) (Zung, 1965). A general symptomatic assessment was performed using Symptom Checklist-90 (SCL-90) (Derogatis, 1977a). HRSA was developed by Hamilton (1959) to determine the level of anxiety and distribution of symptoms, and to measure change in symptom severity. Assessing both mental and somatic symptoms. Higher scores indicate severe anxiety. The psychic subscale addresses the more subjective cognitive and affective complaints of anxiety (e.g., anxious mood, tension, fears, difficulty concentrating), while the somatic component emphasizes features such as autonomic arousal, respiratory, gastrointestinal and cardiovascular symptoms. The presence and severity of symptoms are rated by an interviewer. HRSD, was developed by Hamilton (1960) to measure the severity of depression. The questionnaire is designed for adults and is used to rate the severity of their depression by feelings of guilt, suicidal tendencies, insomnia, anxiety, and somatic symptoms. ZDSI and ZASI each comprise an evaluation of 20 depression and anxiety symptoms and signs in an ascending numerical manner (each item scores from 1 to 4 points), with higher scores reflecting higher intensity of the relevant symptomatology. We chose two self-administered questionnaires and two clinically administered tests, both to ensure accurate diagnosis was correct and to leverage on the multiple points of view supplied by the use of diverse questionnaires. Hamilton scales express the point of view of the psychiatrist while the self-administered questionnaires explore the perspective of the patient: allowing observation of the convergence and divergence of perspectives, which added an important dimension to the study. All patients selected were medically fit and scored 17 or more on the total HRSD (Hamilton, 1960) and/or scored 17 or more on the total 14-item HRSA (Hamilton, 1959). The Symptom checklist 90, SCL-90, is a commonly used self-report instrument to assess the psychological and symptomatic status of individuals ranging from "healthy" to "disorder afflicted" (Derogatis, 1977a). It consists of 90 questions defined in 9 symptoms dimensions (depression, anxiety, phobic anxiety, hostility, obsessive-compulsive, interpersonal sensitivity, somatization, paranoid ideation and psychoticism dimensions) (Derogatis, 1977b).

2.4 Objectives

The main objective of this study was to verify and statistically register the efficacy of SKY treatment in significantly reducing Anxiety and Depression scores ($\alpha = 0.05$). A secondary focus of the study was to evaluate the differences in the scores between patients treated with medication and those not treated, examining co-morbidity factors between anxiety and depression. As an ulterior objective, we attempted to assess whether a potential improvement in patients' overall psychological well-being, awareness and perception of their condition could be induced through SKY treatment.

2.5 Statistical Analysis

The study considered two clinical conditions: Anxiety and Depression. For each condition, the following rating scales were applied: HRSA, HRSD ZASI, ZDSI - SCL-90. Sixty-nine subjects were enrolled in the study. For each relationship between scale and clinical condition, a mixed design factorial 2x4 ANOVA analysis was performed, in which the independent variable (BETWEEN) represents: patients treated with medication, patients not treated with medication; patients with a diagnosis of Anxiety or Depression, and people with no pathological diagnosis. The independent variable (WITHIN) is the repeated measures variable and represents the time points of assessment for Anxiety and Depression: baseline; 2 weeks after treatment; 3 months after treatment; 6 months after treatment. The dependent variable expresses the scores of Anxiety/Depression. The different number of outpatients belonging to the groups of the independent variables (BETWEEN) reflects the prevalence in the general population. To estimate the size of the effect, the statistics: η^2 (obtained from the ratio of the deviance of the trials and the total deviance) and *Cohen's d* were used. In the early stages of the analysis, data pertaining to withdrawal cases (patients not completing the study) were excluded under the List-wise Deletion procedure (12-14 patients). Subsequently, the missing values of Hamilton's scale were analyzed by Little's test for *Missing Completely at Random* (MCAR), allowing us to apply the Expectation-maximization algorithm (Schafer, 1997) to estimate missing values and include the entire sample group of 69 patients in the analysis. The mixed design factorial ANOVA model was applied to Hamilton's Scales. In particular, when the BETWEEN variable is expressed by medication consumption, depression scores were considered. Anxiety scores were considered as well, utilizing a square root transformation to support normality and homogeneity of variances assumptions. When the BETWEEN variable is expressed as diagnosis, Anxiety Scores were considered, also depression scores were taken in to account thanks to a data transformation.

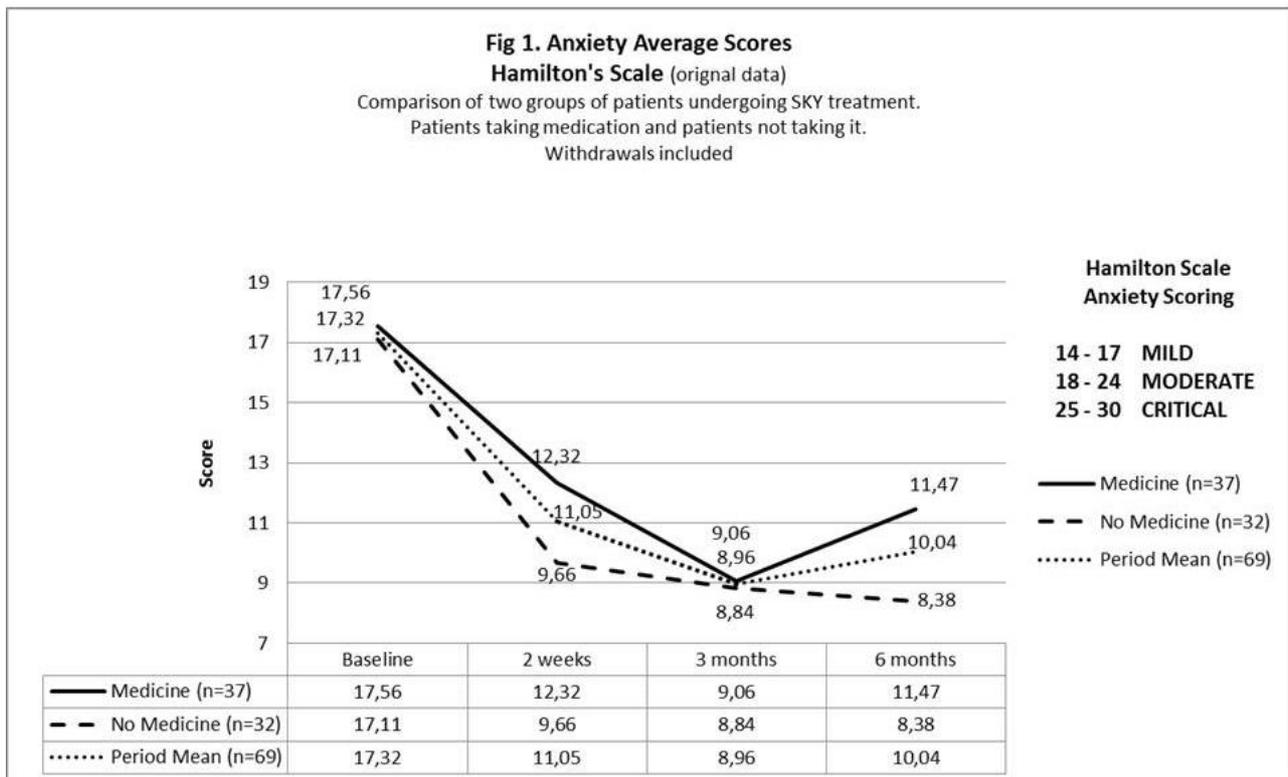
The mixed design factorial ANOVA model was also applied to the (transformed) scores expressed on the Scale Symptom Checklist-90/Global Score Index. Regarding the Zung Self-Rating Scale, the mixed factorial design was abandoned due to the violation (even after the application of data transformation) of the assumptions of model applicability. As an alternative, a one-way ANOVA for repeated measures was applied separately for each of the two groups of the BETWEEN variable. When the data didn't support the assumption of sphericity, a Greenhouse-Geisser correction was used or, as final option, we utilized a multivariate tests (in particular, Pillai-Bartlett's trace). The post-hoc pairwise comparisons of the scores detected at different time points of the study, performed through Bonferroni correction, showed as significant the differences between the pairs of scores. Since Zung Self-Rating Scales' are compiled directly by the subject, whereas Hamilton's Scales' express the assessment by an outside observer (the psychiatrist), we applied the Spearman rank correlation coefficient (ρ) to verify if Zung's scales scores were significantly related to those of Hamilton's Scales. We utilized this non-parametric procedure because the data were not normally distributed. At the beginning of the survey, in order to calculate the sample size, we assumed: $\alpha = 0.05$; $\beta = 0.2$ (power = 0.8) and a minimal clinically important difference (MCID) corresponding to an average anxiety reduction score of 47% (from 17 to 9), so we selected 57 patients. But considering the incidence of withdrawals (12 cases), we raised the sample to 69 patients, obtaining a power of 0.865. Regarding depression average score reduction, the same sample of 69 patients, with a 36.4% MCID (from 11 to 7), expressed a power of 0.685. The reported data set does not include withdrawal patients. When the data refer to the entire sample of 69 patients it is reported in square brackets.

3. Results

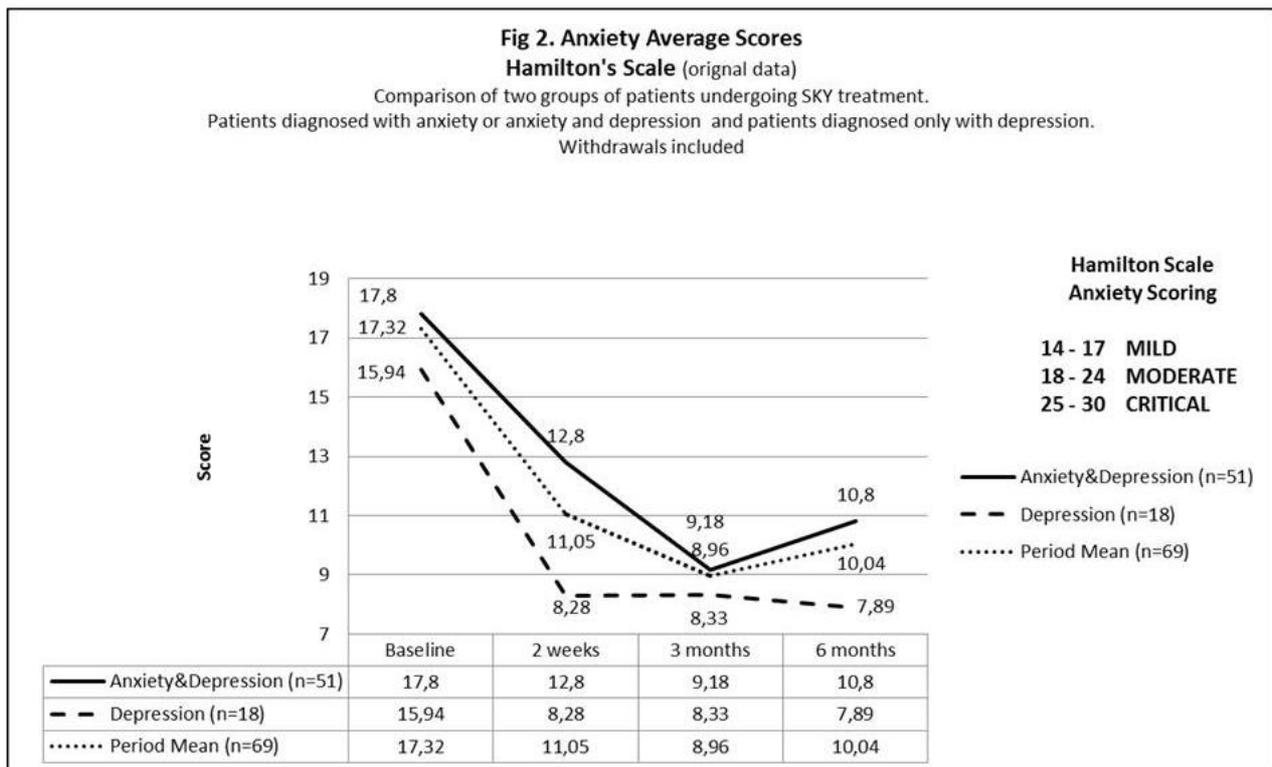
Hamilton Rating Scale for Anxiety (HRSA).

HRSA's scores significantly decreased from baseline to subsequent time points: $F(2.224, 122.315) = 18.959$ ($p < 0.001$) [$F(2.281, 152.808) = 25.763$ $p < 0.001$], and with a moderate effect size (Cohen's $d = 0,66$) [$d = 0,74$]. The main effect of the use of medication to the Anxiety scores is not significant $F(1, 55) = 0.628$, ($p = 0.432$) [$F(1, 67) = 0.309$, $p = 0.580$], nor was the effect of medication consumption to the scores recorded in different time points of the survey $F(2.224, 122.315) = 0.812$, ($p = 0.458$) [$F(2.281, 152.808) = 0.833$, $p = 0.450$]. The post-hoc comparisons, follows a pattern which remains constant throughout all the subsequent analyses, namely: significant score differences were registered between baseline (before SKY treatment) and all the

other time points (after induction of SKY). A plateau was reached after initial intensive treatment illustrated by non-significant score differences between successive time points after baseline. The results expressed as significance between each time point and the former, were: between base-line and 15 days after intensive SKY treatment ($p < 0.001$) [$p < 0.001$]; between 15 days after intensive SKY treatment and 3 months after treatment ($p > 0.1$) [$p = 0.893$]; between 3 months after treatment and 6 months after the treatment) ($p > 0.1$) [$p > 0.1$] [fig.1].



Considering the BETWEEN variable as patient diagnosis, Anxiety scores revealed that Anxiety reduction over time was statistically significant: ($p < 0,001$) [$p < 0,001$]. Effect size is moderate (Cohen's $d = 0,67$) [$d = 0,74$]. The difference in scores between the patients diagnosed with anxiety and those diagnosed with both anxiety and depression proved to be not significant $p = 0,381$ [$p = 0,146$]. The non-significance continues to be reflected in the effect of diagnosis on score differences at different time points of the survey: $p = 0,715$ [$p = 0,379$]. Moreover, post-hoc comparisons demonstrate the previously described pattern: between base-line and 15 days after SKY treatment ($p < 0.001$) [$p < 0.001$], between 15 days after SKY treatment and 3 months after treatment ($p = 0.820$) [$p = 0.617$], between 3 months after treatment and 6 months after treatment ($p > 0.1$) [$p > 0.1$] [fig.2].



Zung Anxiety Self-Rating Scale Medication Group

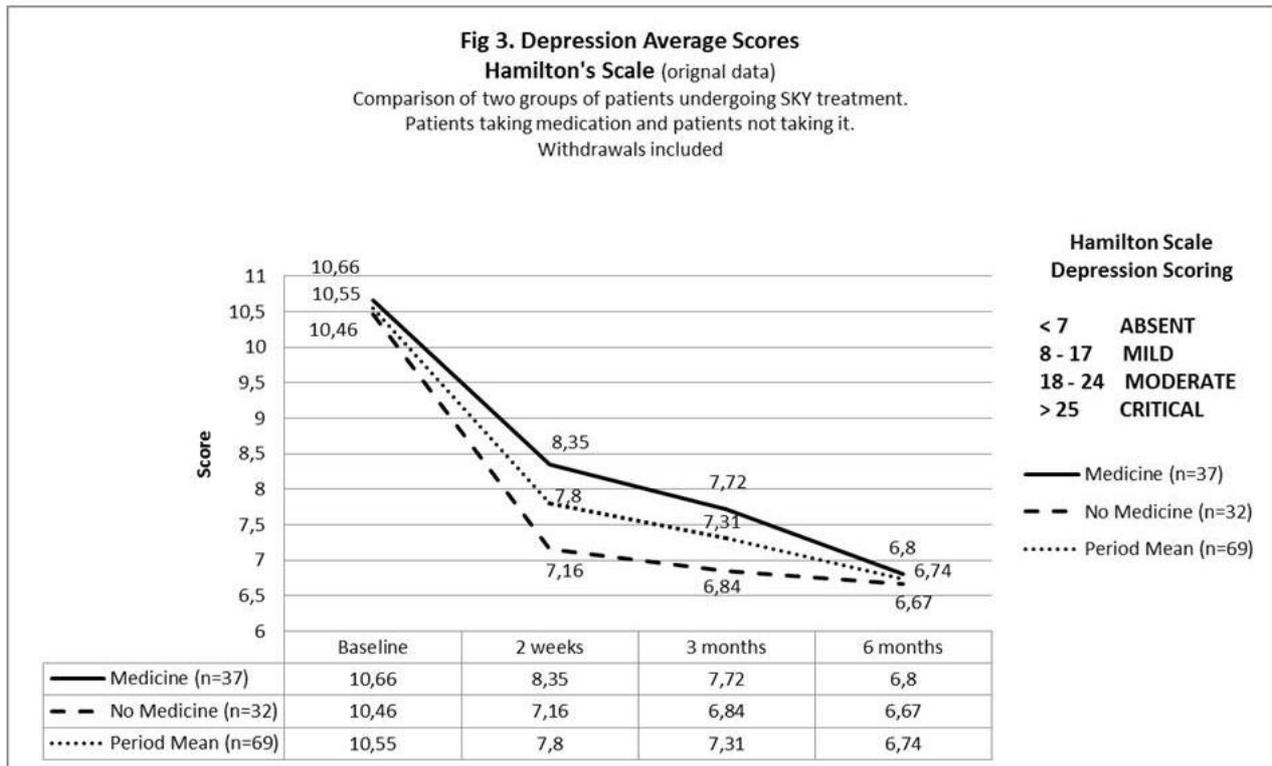
Anxiety scores are significantly reduced after SKY treatment ($p < 0.001$) and with a moderate effect size: $\eta^2 = 0.11$.

Zung Anxiety Self-Rating Scale Non Medication Group

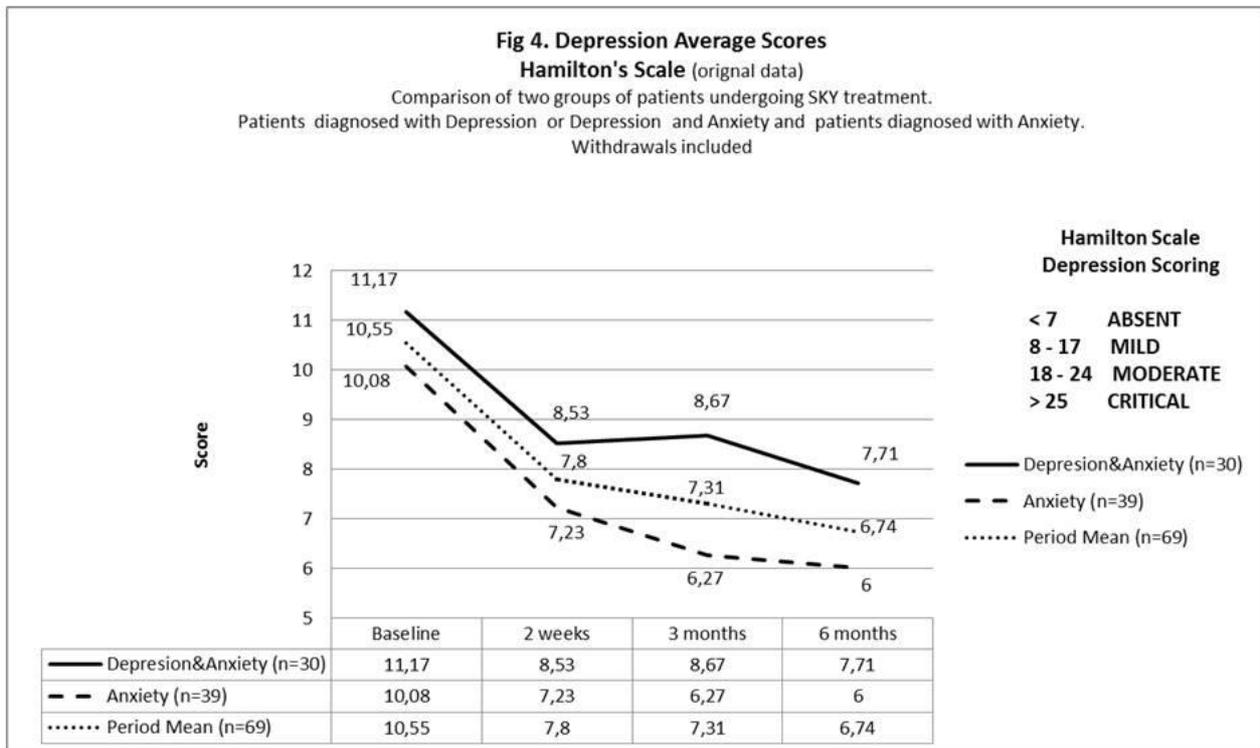
This test demonstrated a significant reduction in anxiety scores from baseline to all other time points in the survey: ($p < 0.001$), illustrated by a large effect size $\eta^2 = 0.19$.

Hamilton Rating Scale for Depression (HRSD)

Depression scores significantly decreased over time both when considering the independent variable BETWEEN as patients receiving pharmaceutical treatment and when taking into consideration the diagnosis of Depression. Regarding medication consumption, the results are as follows: ($p < 0.001$) [$p < 0.001$], with a moderate effect size of: ($d = 0.61$) [$d = 0.67$]. However, once the homogeneity of the variances of the scores between the two groups of patients is established, for all levels of the time variable (Levene's test), both the use of drugs by a group of ($p = 0.637$) [$p = 0.642$] and the interaction between this setting and the different time points of the survey, ($p = 0.657$) [$p = 0.614$] do not seem to significantly affect depression scores (**fig.3**).



Post-hoc tests revealed that SKY treatment elicited a significant reduction in anxiety scores between baseline and 15 days after SKY treatment ($p < 0.001$) [$p < 0.001$] whereas the comparison between the following time points reveals a plateau: 15 days after SKY treatment and 3 months after treatment ($p > 0.1$) [$p > 0.1$], 3 months after treatment and 6 months after treatment ($p > 0.1$) [$p > 0.1$]. In the case of two groups of patients, differing by depression diagnosis, the data were transformed into square root. The results are: [$p < 0,001$ $d = 0.67$]. Also in this case, neither diagnosis [$p = 0,319$], nor its interaction with the different time points of the survey [$p = 0,665$] affect depression scores. Post-hoc comparisons show significant difference between baseline and 15 days after SKY treatment [$p < 0.001$]. On the other hand, there are no significant differences among subsequent time points: 15 days after SKY treatment time points and 3 months after treatment [$p > 0.1$], 3 months after treatment and 6 months after treatment [$p = 0.38$]. [fig.4].



Zung Self-Rating Scale Drug Group

The reduction in Depression scores from the baseline to the subsequent time points is significant ($p < 0.001$), with a moderate effect size: ($\eta^2 = 0.09$).

Zung Self-Rating Scale No Drug Group

Depression scores are significantly reduced from baseline to the subsequent time points: ($p = 0.006$), with a moderate effect size: ($\eta^2 = 0.12$).

Correlation between Hamilton and Zung Scale.

Regarding the degree of correlation between the scales of Hamilton and Zung, the scores are always highly significant: both scales converge towards a same intensity of the symptoms (very low / absent). The assessments made by the psychiatrist who compiles the scales of Hamilton and the perceptions of the patients who complete Zungs' scales show a convergent outcome both for anxiety and depression. The results are shown in **Table 1**.

Table 1 Correlation between Hamiltons' and Zungs' scales for Anxiety and Depression calculated by Spearman's Rank Correlation Coefficient

	<i>n</i>	Values of Spearman's Rank Correlation Coefficient <i>r_s</i>	<i>sig.</i>
ANXIETY			
after 15 days of SKY treatment	69	0,402	0,001 *
after 3 months	64	0,514	< 0,001 *
after 6 months	57	0,656	< 0,001 *
DEPRESSION			
after 15 days of SKY treatment	69	0,376	0,001 *
after 3 months	64	0,744	< 0,001 *
after 6 months	57	0,648	< 0,001 *

* *significant*

Global Score Index of Symptom Check List – 90

The scores significantly decreased from the baseline onwards: ($p < 0.001$), with a moderate effect size: ($\eta^2 = 0.13$). However, the main effect of medication consumption over the GSI scores is not significant: ($p = 0.499$) and neither is the effect of taking medication on the scores drawn from different time points of the survey ($p < 0.396$).

4. Discussion

The statistical analyses employed in this study have verified that the implementation of SKY therapy in a scientifically controlled, medical environment significantly reduces levels of Anxiety and Depression in patients suffering from these disorders, as measured by five different psychological scales, across four main groups (Depression pharmaceutically treated/Not treated, Anxiety pharmaceutically treated/Not treated). The reduction in the scores achieved resulted as being particularly evident after the initial intensive SKY treatment, which was followed by a long plateau phase slowly bottoming out at null anxiety/depression scores. The treatment proved to be equally effective across all four groups, with no evidence of significant differences in the scores measuring the effect of SKY related to anxiety and depression or to the use of medication.

The universal reduction of scores obtained by the SKY procedure is especially relevant in light of the inclusion criteria employed in the study: at baseline all patients were stable in terms of type of medication, dosage of medicine and diagnosis for at least six months prior to participation to the study, implying that the effect of treatment had already reached a plateau before baseline, strongly supporting the evidence that the improvement in patient scores was due to SKY. At the beginning

of the survey, the scores of self-administered and medically-administered scales expressed that the observed phenomena was perceived at varying intensity levels: from ZASI and ZDSI, compiled by the patients, an average "moderate" score emerged, while through HRSA and HRSD, the psychiatrist evaluated the symptoms of the patients as "mild." [fig.4]. The observed significant convergence of Zung's scales scores towards Hamilton's scores over time supports the hypothesis that, as a consequence of SKY therapy, patient perception of the severity of their disorder manifested an incremental alignment with the view of the psychiatrist as treatment progressed. The results are presented in Table 1. Our initial hypothesis was that the clinical use of the SKY procedure could reduce anxiety scores, stabilize mental activity, enhance brain function and resilience to stress (Agte, 2005; Meti and Desiraju, 1984; Meti and Raju, 1993). We also considered the antidepressant efficacy of SKY as demonstrated by previous studies (Naga, 1998; Janakiramaiah et al. 1998; 2000; Gangadhar, 2000; Rohini, 2000; Vedamurthachar, 2006). Our findings suggest the following: both patient groups (with and without pharmacological treatment) showed significant improvements in Anxiety and Depression scores after completing the two week intensive segment of the SKY protocol; this improvement was strengthened in the following six months of weekly follow-ups. The fact that there is no significant difference between the two groups suggest that SKY protocol is an effective complementary therapy for patients undergoing pharmaceutical treatment and also a potential treatment of choice for people not utilizing psychiatric medication. This study suggests that SKY can be considered as a reliable adjunct therapy, or in specific cases of poor response and/or inadequate adherence to pharmacological treatment, an alternative method for treating anxiety disorders and melancholic depression, especially over a long-term time frame. These results suggest that the strong reduction in the scores of the Symptom Check List -90 Global Severity Index (GSI), revealing a decrease of the general psychiatric symptomatology, is associated with an improvement of self-awareness and self-efficacy obtained by regularly overcoming crisis symptoms by the autonomous practice of the SKY Procedure, thus increasing self-esteem and self-confidence. Empowered patients tend to reduce their needs and demands, providing two particularly relevant advantages: firstly, optimizing public health costs, and secondly, highlighting a more effective strategy for improved prevention and treatment of these disorders (Wittchen, 2005).

5. Conclusion

In conclusion, the introduction of SKY Treatment has successfully induced a significant reduction in Anxiety and Depression symptoms in the patients participating in our study. Considering the

strong demand for the improvement in patients' quality of life, as well as the need to reduce the negative impact on the work-force and to decrease the public costs generated by Anxiety and Depression, this study provides extensive evidence to warrant further studies on the efficacy of the SKY Procedure in relieving the symptoms, and at the same time, empowering patients suffering from these conditions. For a more conclusive, in-depth analysis of the efficacy of SKY, the study should be replicated on a larger clinical cohort in a controlled trial. Furthermore, the present study focused exclusively on quantitative data, however, given the socio-psychological nature of the research, in order to further develop the applications of this promising therapeutic approach, an in-depth exploration of the life experiences of the patients during and after treatment, through interviews/videos, could provide relevant utility. Collecting qualitative data in order to enrich understanding with regard to improvements and changes in mental health status could tangibly facilitate health practitioners in integrating the procedure with new ideas and synergies, further enhancing the beneficial effects on the participants' experience. (Villacres, 2014). Regarding potential future strategies for addressing the challenge of gender diversity in propensity to diagnosis and treatment, in order to facilitate access to care for male subjects exhibiting the tendencies of: repression of psychological discomfort, inability to request assistance, and self-isolation, an opportune solution could be to create synergies with already existing organizations dedicated to creating more accessible information and treatment for males suffering from psychological disorders (Bowl 2012; Golding 2012) as well as continuing to widen the diffusion of relevant information through the public health system. An important element emerging from this and previous studies is that once male subjects overcome their resistance to treatment, they demonstrate to be receptive to therapeutic programs such as SKY, and are able to receive significant benefits (Seppälä 2014; Sureka 2014; Carter 2013). This underlines the importance of leveraging on the synergies of existing therapeutic structures providing specifically male-oriented care.

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