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Transdiagnostic treatment using a unified protocol: application for patients with a range of comorbid mood and anxiety disorders

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Tratamento transdiagnóstico utilizando um protocolo unificado: aplicação em pacientes com diferentes transtornos de humor e ansiedade comórbidos

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Abstract

Objective: To evaluate the effectiveness of a unified cognitive-behavioral therapy protocol for group treatment of patients with a range of comorbid mood and anxiety disorders.

Methods: In this open-trial study, the unified protocol was followed for the psychotherapeutic treatment of 16 patients with comorbid mood and anxiety disorders, confirmed by the Mini International Neuropsychiatric Interview. Beck Depression and Anxiety Inventories, the World Health Organization Quality of Life evaluation instrument, and the ARIZONA scale of sexual function were used to evaluate progress in patients throughout the therapeutic process.

Results: All patients showed unipolar depressive disorder. Comorbidity with anxiety disorders was distributed as follows: generalized anxiety disorder, 13 (81.3%); panic disorder, 3 (18.8%); social anxiety disorder, 1 (6.3%); and post-traumatic stress disorder, 1 (6.3%). Improvement was observed in the signs and symptoms of depression ($F = 78.62$, $p < 0.001$) and anxiety ($F = 19.64$, $p < 0.001$), overall quality of life ($F = 39.72$, $p < 0.001$), physical domain ($F = 28.15$, $p < 0.001$)), psychological variables ($F = 9.90$, $p = 0.007$), social functioning ($F = 36.86$, $p < 0.001$), environmental variables ($F = 27.63$, $p < 0.001$), and sexuality ($F = 13.13$; $p < 0.005$). All parameters showed highly significant correlations ($p < 0.01$).

Conclusion: An effort to establish one unified treatment protocol for a whole family of emotional disorders (primarily mood and anxiety disorders) showed benefits in the field of clinical psychology and for the treatment of patients. No other data were found in the literature describing the implementation of the unified protocol in a transdiagnostic group. Our results revealed statistically significant improvement in all variables, suggesting that the protocol proposed can become an important tool to improve quality of life, sexuality, and anxiety/depression symptoms in patients with different diagnoses.

Keywords: Protocol, transdiagnostic approach, anxiety, depression.

Resumo

Objetivo: Avaliar a eficácia de um protocolo unificado de terapia cognitivo-comportamental para tratamento em grupo de pacientes com diferentes transtornos de humor e ansiedade comórbidos.

Métodos: Neste estudo aberto, o protocolo unificado foi seguido no tratamento psicoterápico de 16 pacientes com transtornos de humor e ansiedade comórbidos, confirmados pelo Mini International Neuropsychiatric Interview. Os Inventários de Depressão e Ansiedade de Beck, o instrumento de avaliação de qualidade de vida da Organização Mundial da Saúde e a escala ARIZONA de função sexual foram utilizados para avaliar o progresso em pacientes ao longo de todo o processo terapêutico.

Resultados: Todos os pacientes tinham transtorno depressivo unipolar. A comorbidade com transtornos de ansiedade apresentou a seguinte distribuição: transtorno de ansiedade generalizada, 13 (81,3%); transtorno do pânico, 3 (18,8%); fobia social, 1 (6,3%); e transtorno do estresse pós-traumático, 1 (6,3%). Foi observada melhora nos sinais e sintomas de depressão ($F = 78,62$, $p < 0,001$) e ansiedade ($F = 19,64$, $p < 0,001$), na qualidade de vida geral ($F = 39,72$, $p < 0,001$), no domínio físico ($F = 28,15$, $p < 0,001$)), em variáveis psicológicas ($F = 9,90$, $p = 0,007$), funcionamento social ($F = 36,86$, $p < 0,001$), variáveis ambientais ($F = 27,63$, $p < 0,001$) e sexualidade ($F = 13,13$; $p < 0,005$). Todos os parâmetros demonstraram correlações altamente significativas ($p < 0,01$).

Conclusão: O esforço para estabelecer um protocolo unificado de tratamento para toda uma família de transtornos emocionais (especialmente humor e ansiedade) mostrou benefícios na área da psicologia clínica e no tratamento dos pacientes. Não foram encontrados outros dados na literatura descrevendo a implementação do protocolo unificado em um grupo transdiagnóstico. Nossos resultados revelaram uma melhora estatisticamente significativa em todas as variáveis, sugerindo que o protocolo proposto pode se tornar uma ferramenta importante para melhorar qualidade de vida, sexualidade e sintomas de ansiedade/depressão em pacientes com diferentes diagnósticos.

Descritores: Protocolo, abordagem transdiagnóstica, ansiedade, depressão.

Introduction

The prevalence of anxiety and mood disorders is estimated to be 25% in the general population.[1] In parallel, there is a greater awareness of the need to treat these clinical conditions, as they can affect social coping skills and make it difficult for an individual to be successful in society.[1-3] However, much of the population lacks sufficient financial resources to pay for individual medical treatment.

Studies on the use of cognitive-behavioral therapy (CBT) in group treatment settings have demonstrated satisfactory results,[4-7] and a meta-analysis[8] has indicated significant positive results of CBT in mixed disorders (d = 0.26, 95% confidence interval = 0.44 to 0.08). Treatment effectiveness is also influenced by the adjustment to a group situation, indicating that dysfunctional thoughts associated with anxiety disorders are usually damaging to the effectiveness of group therapy.[5,6]

Anxiety disorders as comorbidities in a group appear more exacerbated than mood disorders. Fear, worry, or decision-making are characteristics of thought that seem to be common in these patients.[5-8] However, in group psychotherapy, a primary treatment focus has to be elected, so that therapists can focus on connecting symptoms and follow the patient's experience during the process, promoting open communication in terms of both social skills and cognitive restructuring.[7-11]

In recognition to the empirical origin of CBT, the treatment protocol usually provides measures for patients to focus on during their treatment and assist them in determining their progress.[12] There is currently much interest, both clinically and scientifically, in the active ingredients of CBT, and in how therapists might focus their interventions to be effective across diagnoses. Given the significant rates of comorbidity encountered in clinical practice, the notion of formulating and intervening with transdiagnostic underlying cognitive and behavioral processes has become the subject of increasing attention.[12-14]

The protocol can be a guide for the therapist and the patient to analyze treatment progress, and should include four therapy components: 1) psychoeducation/boosting motivation (increasing self-knowledge and becoming a partner in therapy); 2) cognitive reappraisal (learning to think accurately about one's own thinking); 3) preventing emotional avoidance (accepting emotional experience and increasing emotional literacy); and 4) changing behavioral habits in the context of exposure treatment (facing fears and learning new habits).[13,14] The conceptual clinical process requires the setting of goals and their inclusion in the treatment.[1-6,12]

The unified protocol can be applied individually or in groups and consists of therapeutic procedures that enable patients with severe multiple disorders to participate in the same group. Emotions are recognized, regulated and restructured through scientific techniques that reinforce new knowledge and behavior before the patient's problems surface.[13,14] There are few published studies that evaluate the results of the unified protocol, especially in a group intervention setting.

Therefore, the objective of the present study was to evaluate the effectiveness of a unified CBT protocol for group treatment of patients with a range of comorbid mood and anxiety disorders.

Method

This longitudinal study used the transdiagnostic unified protocol as the therapeutic intervention, with a focus on CBT, to treat patients diagnosed with unipolar mood disorder of mild to moderate severity and comorbidity with anxiety disorders. The following inclusion criteria were adopted: diagnosis of depression by a psychiatrist and confirmed using the Mini International Neuropsychiatric Interview (MINI)[14,15]; at least one diagnosis of anxiety disorder confirmed using the MINI; no changes in psychopharmacology drugs or dosages in the 4 months prior to or during the psychotherapeutic protocol (to ensure medication stability throughout the therapeutic process); attending and completing the initial interview; having enough cognitive ability to understand the instructions; and being at least 18 years old.

Initially, 148 patients who had voluntarily sought medical treatment at a public health service and were in a waiting list for group treatment were invited to participate in screening for possible inclusion in this study. According to the inclusion criteria mentioned above, patients should have both unipolar depression and an anxiety disorder. Moreover, they could not have neurological problems, cognitive deficits, or personality disorders. Patients were assessed based on referral by the health center psychiatrist and on MINI interview results, applied by trained psychologists. Of all patients who agreed to be evaluated for possible inclusion in this study, 16 fulfilled the criteria and were selected to receive treatment with a unified transdiagnostic protocol. Selected patients were divided into two groups of eight, all of whom participated in the whole treatment process (total of 12 sessions).

Treatment followed the four components described above, i.e., psychoeducation/boosting motivation (to identify and understand emotions), cognitive reappraisal (to learn with the emotions and understand the influence of thought on reactions and behaviors), preventing emotional avoidance (to understand and confront

physical emotions), changing behavioral habits in the context of exposure treatment (to learn how to confront in exposure treatment and to solve problems).

The protocol was applied in the two groups over 12 sessions lasting for 2 hours each. The main procedures followed in each section are described below.

Session 1

Orient the patient to treatment and apply scales to assess anxiety, mood, quality of life, and sexual functioning. Orientation to treatment is conducted after providing information on the group CBT model for the treatment of anxiety and mood disorders. The aim is to demonstrate to patients the importance of setting goals and accomplishing tasks at home, such as reading information about the characteristics of signs and symptoms of anxiety and depression prepared by the therapist.

Session 2

Identify emotions. At this stage, patients get in touch with their emotions by reading about the disorders presented as complaints. This session is called bibliotherapy, and it begins with a group discussion on the development of behavioral strategies for troubleshooting and overcoming obstacles in the treatment based on goals.

Session 3

Understand emotions. Based on the reports of situations encountered by patients during the previous week, the consciously recognized feelings of each participant are identified in the group. Thereafter, group participants understand their feelings and the situations in which they are raised and reinforced. Thus, psychoeducation and a correct understanding of thoughts and feelings are achieved, and emotion regulation and self-monitoring symptoms become the focus.

Session 4

Learn to observe emotions and subsequent reactions. Patients at this stage of treatment already know their automatic thoughts and recognize feelings related to anxiety and mood. Based on this understanding, an intervention using psychoeducation and cognitive correction is conducted, enabling the analysis of thoughts, emotion regulation, and the introduction of self-monitoring relaxation techniques for self-correction when not in the therapy group.

Session 5

Understand the influence of thoughts: thinking the worst and risk estimates. Thoughts have a direct influence on emotions and behavior. This psychoeducational intervention introduces the cognitive restructuring of thoughts, the analysis of emotion regulation and self-monitoring, and the management of anxiety and stress with relaxation techniques. The search for evidence of automatic thoughts is introduced, and finally, the evaluation of social skills begins with routine situations in the patient's lives, which differ in terms of aggression, passivity, and assertiveness.

Session 6

Understand the behavior and the influence of emotion. Identify the relationship between thoughts, feelings, and behaviors. This psychoeducational intervention enables patients to understand what is real and what is imaginary. Emotion regulation, self-monitoring of thoughts, feelings, and actions, and the management of anxiety and stress with relaxation and cognitive restructuring are discussed. Finally, social skills training is conducted, beginning with real situations experienced by each patient and discussion of the most appropriate response in each case.

Session 7

Understand behavior and emphasize the influence of emotion on behavior. In this phase of treatment, it is important to monitor mood and anxiety. Here, the psychoeducational intervention promotes emotion regulation, cognitive restructuring, the management of anxiety and stress with relaxation, and social skills training, beginning with real situations experienced by each patient, choosing the most appropriate response and applying it, and therefore promoting problem-solving.

Session 8

Understand and confront physical sensations. In this step, the identification of emotions and thoughts through self-monitoring are already functional responses and assist in the management of anxiety. Each patient begins to have the confidence necessary to confront anxiogenic situations and learns that practicing relaxation and training social skills are essential for dealing with physiological symptoms.

Session 9

Put into practice the understanding of the influence of emotion on thinking and behavior. This psychoeducational intervention aims to regulate the emotional state and restructure the beliefs of the group. Management of anxiety and stress via different relaxation techniques is promoted, and social skills are practiced, leading to the resolution of problems.

Session 10

Put learned responses and behaviors into practice in situations that provoke a dysfunctional emotional state. At this time, patients are able to assess thoughts and feelings that change the signs and symptoms of anxiety and depression. Group treatment reinforces recent learning about emotions and behavior. The functional response of self-monitoring promotes the relief of depressive and anxiogenic symptoms and the implementation of social skills. Treatment is reaffirmed with the introduction of relapse prevention using situations that will possibly be faced in the future and the correction of patterns of thoughts and dysfunctional beliefs.

Session 11

Motivate continuous learning through problem situations and future relapse prevention. The group reviews the emotional change obtained with treatment and self-monitoring, which promoted the learning of functional responses for the relief of symptoms experienced at baseline. Relapse prevention, including future situations, and the correction of patterns of thoughts and dysfunctional beliefs are also reviewed.

Session 12

Finish treatment, but promote continuing therapeutic practices. At this stage, measures taken at baseline are reviewed. The group compares the scores obtained at the beginning and end of treatment using the unified protocol.

Patients' sociocultural data were collected and included sex, age, occupation, religion, education, comorbidities, and drug use. The following instruments were used: MINI version 5.0,[14,15] Beck Depression Inventory (BDI),[16] Beck Anxiety Inventory (BAI),[17,18] the World Health Organization Instrument for the assessment of quality of life (WHOQoL-bref),[19] and the ARIZONA scale of sexual function.[20]

Descriptive statistics were used to analyze sociodemographic data, expressed as the absolute frequencies and percentages or as means and standard

deviation. WHOQoL-bref, BDI, BAI, and ARIZONA results were expressed as means and standard deviation. Treatment results were assessed using repeated measures analysis of variance (ANOVA) followed by Greenhouse-Geisser correction to avoid an increase in type I error. Significance was set at $p < 0.01$.

This research project was approved by the Research Ethics Committee of Universidade Federal do Rio de Janeiro (UFRJ), and all patients signed an informed consent form.

Results

Sample characteristics for sex, age, occupation, religion, education, comorbid anxiety disorders, and drug use are presented in Table 1.

Table 1 – Sample characteristics

	No. (%)
Sex	
Female	14 (87.5)
Male	2 (12.5)
Age*	35.63±12.09 (18-58)
Occupation	
Student	4 (25)
Housewife/househusband	3 (18.8)
Unemployed	1 (6.3)
Employed	5 (31.3)
Autonomous	3 (18.8)
Religion	
Atheist	1 (6.3)
Catholic	5 (31.3)
Evangelical	4 (25)
Spiritualist	6 (37.5)
Other	2 (1.9)
Education	
Elementary school	2 (12.5)
High school	14 (87.6)
Comorbidities	
Generalized anxiety disorder	13 (81.3)
Panic	3 (18.8)
Social phobia	1 (6.3)
Post-traumatic stress disorder	1 (6.3)
Medications	
Antidepressants	9 (56.3)
Anxiolytics	4 (25)
Other	3 (18.8)

* Mean ± standard deviation.

Comparison of the results obtained for signs and symptoms of anxiety, depression, sexuality, overall quality of life, and specific domains before and after treatment are shown in Table 2. Patients made excellent progress in all areas.

Results at the beginning and end of treatment and comparison of measurements obtained in the two periods

	Baseline	End of treatment	Type III sum of squares	df	Mean square	F	p	η2
Quality of life	75.81±15.07	94.00±8.94	2646.28	1	2646.28	39.72	< 0.001	0.73
Physical	21.81±5.39	27.06±4.07	220.50	1	220.50	28.15	< 0.001	0.65
Psychological	17.88±4.39	21.56±2.15	108.78	1	108.78	9.90	0.007	0.39
Social relationships	8.56±2.70	12.44±2.15	120.12	1	120.12	36.86	< 0.001	0.71
Environment	23.69±4.71	29.56±3.07	276.12	1	276.12	27.63	< 0.001	0.65
Anxiety	19.56±14.35	9.19±7.46	861.125	1	861.125	19.64	< 0.001	0.57
Depression	20.94±11.64	8.25±7.24	1287.78	1	1287.78	78.62	< 0.001	0.84
Sexuality	15.50±9.07	11.75±7.28	112.50	1	112.50	13.13	0.003	0.47

df = degrees of freedom.

Discussion

The primary objective of this study was to evaluate the effectiveness of a unified CBT protocol in the group treatment of patients with a range of comorbid mood and anxiety disorders. Secondary objectives were the reduction of signs and symptoms of anxiety and depression and improvement in quality of life, which will be evaluated in light of the patient's status.

At the start of treatment, patients evaluated in both groups showed depression and anxiety ranging from moderate to severe according to the scores obtained using the Beck inventories. After 12 treatment sessions with the unified CBT protocol, all indicators reduced, attesting to the effectiveness of the protocol and to its superiority in group settings compared to other proven clinical approaches to anxiety disorders,[7,8,21,22] e.g., mood[23,24] and apathy.[25] In this study, we verified the effectiveness of group CBT treatment for patients with a variety of mood, anxiety, and comorbid disorders, as the intervention model provided benefits for both the patient and the therapist.

Psychoeducational strategies, self-monitoring of thoughts, exposure, prevention and management of responses have all shown good results in previous studies[22,26,27] and were part of the techniques applied in the unified protocol of group CBT. These techniques facilitate the identification of thoughts that influence emotions and behaviors and that are generators of anxiety or depression; such awareness gives patients the security necessary to face situations and make decisions.

Implementing the unified protocol in group CBT with patients with a range of disorders allowed for reflection on treatment practices, with an emphasis on the feasibility of not separating groups according to specific disorders. Such separation is usually adopted because each therapy is aimed at treating a single disorder, and as a result a group of patients receives one single treatment according to the investigated problem[21,22,25-30] (for example, a treatment group for mood disorders or social phobia).

In the present study, significant improvement in quality of life was observed for all the participants in the sample (F = 39.72, p < 0.001), including the physical (F = 28.15, p < 0.001), social (F = 36.86; p < 0.001), psychological (F = 9.90, p = 0.007), and environmental domains (F = 27.63, p < 0.001). Studies have shown that the relationships established in treatment groups promote the instillation of hope and enhance quality of life, especially when individuals learn how to recognize and regulate their emotions through anxiety management during interpersonal interactions.[4-7] These phenomena were observed in our group and may have contributed to the good results obtained.

When the unified CBT protocol is adopted in group treatment settings, including patients with a range of disorders, quality of life and its domains become the focus of intervention, as the experience of the group resembles the daily lives of patients. The skills learned in this group setting, including social skills and assertiveness training, are practical and translate into real life experiences outside the treatment setting.

The results obtained for all variables related to quality of life, in addition to signs and symptoms of anxiety and depression, were satisfactory in patients who underwent to the unified protocol. Treatment helped them identify thoughts, emotions, and behaviors that promote safety, express feelings in an assertive manner, and learn skills for handling stress and anxiety, thus restructuring their emotional state.[31-33] These achievements are fundamental to the goals of cognitive-behavioral group treatment using the unified protocol.[12-14]

Improvement was also observed in sexual functioning: there was a statistically significant difference between ARIZONA scores obtained at the beginning vs. at the end of treatment (F = 13:13, p < 0.003). Surveys have shown that sexual functioning is associated with anxiety and depression.[34,35] Dissatisfaction with overall sex life (37.5%) and sexual anxieties (44.2%) were substantial in our subjects, corroborating previous findings.[34] Also, increased depression and anxiety levels were associated

with a disturbed body image and with decreased levels of sexual satisfaction (86.98±23.63).[35] This result suggests the need for further study about sexual functioning in individuals with mood and anxiety disorders and on the therapeutic effects of the unified protocol on sexuality, even when these areas are not targeted in the same approach.

As limitations of the present study we can mention the small sample size (only 16 participants) and the fact that it was an open trial. This is the first study to evaluate the effectiveness of a new treatment protocol in a Brazilian population. Therefore, despite the small sample, results were important and showed good results both in reducing signs and symptoms of depression and anxiety and in improving the patients' quality of life in various aspects. Also, the study did not adopt a protocol to measure treatment adherence.

The fact that patients were using psychotropics could also be considered a limitation. In order to ensure that the findings would be a result of the therapeutic process under investigation rather than of medication use, only patients without any change in medication in the 4 months preceding the study and with stable clinical conditions were included. Moreover, none of the patients changed the type or dosage of the medication used over the course of the psychotherapeutic treatment. In view of these measures, we have reason to believe that the improvements observed were a result of the therapeutic process using the unified protocol. Future studies, with larger samples, should be conducted, especially randomized clinical trials, to confirm our preliminary findings.

Conclusion

The use of a unified transdiagnostic protocol in treatment groups allows for a greater number of patients to benefit from treatment with trained therapists, at a lower cost, and with greater treatment efficiency. Moreover, it offers the advantages of social learning through the exchange of experiences among patients.

In our opinion, several factors favored success of this unified protocol treatment, e.g., its focus on treatment, the possibility to express feelings and flexibly interact with the therapists, the patients' willingness to actively participate in the evaluation of problems, their ability to recognize that symptoms have a psychological origin, the group's curiosity about one's self, openness to new ideas, realistic expectations regarding treatment results, and their willingness to make a reasonable sacrifice for a short time (3 months), of either money or time, to address issues commonly found to be unpleasant.

Given the positive results here described, refinement of an effective treatment program for groups of patients with different mild to moderate anxiety and mood disorders is warranted, as there are few studies describing CBT approaches in groups of patients with a range of disorders. It is important to note that, in this context, strategies and techniques known to be successful in individual treatments should be adapted to groups. Specifically, a group setting provides more examples for making connections between thoughts and feelings than can be obtained in individual therapy.

The patients who participated in the unified CBT protocol for group treatment obtained good results in the elimination and management of anxiety and phobic symptoms, coping with anxiogenic situations, troubleshooting, and restoring previous mood states. In addition to these achievements, they improved their quality of life, especially with regard to the physical domain, social relationships, and the environment. In fact, environmental variables promoted an increase in social skills and led to increased self-esteem and motivation for life.

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