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Journal of Basic and Applied Psychology Research

Biannual Publication, Vol. 5, No. 10 (2024) 1-7

JOURNAL OF BASIC AND APPLIED PSYCHOLOGY RESEARCH

ISSN: 2683-2267

Effectiveness of the unified protocol on symptoms of anxiety and depression in Mexican adults.

Efectividad del protocolo unificado en síntomas de ansiedad y depresión en adultos mexicanos.

Horacio Balám Álvarez-García [a.]

Abstract:

Emotional disorders, such as anxiety and depression, represent a public health problem worldwide due to the impact they have on the quality of life of the people who suffer from them. Clinical psychology began to develop various interventions for the specific treatment of each of them. However, research and clinical practice have shown the practical limitations that this entails. Due to this, various research groups began to develop transdiagnostic interventions such as the Unified Protocol (UP) to overcome these limitations. Objective: This article reports the effectiveness of the PU in face-to-face mode in users of a civil association (n=3) who presented symptoms of anxiety and depression. Method: An intrasubject design was carried out with pre-and post-treatment measurements and visual inspection. The instruments used were the PHQ-9, GAD-7, DERS-E, ODIS and OASIS. An analysis was performed through the objective clinical change (OCC). Results: A decrease in the scores was observed in the three participants in the PHQ-9, GAD-7, and DERS-E, compared with the downward trend in the ODSIS and OASIS scores. Conclusion: The intervention was clinically significant for the participants and evidenced the flexibility in applying the UP. However, the main limitations were the sample size, the lack of instruments measuring aspects of personality, a dimension used in other research as an indicator of change, and a follow-up evaluation.

Keywords:

Unified Protocol, Emotional Disorders, Transdiagnostic, Neuroticism.

Resumen:

Los trastornos emocionales, como ansiedad y depresión, representan un problema de salud pública a nivel mundial debido al impacto que tienen en la calidad de vida de las personas que lo padecen. La psicología clínica, comenzó a desarrollar diversas intervenciones para el tratamiento específico de cada uno de ellos. Sin embargo, la investigación y la práctica clínica han evidenciado las limitaciones prácticas que conlleva. Debido a ello, diversos grupos de investigación comenzaron a desarrollar intervenciones transdiagnósticas como lo es el Protocolo Unificado (PU) para superar estas limitaciones. Objetivo: en el presente artículo se reporta la efectividad del PU en modalidad presencial en usuarios de una asociación civil (n=3) que presentaban síntomas de ansiedad y depresión. Método: se realizó un diseño intrasujetos con medidas pre y post tratamiento e inspección visual. Los instrumentos utilizados fueron el PHQ-9, GAD-7, DERS-E, ODIS y OASIS. Se realizó un análisis a través del cambio clínico objetivo (CCO). Resultados: se observó una disminución en los puntajes en los tres participantes en el PHQ-9, GAD-7, DERS-E, lo cual se comparó con la tendencia a la baja en los puntajes de ODSIS y OASIS. Conclusión: la intervención fue clínicamente significativa para los participantes y evidencia la flexibilidad en la aplicación del PU, sin embargo, las principales limitaciones fueron el tamaño de la muestra, el no contar con instrumentos que midieran aspectos de personalidad, dimensión que ha sido utilizada en otras investigaciones como indicador de cambio y una evaluación de seguimiento.

Palabras Clave:

Protocolo Unificado, Trastornos Emocionales, Transdiagnóstico, Neuroticismo.

INTRODUCTION

Anxiety and depression are emerging as the most prevalent disorders worldwide (3·1%); it is estimated that the costs generated by the analysis, detection, and treatment are close to 125.3 million dollars, which has become a public health problem (GBD 2019; Mental Disorders Collaborators, 2022). Within global statistics, it is reported that there are 45.82 million people who suffer from an emotional disorder, with 28.68 million cases of anxiety (Yang et al., 2021) and 25.8 million of depression (Liu et al., 2020).

Currently, clinical psychology presents an extensive list of effective treatments for the management of anxiety and depression disorders; however, Cognitive Behavioral Therapy (CBT; Carpenter et al., 2018) and Acceptance and Commitment Therapy (ACT; Ost, 2014) are the treatments with the greatest empirical support (Zhang et al., 2019). Due to the high comorbidity between disorders, treatments will focus on central and transdiagnostic components, which will allow for a more flexible and idiographic treatment (Sauer-Zavala et al., 2017). In this framework, the Unified Protocol (UP) for emotional disorders (ED) is a new alternative that has been presented as

[a] Corresponding author, Universidad Nacional Autónoma de México, https://orcid.org/0000-0001-9533-2515, Email: hbgarcia_mosh11@hotmail.com

Received: 01/08/2023, Accepted: 27/11/2023, Published: 05/01/2024

DOI: https://doi.org/10.29057/jbapr.v5i10.11463

promising in the last ten years (Barlow et al., 2016; Ellard et al., 2010).

EDs are a transdiagnostic category that encompasses anxiety and depression. They are characterized by three elements: 1) Experiencing emotions in a negative way, 2) Presenting aversive reactions toward emotional experiences, and 3) Avoiding or suppressing emotional experiences as forms of regulation (Bullis et al., 2019). The triple vulnerability model proposes that the origin of these problems focuses on the interaction of three dimensions: the generalized biological vulnerability associated with temperament (divided into neuroticism and extraversion), and the generalized psychological vulnerability related to the perception of emotional events as unpredictable and uncontrollable and finally the specific psychological vulnerability in which associative learning is generated between a specific situation or object with the unpleasant emotion (anxiety for example) generating avoidance strategies (Barlow et al., 2014; Sauer-Zavala & Barlow, 2021). This model has shown consistency in the epidemiological profiles of various anxiety disorders (Raines et al., 2016; Ranjbari et al., 2018), providing a broad framework for its adoption in public health (Lahey, 2009).

Under this etiological model, ED's main characteristic is a deficit in emotional regulation, understanding the last as the set of strategies that modulate the intensity, duration, expression, and appearance of emotions (McRae & Gross, 2020). Therefore, the UP will have the following objectives: 1) Teach the adaptive value of emotions, 2) Define and modify avoidance strategies that reduce emotional discomfort, and 3) Increase tolerance to emotional discomfort. To achieve these objectives, the treatment is divided into eight modules (See Table 1) taught between 12 and 15 sessions on a weekly basis (Barlow et al., 2011).

Table 1.

Unified Protocol Modules

N	Name	Objective	Technique
1	Setting goals and maintaining motivation.	Help the patient identify the achievements they wish to obtain in the treatment and also identify their motivation level.	Register format. Decisional balance.
2	Understanding emotions	The patient is taught to identify and decompose his response into three elements (thought, emotion, behavior) and observe the short- and long-term consequences.	ARCO registration format
3	Full emotional awareness.	The patient is taught to use mindfulness as a strategy to avoid labeling their emotional experience.	Meditation. Induction to full consciousness. Anchor in the present moment
4	Cognitive flexibility.	Teach the patient to identify their thought pattern associated with the emotional experience in order to develop other more functional thought patterns.	Ambiguous image exercise. Psychoeducation in automatic thoughts. Cognitive flexibility practice record.
5	Opposing emotional behaviors.	Teach the patient to identify the avoidant pattern of emotional responses and generate new alternative behaviors.	List of emotional behaviors. Registration of alternative actions.
6	Understand and cope with physical sensations.	Patients are taught to identify the physical sensations associated with emotions to develop tolerance to them.	Test of physical sensations. Interoceptive exposures.

N	Name	Objective	Technique
7	Emotional exposures.	Patients are taught to identify internal and external triggers of emotional responses in order to increase tolerance to them.	Exposure hierarchy. Live exposure or imagination
8	Recognize your achievements and look to the future	The patient is taught to identify new scenarios that trigger an emotional response and design coping plans for them.	Progress evaluation Practice plan

Note. ARCO is an acronym used in the registry for the patient to record the antecedent (A), the three response elements (R), and the short- and long-term consequences (CO).

This is functional analysis training for the patient. One of the advantages that has been observed in the implementation of the UP is that the therapist can adjust the number of sessions required for each module according to the patient's needs; an example is the adaptation carried out in patients with a high risk of developing psychosis (Peláez et al., 2022). In addition to this, it is reported that the way of administration can be in person (one-on-one or in a group) or through teleconsultation, finding similar results (Osma et al., 2021; Schaeuffele et al., 2022).
With this background, the purpose of this work was to evaluate the effectiveness of UP applied to three people with symptoms of anxiety and depression. As a secondary objective, we sought to show the difference between the modules administered to each of the consultants.

METHOD

Research design

The present study is quantitative within-subject with pre-treatment and post-treatment measurements (Ato-García & Vallejo-Seco, 2015).

Participants

The sample was non-probabilistic for convenience and was composed of three participants: two women and one man. The age range was 31 to 47 years; all had a history of anxiety and depression symptoms, according to copies of clinical records that were provided by a first-level health center. They were originally from Mexico City and were not receiving any pharmacological treatment (See Table 2).

Table 2.

Sociodemographic data

Data	Participants		
	1	2	3
Sex	Women	Men	Women
Age	31	47	39
Civil status	Single woman	Married	Free Union
Occupation	Businessman	Warehouse assistant	Housewife
Education level	High School	High School	High School

Instruments

•Patient Health Questionnaire 9 (PHQ-9) Self-administered instrument that assesses the presence and severity of depressive symptoms. It is made up of nine items on a Likert scale ranging from 0 (not at all) to 3 (almost every day). The evaluation consists of the sum of the scores for each item, which has a range of 0 to 27. These scores are interpreted from 0 to 5 (mild), 6 to 10 (moderate), 11 to 15 (moderately severe), and 16 to 27. (severe). Within its psychometric properties, the Mexican version has high internal consistency with a Cronbach's alpha of 0.89 (Familiar et al., 2015).

•Generalized Anxiety Disorder 7 (GAD-7). The self-administered questionnaire that assesses the presence and severity of generalized anxiety symptoms. It is made up of seven items on a Likert scale ranging from 0 (not at all) to 3 (almost every day). The evaluation consists of the sum of the scores for each item, ranging from 0 to 21. It is interpreted that a score greater than ten is considered generalized anxiety. Within its psychometric properties, the version translated into Spanish has high internal consistency with a Cronbach's alpha of 0.80 (García-Campayo et al., 2010). It has been used in previous studies in the Mexican population (Gaitán-Rossi et al.,2021).

•Difficulties in Emotional Regulation Scale (DERS-E).
Self-applicable questionnaire that evaluates the level of emotional regulation. It is made up of four factors: A) non-acceptance of emotional responses, B) difficulty in addressing goals, C) lack of emotional awareness, and D) emotional clarity. It has a total of 24 items on a Likert scale ranging from “Almost never” to “Almost always.” Within the psychometric properties, the version translated and adapted to Mexico showed a Cronbach's alpha of 0.85 (Marín-Tejeda et al., 2012).

•Overall Anxiety Severity and Impairment Scale (OASIS). The Self-applicable questionnaire that evaluates the interference, frequency, intensity, and work and social interference of anxious symptoms. It is composed of 5 items on a Likert scale ranging from 0 (I did not feel anxious) to 4 (Constant anxiety). For interpretation, a total sum is made, and high scores are interpreted as greater severity and deterioration. Within the

psychometric properties, the version translated and adapted to Spanish showed a Cronbach's alpha of 0.87 (Osma et al., 2019).
•Overall Depression Severity and Impairment Scale (ODSIS). Self-applicable questionnaire that evaluates the interference, frequency, intensity, work, and social interference of depressive symptoms. It is made up of 5 items on a Likert scale ranging from 0 (I did not feel depressed) to 4 (Constant depression). For interpretation, a total sum is made; high scores are interpreted as greater severity and deterioration. Within the psychometric properties, the version translated and adapted to Spanish showed a Cronbach's alpha of 0.94 (Osma et al., 2019).

Procedure

A civil organization in Mexico City dedicated to managing low-income housing support was contacted. The psychotherapy service was offered free of charge to users who presented symptoms of anxiety and depression. For this, two informative talks were given about the project, and at the end, the therapist's data was distributed for further information. As a result of these conversations, eight users requested the service; however, only three agreed to provide their data for the investigation.

The intervention was carried out by a clinical psychologist with a master's degree in cognitive behavioral therapy and was part of the supervision process by a Doctor of Psychology certified in UP; It had a total of 17 sessions divided into an initial evaluation session (pre), 15 PU sessions (Barlow et al., 2011a) and a final evaluation session (post).

Derived from the case formulation made after session one, the UP was adapted to the characteristics of the three participants. Participant One presented excessive repetitive thoughts within her emotional experiences, so modules three and four had a greater number of sessions with the aim of providing her with strategies that would help reduce them. On the other hand, Participant Two showed excessive emotional behaviors, so she dedicated more time to module five with the aim of working on alternative actions that would have long-term adaptive consequences. Finally, participant three showed aversive emotional experiences in multiple contexts, so she spent more time creating hierarchies and subsequent exposure within module seven (See Table 3).

Analysis of data.

It was decided to use the Objective Clinical Change Index (OCC) expressed as a percentage (Cardiel, 1994) to compare the scores obtained on the PHQ-9, GAD-7, and DERS-E scales. These contrasts were made between pre and post. It is recommended to evaluate the clinical significance of the effects of a psychological treatment. It is obtained by calculating the difference between the post and pre divided between the latter, indicating that a percentage ≥ 20% is clinically significant. In addition to these analyses, visual inspection of the OASIS and ODSIS was used in accordance with their use in previous studies (Osma López, 2019).

Table 3.
UP adaptation.

Patient	Module	Number of sessions
1-Women	Full emotional awareness.	3
	Cognitive flexibility.	3
2-Man	Opposing emotional behaviors	4
3-Women	emotional exposures	5

RESULTS

Regarding the scores obtained in the questionnaires, a general decrease is observed in the three scales of all participants; the OCC shows a clinically significant percentage in the symptoms of anxiety and depression; however, it is observed that in emotional regulation, the percentage is slightly higher than 20%.

Individually, we can observe, for example, that Participant 1 had a decrease of 7 points on the GAD-7 (Pre=12, Post=5), going from having moderate to mild anxiety symptoms. Likewise, participant 2 presented a decrease in the DERS-E of 30 points (Pre=125, Post=95), which is associated with an improvement in the emotional regulation process, which agrees with the adaptation of the sessions of UPs carried out (see Table 4).

Table 4.
UP results in the participants.

	Participants								
	1			2			3		
	Pr	Pt	O %	Pr	Pt	O %	Pr	Pt	O %
PHQ-9	17	9	88	15	10	50	24	14	71
GAD-7	12	5	71	14	8	75	18	8	80
DERS-E	99	74	33	125	95	33	86	70	22

Note: Pr= Pre, Pt= Post, O=OCC

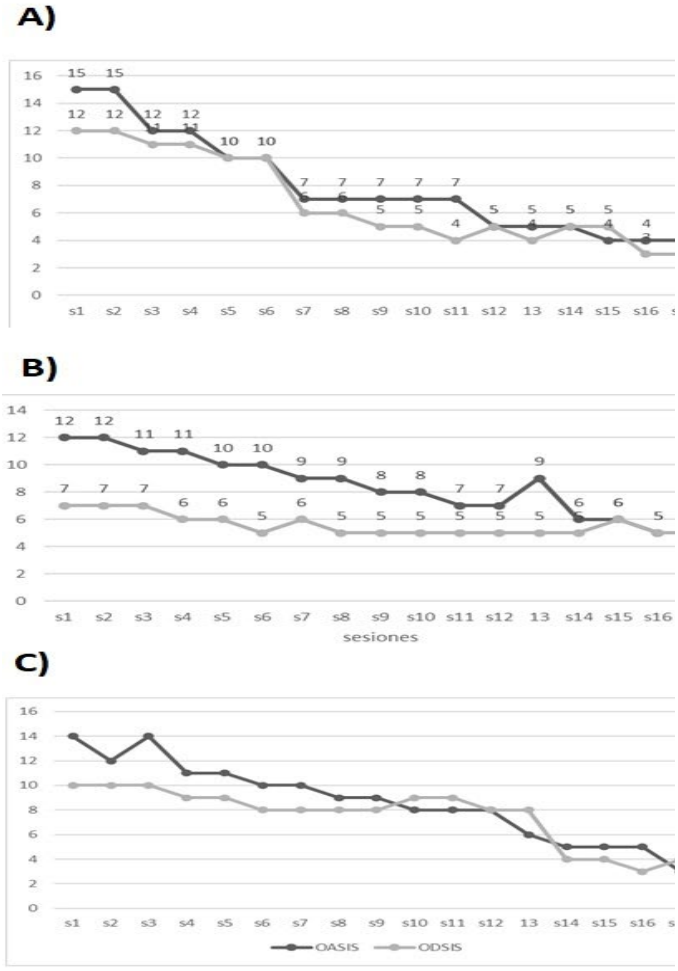
Regarding the visual inspection carried out in the ODSIS and OASIS records (See Figure 1), a downward trend is observed in the three participants, however, in the case of participant two an increase is observed in the final session. , without reaching the levels of the first sessions.

DISCUSSION AND CONCLUSIONS

Under these results, it can be seen that the participants had a general improvement in anxiety and depression symptoms, in

addition to improving their emotional regulation skills compared to the beginning of treatment. This is consistent with the data observed in two previous studies carried out. in Mexico (Domínguez-Rodríguez et al.,2020; de la Rosa-Gómez et a., 2022).

Figure 1.
ODSIS and OASIS scores.



Note: A = Participant 1, B = Participant 2, and C = Participant 3.

In addition to this, no limitations were observed in the application, and the participants seemed comfortable with the treatment due to its structure and clarity in the objectives to be worked on. This is important since it has been previously reported that, despite the advantages of the group format, the UP is more accepted in the individual format (Osma et al., 2018).

However, because the sample was not very large, the data presented must be taken with caution since they do not present strong statistical analyses or more measurement instruments that allow showing a better significance, as was shown in schizoid personality (Osma et al., 2018) and post-traumatic stress disorder (Kato et al., 2021). Another important element is that no evaluation was applied that would allow us to know the temperament of the patients (neuroticism/extraversion), and the changes that could have been generated due to the UP, which has already been reported today (Zemestani et al., 2022).

As we can see, UP turned out to be a flexible and effective treatment for managing symptoms of anxiety and depression and helped improve emotional regulation strategies. However, future studies should include evaluations associated with temperament, in addition to seeking to expand the sample or carry out a case design with greater methodological rigor, for example; multiple baseline design. Finally, it is considered that the present work will help clinical psychologists to have a first approach to the UP and will allow them to know the necessary modifications when applying it.

Financing

This study did not have any type of funding.

Conflict of interests

The author does not present any conflict of interest.

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