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Transdiagnostic Unified Protocol for Women with Breast Cancer: A Preliminary Study

Flavia Arrigoni*, José I. Navarro Guzmán

Universidad de Cádiz, España

Abstract

This article aimed to explore the feasibility and clinical utility of the online Unified Protocol to improve emotional regulation with women diagnosed with breast cancer. Method. Research with a quantitative, exploratory, descriptive and interactive approach, with a quasi-experimental design, pre-posttest for paired samples. Nine women with an average age of 53 years (*SD*= 9.5; range from 41 to 71) participated in a psychological intervention of 12 weekly 90-minute sessions. A statistically significant change (p <.05) between pre and post-test measurements in Anxiety (t= 2.777; p= .024), Quality of life (Z= -2.670; p= .008), Optimism (t= -2.785; p= .024) and Positive Affect (t= -3.834; p= .005) were found. The size of the effect was moderate in Optimism and big in Anxiety, Quality of life and Positive Affect. High levels of treatment satisfaction were found. The intervention was useful to improve the emotional regulation of women with a medical condition in a pandemic context.
Key words: Transdiagnostic Unified Protocol, emotional regulation, tele-psychology, breast cancer.

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Novelty and Significance

What is already known about the topic?

- The effectiveness of the Transdiagnostic Unified Protocol for the transdiagnostic treatment of emotional disorders in medical contexts has been slightly proven.
- It has been underlined the high prevalence of anxiety and depression symptoms in patients with cancer.

What this paper adds?

- It analyzes the clinical utility of a psychological intervention based on the Transdiagnostic Unified Protocol for the treatment of emotional disorders with women with breast cancer.
- It assesses the feasibility of a psychological intervention to improve the emotional regulation of women with a medical condition in a pandemic context.

In Spain, 1.8 million women suffer from at least one anxiety disorder (7.8%) and 1.2 million from some mood disorder (5.4%) (Ministerio de Sanidad, Consumo y Bienestar Social, 2019).

Breast cancer is the most common cancer disease in women worldwide, leading the causes of cancer mortality (14.7%). Cancer diagnosis and treatment usually cause depressive and/or anxious symptoms (Arbulú La Torre, 2019). It has become the second cause of death due to disease in women with an age range between 30-54 years. Due to its high incidence and mortality, it is considered as one of the diseases that generates more alertness in women, becoming a key issue for the public health (Protesoni & Grille, 2021). Protesoni & Grille (2021) have found that emotional discomfort in this population (anxious and depressive symptoms) is significant, especially in the initial stages. This justifies the implementation of psychological intervention for this group.

Places where people with a medical condition are gathered "may be suitable for the detection of problems of emotional dysregulation and for the intervention of these through intensive programs of short-medium duration" (Osma & Sauer Zabala, 2019, p. 328).

*Correspondence: Flavia Arrigoni, Universidad de Cádiz, España, Facultad de Ciencias de la Educación, Campus Río San Pedro, 11519 Puerto Real, Cádiz, España. Email: flavia.arrigoni@uca.es

Tele-psychology is the "provision of psychological services through information and communication technologies" (American Psychological Association, 2013) and offered users the possibility to access a timely and quality psychological service during the pandemic by COVID 19.

Barlow *et alii* (2015, 2019a, 2019b) have designed and evaluated a simple protocol with an optimal cost/benefit ratio: the Unified Protocol (UP) for the transdiagnostic treatment of emotional disorders. It is a cognitive behavioral intervention that focuses on the factors involved in the genesis and maintenance of the difficulties in emotional regulation shared by different emotional disorders. It promotes the acquisition of new and healthier strategies to regulate emotions (Barlow *et alii*, 2019b).

Results of previous studies have shown the efficacy of UP for the treatment of emotional disorders in different health conditions prevalent in women: breast cancer (Weihs, McConnell, Wiley, Crespi, Sauer-Zavala, & Stanton, 2019), chronic pain (Payne, 2018) or infertility (Martínez Borba, Osma, Crespo Delgado, Andreu Pejó, & Monferrer Serrano, 2022; Osma, Suso Ribera, Martínez Borba, & Barrera, 2020) as well as in other medical conditions (Osma, Martínez García, Quilez Orden, & Peris Baquero, 2021).

The results obtained from the group application of UP for the prevention of emotional disorders in different populations in non-clinical contexts are also promising (Arrigoni, Marchena Consejero, & Navarro Guzmán, 2021, 2022, 2023; Botella Arbona, García Palacios, Díaz García, González Robles, & Castilla López, 2019; Osma, Quilez Orden, Ferreres Galán, Meseguer, & Ariza, 2022a; Sauer-Zavala, Tirpak, Eustis, Woods, & Russell, 2021).

In our study we chose a synchronous online group intervention, which involved a weekly meeting between the therapist and the participants via video chat.

The main objective was "to explore the clinical feasibility and usefulness of group UP online program with a group of women with a breast cancer diagnosis (current or in remission)."

METHOD

Design and Participants

This was a quantitative study with an exploratory-descriptive and interactive approach, with a quasi-experimental design, with pre- and post-test measurements for paired samples.

Participation was voluntary and without financial compensation. All participants signed an informed consent. Participants were nine women with an average age of 53 years (*SD*= 9.5; range 41-71).

Assessment Protocol

Overall Anxiety Severity and Impairment Scale (OASIS; Norman *et alii*, 2006; Osma & Sauer Zabala, 2019). It evaluates the frequency, severity, and interference of anxiety during the last week. It is composed of five elements that are scored on a Likert scale ranging from 0 (I did not feel anxious) to 4 (constant anxiety). Total score ranges from 0 to 20. Scores higher indicate higher frequency, severity, and interference of anxious symptomatology. In the Spanish version, the cut-off point established in the clinical sample was 10 points (Osma & Sauer Zabala, 2019) and in the nonclinical population of 4 points (Osma, Martínez Loredo, Díaz García, Quilez Orden, & Peris-Baquerom 2022b). The OASIS has good internal consistency (alpha of Cronbach of 0.94; Osma *et alii*, 2022b).

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Overall Depression Severity and Impairment Scale (ODSIS; Bentley, Gallagher, Carl, & Barlow, 2014; Osma & Sauer Zabala, 2019). General scale to evaluate the frequency, intensity and interference of depressive symptoms experienced during the last week. It consists of five items with answers ranging between 0 (I did not feel depressed) and 4 (constant depression). Total scores range from 0 to 20, and higher scores indicate a greater severity of depressive symptomatology. In the Spanish version, the cut-off point in the clinical sample was 10 points (Osma & Sauer Zabala, 2019) and in the nonclinical population of 5 points (Osma *et alii*, 2022b). The ODSIS shows excellent psychometric properties (alpha of Cronbach of 0.95; Osma *et alii* 2022b).

Quality of Life Index Spanish version (QLI-Sp; Mezzich, Cohen, & Ruipérez, 1996; Mezzich, Ruipérez, Pérez, Yoon, Liu, & Mahmud, 2000). Self-report that assesses quality of life in ten areas or dimensions. Contains 10 items that are classified on a Likert scale of 10 points ranging from 1 (Poor) to 10 (Excellent). The higher the score, the higher the quality of life. An overall index is calculated by summing all elements (total range is 10 to 100). Those items are physical well-being, emotional well-being, self-care and independent functioning, occupational functioning, interpersonal functioning (including family functioning), social emotional support, community and service support, personal realization, realization quality of life in general. In the study of its Spanish validation, showed a Cronbach alpha of 0.88.

Questionnaire of Optimism (COP; Pedrosa, Celis Atenas, Suárez Álvarez, García Cueto, & Muñiz, 2015). This questionnaire assesses dispositional optimism in a brief and reliable way with independence from the application context and age of the target population. It has 9 items with a 5-point Likert scale, where 1 corresponds to "totally disagree" and 5 to "in full agreement". A general index is calculated by adding together all elements (total range is from 9 to 45). Pedrosa *et alii* (2015) obtained a Cronbach alpha of 0.84.

Scale of Positive and Negative Affection, Spanish adaptation (PANAS; Sandín, Chorot, Lostao, Joiner, Santed, & Valiente, 1999; Watson, Clark, & Tellegen, 1988). Self-report of 20 items that assesses two dimensions in two independent scales: positive affect (AP) subscale and negative affect (AN). It includes 10 positive affect descriptors and 10 negative effects. These items are scored according to a Likert scale that goes from 1 (nothing or almost nothing) to 5 (much). Each scale has a score that ranges from 10 to 50. Higher scores indicate a more positive or negative affect. In Spanish women, the normative data for positive and negative obtained a M= 32.52 (SD= 8.46) and a M= 20.61 (SD=7.73), respectively (López Gómez, Hervas-Torres, & Vázquez, 2015). The Spanish PANAS version has shown good internal consistency both on the positive (Cronbach's alpha of 0.87) and negative scale (Cronbach's alpha of 0.89).

Clinical Outcomes in Routine Evaluation-Outcome Measure, Spanish adaptation (CORE-OM; Feixas Evans *et alii,* 2012; Trujillo, Feixas, Bados, & García Grau, 2016). The CORE-OM is a reliable and valid instrument for assessing psychological distress and monitoring progress and change in psychotherapy. It has 34 items with five-point Likert scale ranging from 0 (at all) to 4 (all the time). It focuses on the last 7 days. It evaluates 4 dimensions: well-being, symptoms, general functioning and risk. The VISI scale (Visibility) is obtained by adding the scores of those 4 scales. Lower scores reflect a decrease in psychological distress and a greater therapeutic progress (Trujillo *et alii*, 2016). The VISI scale of the Spanish version has shown very good psychometric properties with an alpha of Cronbach of 0.94 (Trujillo *et alii*, 2016).

Satisfaction/Opinion-Adapted Scale (Borkovec & Nau, 1972). This instrument evaluates participants´ satisfaction level with six different aspects of the received treatment: the logic of the treatment, the treatment received, if they would recommend the treatment, the usefulness for other problems, the usefulness for their own problem and aversion to the treatment. A Likert scale ranging from 0= Not at all to 10= A lot, was used to assess the satisfaction level. Higher scores reflect higher satisfaction's level with the received treatment and the opposite with the final item (aversion to the treatment).

Intervention

Standardized UP of 8 modules was applied (Barlow *et alii*, 2019a): Setting goals, Understanding emotions, Emotional Consciousness, Cognitive flexibility, Opposing

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emotional behavior, Facing the physical sensations, Emotional Exposure and Steps to follow. The UP and additional material (relaxation techniques, positive affect regulation and other material) were available to participants.

The hole intervention was online through the Google meet platform and 12 group synchronous sessions were developed weekly. The duration of the sessions was one hour and a half and the intervention was delivered from October to December 2020, in a context of pandemic in Spain.

All sessions were coordinated by the same therapist and the program included assignment of in-between sessions tasks. To assess the feasibility of the proposed intervention, the Satisfaction/Opinion-Adapted Scale from Borckovec and Nau (1972) was used.

Data Analysis

The sociodemographic characteristics of the total sample were analyzed, and descriptive statistics of the different instruments used were obtained (the mean and standard deviation were calculated). To check statistically significant differences in pre and post intervention measurements, the level of significance was established in $p < .05$. The effect size was calculated with Cohen' *d* (Cohen, 1988). SPSS 21 was used.

RESULTS

Sociodemographic data of Participants are included in Table 1. The 44.4% of the participants were married and an equal percentage were single, 33.3% lived with their partner and children. 66.7% had university studies and 22.2% had vocational training (see Table 1).

Table 1. Sociodemographic data of Participants.

Sociodemographic Data		*N*
Civil status	Single	4
	Married	4
	Separated	1
Lives with…	Romantic partner	2
	Partner & children	3
	Parents	1
	Other	3
Nationality	Spanish	9
Children	0	4
	2	4
	4	1
Educational level	Primary School	1
	Complete University studies	6
	Professional Training	2

Also, the main data about health status from Participants are included in Table 2. The 33.3% acknowledged having some kind of disease and a similar percentage taking some kind of medication. Only one participant would be in psychiatric or psychological treatment (see Table 2).

In relation to the clinical utility of the applied psychological intervention after the participation in the program, a decrease in interference and severity associated with anxiety (OASIS) was observed. Anxiety was reduced by 3 points and statistically significant differences were found between pre- and post-test measurements (t= 2,777; p= .024) (see Table 3).

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Table 2. Health status data from Participants.

Health status		*f* (%)
Illness	Yes	3 (33.3)
	No	4 (44.4)
	DK/DA	2 (22.2)
Medication	Yes	3 (33.3)
	No	4 (44.4)
	DK/DA	2 (22.2)
Psychological/Psychiatric treatment	Yes	1 (11.1)
	No	7 (77.8)
	DK/DA	1 (11.1)

Notes: DK/DA= Do not know/Do not answer; *f*= frequency.

Table 3. Descriptive statistical data of pre- and post-test (*M*, *SD*), Cohen' *d* and significance.

Battery		Minimum	Maximun	*M*	*SD*	Increase/ Decrease	*d*	*t*/*Z*
OASIS	Pretest	6	16	10.22	3.34	*- 3*	*-1.06*	2.77*
	Postest	5	11	7.22	2.16			
ODSIS	Pretest	0	15	6.11	5.68	*- 0.66*	-0.15	.530
	Postest	2	10	5.44	3.08			
QLI-Sp	Pretest	40	76	62.55	12.25	*9.77*	0.94	2.670 **
	Postest	59	83	72.33	8.13			
COP	Pretest	20	36	28	5.45	*2.66*	0.58	2.78*
	Postest	26	36	30.66	3.5			
PANAS PA	Pretest	13	37	27.66	7.87	5.22	0.78	3.83*
	Postest	24	40	32.88	5.32			
PANAS NA	Pretest	12	34	26.66	6.72	-1.77	-0.29	1.052
	Postest	18	33	24.88	5.46			
CORE OM VISI	Pretest	25	72	47.33	14.95	-5	-0.35	1.680
	Postest	22	67	42.33	13.51			

Notes: COP= Optimism Questionnaire; CORE OM VISI= Clinical Outcomes in Routine Evaluation-Outcome Measure; *d*= Cohen' *d*; OASIS= Overall Anxiety Severity and Impairment Scale; ODSIS= Overall Depression Severity and Impairment Scale; PANAS PA= PANAS Scale of Positive Affect; PANAS NA= PANAS Scale of Negative Affect; QLI-Sp: Quality of life Inventory-Spanish version; *= p <.05; **= p <.001.

In the ODSIS questionnaire, the post-test showed a decrease in interference and severity associated with depression. Although no statistically significant differences were found between pre- and post-test measurements, the mean quantitative decrease observed in the post test was 0.66 points.

After participation in the program, an increase in the quality of life of the participants was observed. Statistically significant differences were found between pre- and post-test measurements of QLI-Sp (Z= -2.670; p= .008). The mean quantitative increase observed in the post test was 9.77 points.

Statistically significant differences were found between pre- and post-test measurements of POP (t= -2.785; p= .024). The mean quantitative increase observed in the post test was 2.66 points.

Regarding the positive effect of PANAS, in the post-test measurements of the participants, an increase in it was observed, with statistically significant differences between the pre- and post-test measurements (t= -3.834; p= .005). However, in relation to the negative affect variable, the results obtained from the Student' t did not show statistically significant differences. In any case, positive affect increased by 5.22 points; and negative affect decreased by 1.77 points.

The overall Visibility Scale (VISI) of the CORE-OM showed a decrease in post-test measurements: a lower score reflects greater well-being and progress in treatment. Although the mean quantitative decrease observed in the post test was 5 points, no statistically significant differences were found between the pre and post-test measurements.

The means, typical deviations and effect size of the results of the instruments administered are shown in Table 3. The effect size was moderate in Optimism (0.58), and large in Anxiety (1.06), Quality of Life (0.94) and Positive Affect (0.78). In the

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rest of the variables the effect size was small (it ranged between 0.05 and 0.35), In summary, statistically significant changes were observed in four variables in study: Anxiety (t=2.777; p=.024), Quality of life (Z=-2.670; p= .008), Optimism (t=-2.785; p= .024) and Positive Affect (t=-3.834; p= .005) (see Table 3).

In relation to the feasibility and satisfaction with the intervention, the results of the Satisfaction/Opinion Scale showed high levels of satisfaction (between 8.66 and 9.44) with the different aspects related to the intervention program received: logic of treatment, satisfaction with treatment, treatment recommendation to others with similar problems and usefulness of treatment, both for other psychological problems and for their own specific problem. The results of the treatment opinion are shown in Figure 1.

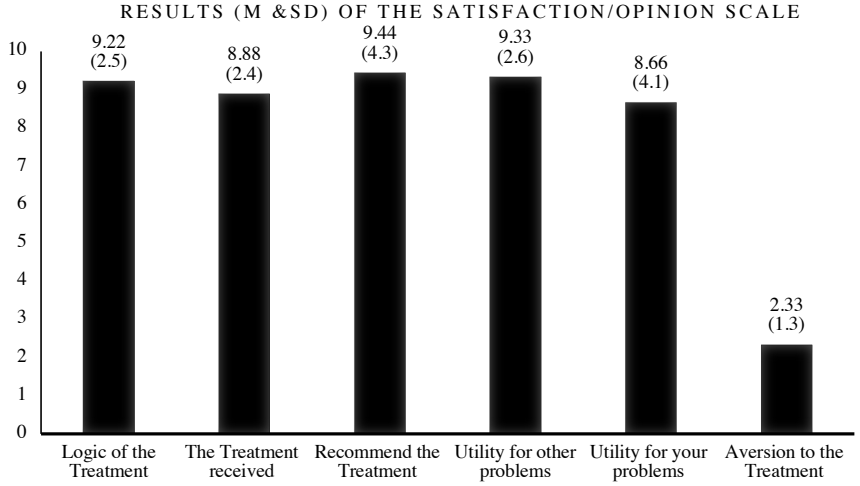

Figure 1. Results obtained in the Satisfaction/Opinion Scale.

DISCUSSION

Results are reported from the application of a psychological intervention based on the UP, an intervention that has proven effective in improving the emotional regulation of women with a medical condition, from a perspective of selective prevention of health, in a nonclinical context.

Păsărelu, Dobrean, Andersson, & Zaharie, (2021) consider that transdiagnostic interventions implemented through the internet have been shown to be effective for the treatment of anxiety and depression in adults.

In Mexico, 44% of women with breast cancer have comorbidity with depression and 88% with anxiety (Martínez Cuervo, Zamudio Silva, Rodríguez Medina, Luna Flores, Landa Fernández, & Domínguez Trejo, 2020). The results of an implemented group cognitive-behavioral intervention were effective in reducing anxiety-depressive symptoms in the group of women with breast cancer: they found statistically significant differences between pre- and post-intervention measurements in depression (Z= -3.182, p= .001) and anxiety (Z= -2.697, p= .007).

In the present study, the pre mean of OASIS (M= 10.22) was above the cut-off point of M= 10 for the clinical population (Osma & Sauer Zabala, 2019), however, after

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the intervention, the scores approached the cut-off point of the nonclinical population (M 4; Osma *et alii*, 2022b) with an *M*= 7.22 in the post test.

Even in an adverse context, participation in the intervention program would have promoted a statistically significant decrease in anxiety of the participating women, with a large effect size (1.06).

Because women with breast cancer are three times more likely to develop clinically significant depression during the year following diagnosis, Weihs *et alii* (2019) designed a preventive intervention for women with a diagnosis of breast cancer at risk of depression. They performed a 6-week adaptation of the UP: the Unified Protocol for the Prevention of Depression after Cancer (UP PDAC), adapted for women with breast cancer at high risk of depression. This study allowed to verify the acquisition of new strategies of emotional regulation, a reduction of avoidance and the decrease of the risk of recurrent depression after a first major depressive episode.

Weihs *et alii* (2019) recommend further research in this line as they understand it could become an effective evidence-based approach to reduce the risk of clinical depression and its complications for cancer patients. Regarding Depression, in our study the pre mean of ODSIS (*M*= 6.11) was below the cut-off point of *M*= 10 reported by Osma and Sauer Zabala (2019) for the clinical population

After the intervention, there was a reduction in it, so the mean post (*M*= 5.44) approached the cutoff point of the nonclinical population (*M* 5; Osma *et alii*, 2022b). This data is of interest, considering the comorbidity of such symptoms in women with a diagnosis of breast cancer.

On the other hand, after the intervention, a statistically significant increase in Optimism, Quality of life and Positive Affection was observed. In addition, a decrease in Negative Affect and psychological distress was found.

The results allow us to verify the clinical usefulness of the intervention, since it helped people who felt good (non-clinical context), maintained their level of general well-being and even improved it, despite the context of a 9-month pandemic and their medical condition.

It is estimated as a strength of the present study to have applied UP with women with a breast cancer diagnosis, a topic not yet studied. Its implementation was cost-effective, not stigmatizing for the participants and allowed to care for those who presented a diagnosis of breast cancer in a context of pandemic.

Limitations of the present study include, in the first instance, the size of the sample and the type of the sample (incidental, non-probability, voluntary). Other limitations were the lack of a control group and the fact that no actions were implemented to assess the effective use that each participant made of the additional material available (relaxation techniques, positive affect regulation and other material).

It is estimated that it would be of interest to replicate the present study with a larger sample through a randomized controlled clinical trial.

The pandemic is associated with a negative impact on the well-being and health; therefore, it was appropriate to promote health prevention instances in the context of pandemic by COVID 19, especially with people who present a particular medical condition, in this case a diagnosis of breast cancer (current or in remission), which increased the likelihood of developing some emotional mismatch.

The UP has shown a feasibility and preliminary clinical utility in various populations such as women victims of gender violence, university students, women in infertility treatment, among others (Arrigoni, Marchena, & Navarro, 2023; Martínez

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Borba *et alii*, 2022; Sauer Zabala *et alii*, 2021; Osma *et alii*, 2022b), and even with women diagnosed with breast cancer (Weihs *et alii*, 2019).

The preliminary results obtained are promising and allow us to conclude that participating in a selective health prevention program, in group format, online, synchronous, helped improve the emotional regulation of the participating women.

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