

Women of Cultural Diversity and Complex Post Traumatic Stress Disorder: Group Intervention with STAIR Model

Sara Guila Fidel Kinori^{1,2,6*}, Gloria Palomar Martinez¹, Carolina Ramos Sayalero^{1,2}, Estela García Gea^{1,2}, Constanza Daigre Blanco^{1,6,7}, Guillem d'Efak Fullana-Ferre^{3,4}, José Antonio Ramos-Quiroga^{1,2,5,6,7}

¹Department of Psychiatry, Hospital Universitari Vall d'Hebron, Barcelona, Catalonia, Spain

²Group of Psychiatry, Mental Health and Addictions, Vall d'Hebron Research Institute (VHIR), Barcelona, Catalonia, Spain

³Museu Nacional d'Art de Catalunya, Barcelona, Spain

⁴Universitat Pompeu Fabra, Barcelona, Catalonia, Spain

⁵Psychiatric Genetics Unit, Vall d'Hebron Research Institute (VHIR), Barcelona, Catalonia, Spain

⁶Biomedical Network Research Centre on Mental Health (CIBERSAM), Instituto de Salud Carlos III, Madrid, Spain

⁷Department of Psychiatry and Forensic Medicine, Universitat Autònoma de Barcelona, Barcelona, Catalonia, Spain

Abstract

Background: The improvement in the assessment of women with Complex PTSD diagnosis has made it easier to offer special treatments with scientific evidence. In Spain, non-native women present a high percentage of this disorder and require a specific approach.

Objective: Develop a Pilot Study adapting the STAIR modular program to Spanish for women of cultural diversity, and apply it in a group format in two different settings: a General Hospital and an Arts Museum.

Method: 26 culturally diverse women were randomized into two groups, offering the STAIR program in 10 consecutive weekly sessions, with a pre- and post- evaluation, and a follow-up during the first year. A non-parametric statistical analysis for repeated measures was used.

Results: All the participants showed significant improvement ($p < 0.001$) in anxiety, depressive and post-traumatic stress symptoms, and in quality of life. Overall symptomatic improvement was identified in the participants, despite the fact that satisfaction with the treatment was lower in the Museum group setting with Art in Health approaches.

Conclusions: The cross-cultural adaptation of the STAIR Model has been useful in the symptomatic improvement of the participants, but it is necessary to get better with Arts in Health perspective.

Keywords: Complex PTSD • STAIR model • Group intervention • Longitudinal study

Introduction

Women in the general population have a high prevalence of various psychopathological disorders, but the diagnosis of Complex PTSD is significantly higher in women than men. Various factors determine this, but fundamentally the possibility of being in situations of violence and other major stressors, in many cases cumulatively and for a long time, added to factors linked to social inequality, like access to social and economic resources, which makes them a population at risk and vulnerability for the development not only of social exclusion but also of serious mental health disorders [1,2].

In the last twenty years, immigration in Spain has increased significantly and 47% of total migrants are women [3]. The migration process can generate multiple stressors, due to the situation in the country of origin, the conditions of migration and the route to the country of destination as well as adaptation

to the host country. Throughout this process, due to social situations of gender inequality, women may have suffered more frequently from situations of various kinds of violence. In a survey on gender violence in Catalonia, 70% of women born abroad had suffered some type of gender-based violence from the age of 15 [4,5]. The more vulnerable conditions and having been a victim of violence against women increase the risk of presenting symptoms of post-traumatic stress, depression or anxiety [1].

Culturally diverse women may have greater difficulty in benefiting from traditional psychological treatments due to a different cultural expression of symptoms (e.g. higher prevalence of somatization) and cultural understanding of non-medical symptoms. The language barrier, when present, also makes it difficult to understand therapy and verbally express symptoms. Therefore, there is a need to investigate and develop new treatments that adapt traditional therapies to new non-medical contexts and use innovative methodologies of therapeutic intervention [6].

On the opposite side, the diagnosis of Complex Post-Traumatic Stress Disorder (Complex PTSD) has increased in visibility since being incorporated into the psychodiagnostic manuals, especially and officially WHO releases new International Classification of Diseases (ICD-11), in June 2018 [7-9]. The main characteristics of the disorders are the nuclear criteria of PTSD (re-experiencing, avoidance, hyperarousal and numbing symptoms), in addition to at least one of the three other features: affect dysregulation, negative self-concept and interpersonal difficulties.

In recent years, interest has grown in designing therapeutic strategies that provide effective responses to these disorders and give rise to greater knowledge about this diagnostic category, the development and updating of various treatments, with high evidence of their effectiveness [10-12].

***Address for Correspondence:** Sara Guila Fidel Kinori, Department of Psychiatry, Hospital Universitari Vall d'Hebron, 119-129, 08035 Barcelona, Spain; Tel: +(34)616584052, E-mail: sgfidel@gmail.com

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One of these strategies, with strong scientific evidence of its efficacy and efficiency, is the STAIR (Skills Training in Affective and Interpersonal Regulation) Model, by Dr. M. Cloitre [13-15]. This psychological intervention has been widely used in several healthcare contexts [16-18]. STAIR Modular treatment was initially developed for veteran soldiers from the USA, but developed in different individual and group formats, and integrates the two most core symptomatic blocks of Complex PTSD: manage emotional dysregulation and improve interpersonal relationships. This treatment is derived from cognitive-behavioral framework, but focused on the core symptoms of Complex PTSD: strategies for improvement on emotional regulation and in interpersonal disturbances relationships, as Dr. Cloitre designed this manualized intervention.

Two programs of our Psychiatry Service, the Transcultural Psychiatry Program and the Traumatic Stress Program, based on a formal invitation from the Catalonia National Art Museum (MNAC), designed this study, to cover an essential need of this special patient group. In Spain, there are very few initiatives related to the approach to Complex PTSD and according to actual research publications, there is no experience of the application of the STAIR model in our environment.

Trauma Group therapies, focused on traumatic experiences and their emotional repercussions, facilitate addressing the need to make sense of those past traumatic experiences, and promote the development of management and motivation skills to live more fully in the present, and to be able to plan for the future, in a context of security and trust. When applied to women of diverse cultural backgrounds, both internal and external barriers result in poor adherence to treatments [16,19]. For this reason, it is proposed to carry out a therapeutic treatment based on a manualized and verified treatment (STAIRS), translated and adapted to a health environment and an art in a community environment such as the museum, with the aim of facilitating adherence, helping to resolve symptoms and improving quality of life.

MNAC has a community development line, with the aim of bringing the museum and its artistic collections closer to the general population. Under this initiative, they have already developed other projects in our hospital and, considering that the population served in both programs is mainly middle-aged women, the study and adaptation of the STAIR were oriented for an intervention in two parallel settings. One group performed the STAIR intervention at the Hospital and the other group at the National Museum. The psychological interventions of the STAIR Model were conducted by two clinical psychologists who are experts in psychological trauma, in both contexts. Through this parallel design, we also wanted to measure the benefit that the environment has in the application of manualized health intervention, in this case Museum as a community, non-sanitary setting.

This pilot study sought to apply structured psychological intervention (STAIR Model), adapted culturally to our community, in a STAIR group interventions to assess effectiveness in migrant women with complex trauma, randomizing two simultaneous groups, in the hospital context, and the second one, at the MNAC museum. Arts in Health strategies in Museum contexts forms part of diverse Arts in Health practices, related to applying arts initiatives to health problems, physically and mentally, in a healthcare continuum, and had extensive evidence about its efficacy in health promotion [20-23]. Health and well-being developed in community settings; including not only arts expressions, but also buildings and environment, have an impact on the determinants of ill-health promotions, by changing individuals' attitudes and improving communication, understanding, attitudinal change and clinical outcomes [24,25].

The aims of the study were: (1) design a pilot study based on a group psychotherapeutic intervention strategy, for women from cultural diversity who present symptoms of complex post-traumatic disorder and/or affective stress, at a mild-moderate level, (2) translate to Spanish and culturally adapt the STAIR Modular approach for these group interventions, apply in two different settings and use methodologies appropriate to the context: group therapy following the STAIR model in the hospital and the same therapy adapted to the context of a public art museum (MNAC) and (3) analyze the results in the development of the intervention, as a whole group and according to the area and the methodology applied.

Our hypotheses were: (1) the two STAIR groups will have an improvement in the traumatic stress symptoms, in the levels of affectivity, anxiety and quality of life but those that develop the therapeutic program at the MNAC will present more satisfaction with the intervention, and (2) the MNAC is "non-healthcare", community and open space, where the possibilities of interaction and generating positive stimuli are highly enhanced. This factor is a promoter of health and well-being.

Methods

Design and setting

A single-center randomized, comparative, prospective study to assess the effectiveness of a group psychotherapeutic intervention in parallel in two different settings.

The 26 women with cultural diversity and complex PTSD from the Transcultural Program were evaluated by expert psychologists and randomly assigned to the same psychotherapeutic treatment but in different settings: the hospital context, with the group psychological intervention as usual, and the second, developed in the MNAC museum.

Procedure

The participating women were recruited from the Transcultural Psychiatry Program of Vall d'Hebron University Hospital, where they were previously diagnosed by Complex PTSD criteria by two expert psychiatrists, and already in a high percentage (24 of the total group, 93%) undergoing psychopharmacological treatment.

Fifty-one culturally diverse women were evaluated by two senior clinical psychologists and finally 26 were randomly assigned to each psychotherapeutic group (Figure 1). They were incorporated to the two study groups randomly (1:1) by blocks using an Excel file. Each group carried out its group treatment in the defined setting: museum and health service, with the same number and content of sessions. The two psychologists, with trauma expertise and cultural competences, applied STAIR sessions in both contexts, but at the museum it was added the support of two educators, who were experts in the community and educational use of the museum.

In the evaluation session prior to the group assigned, informed consent was requested for participation in the study and full information provided about the whole procedure. When the patient accepted, a semi-structured interview was performed and evaluation questionnaires were answered.

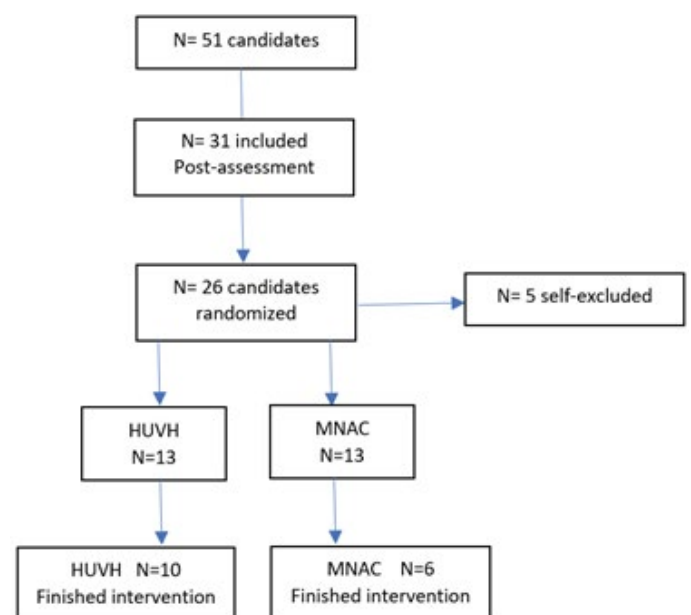


Figure 1. Randomization flow chart.

The ten sessions were structured and developed in parallel for both groups and four follow-ups were planned and designed, to assess the impact and the possibility of clinical improvement. These individual evaluation sessions were held immediately after the group session, in which the clinical evaluation questionnaires and a group satisfaction questionnaire were applied. New evaluation sessions were held 3, 6 and 12 months after the intervention, by a telephonic interview, because of COVID-19 restrictions (Figure 2).

All ethical and legal requirements were met before starting the study. The report of the project, the patient information and the informed consent form were approved according to local and national regulations before initiation. All participants were informed about the objective of this study and its characteristics as a comparative research study. The study was conducted in accordance with the principles of the Declaration of Helsinki in 2008. The final version of the protocol was approved by the Ethics Committees of Vall d'Hebron University Hospital, Barcelona, Spain (Research Project PR (AG) 115/2019).

Patients did not receive any financial compensation; only transport vouchers to facilitate access to the ten sessions.

Participants

Twenty-six candidates from the fifty-one original recruitment were randomized. The inclusion criteria were: (1) migrants with cultural diversity, (2) time of residence in Catalonia equal to or greater than one year, (3) voluntary participation and signing of the Informed Consent, (4) knowledge of the Spanish language, (5) age between 18 and 60 years, (6) having carried out the individual psychological evaluation, and (7) obtaining results consistent with mild-moderate levels of affective symptoms and/or traumatic stress disorders. Exclusion criteria were: (1) obtaining results consistent with severe levels of affective symptoms and/or traumatic stress, and (2) presenting behaviors that hinder group dynamics.

Intervention

Psychological treatment: STAIR (Skills Training in Affective and Interpersonal Regulation) Modular and manualized program by Dr. M. Cloitre, currently extended and replicated in various contexts and with various clinical populations, has shown significant scientific evidence on its efficacy [13,26,27]. STAIR is a modular model, focused on the needs that people present after going through potentially traumatic experiences, especially after complex and cumulative stressful events.

The STAIR Therapy philosophy of the therapeutic model holds that recovery from trauma means not only making sense of what happened in the past, but also creating resources to live in the present in a positive and engaged way [26].

The author and her collaborators have pointed out that there are two fundamental issues in order to address, from an individual and a group perspective, the nuclear aspects affected in people experiencing post-traumatic incidents. The first is "Emotional Regulation", understood as the identification of emotions and their alterations, as well as helping to identify how their affectation conditions interpersonal relationships. The second theme is "Interpersonal is functioning", which seeks to increase awareness of the difficulties that complex and difficult experiences of the past caused on self-perception and hetero-perception, incorporating resources to improve social functioning especially that of receiving and giving support. STAIR's

psychological strategies come from different sources, but its basis is the cognitive-behavioral model adapted to the clinical population with chronic PTSD and complex PTSD.

The eight original sessions from Cloitre's design were maintained, adding an introductory group session, then the four sessions on Emotional Regulation strategies, then four on Interpersonal Relations, and later a closing session, making ten sessions in total [16].

Treatment integrity: The two therapists participating in the study, experts in the field of PTSD and Trauma reactions, with cultural competences, were trained to optimize treatment integrity. They took the online course, completing the modules of the STAIR Program, from the website of the United States War Veterans Association (https://www.ptsd.va.gov/professional/continuing_ed/STAIR_online_training.asp), during the last quarter 2018 and the first of 2019. These professionals also translated the modules and the original materials to Spanish and these contents were supervised by an expert bilingual professional.

Both clinical psychologists participated in the Hospital and Museum settings, but in the last one, two museum educators were added, to facilitate the knowledge and use of the museum spaces.

The diagnosis of Complex PTSD and its severity were previously performed by mental health professionals, psychiatrists from the Transcultural Programme. The pharmacological treatments throughout the process were also supervised by them, and the patients of both groups maintained the usual follow-ups.

Measures

Assessments: In the preliminary assessment, the group applies a data collection protocol through a semi-structured interview that includes socio-demographic data and several instruments. The type of screening and psychopathological assessment tools and the time of application are defined in Table 1.

Questionnaire for traumatic experiences (TQ): The TQ consists of 19 items that quantify the presence of stressful events throughout life, the age at which they were experienced and their duration, and 27 other items related to the characteristics and symptoms associated with the event marked by the patient as the most unpleasant (nine about the characteristics of the event and 18 about symptoms of post-traumatic stress disorder associated with said event) [28].

Each item is answered in a response format of dichotomous type "no or yes" that is scored 0 or 1. The total score is obtained from the sum of the affirmative responses to the 18 items about PTSD symptoms, and goes from 0, which represents absence of PTSD symptoms, to 18, which represents the highest degree of severity of PTSD symptoms.

The Spanish version of the TQ, used in this study, has shown adequate reliability and validity for assessing PTSD patients in daily clinical practice. Regarding reliability, the internal consistency of Cronbach's index was 0.67 [29].

Davidson trauma scale (DTS): The DTS is a 17-item self-report scale, about symptoms present in the last week, regarding exposure to a traumatic experience, and differentiates in two columns the frequency and severity of these symptoms (17 items on frequency and 17 on severity). Items are rated on a 5-point frequency (0="not at all" to 4="every day") and severity scales (0="not at all distressing" to 4="extremely distressing"). Based on the DSM-IV criteria, it fundamentally includes the intrusion and avoidance symptoms, prototypical of the diagnosis. Its primary purposes are to measure symptom frequency and severity and to evaluate treatment, and the total score is the sum of the values of both categories: frequency and severity, the cut-off value for severity being 40 points. Regarding reliability, various studies show an internal consistency of Cronbach's index between 0.97 and 0.99 [30]. The Spanish validation was used in this study [29].

Hospital depression and anxiety scale (HAD): The HAD is a 14-item self-questionnaire that contains seven items reflecting anxiety and seven

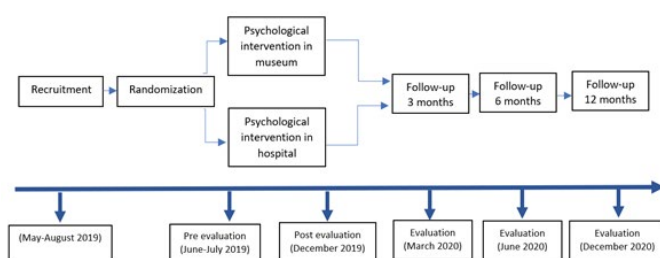


Figure 2. Study timeline.

Table 1. Screening and psychopathological assessments tools.

Questionnaire	Author	Variables that it studies	Time of Application
TQ: Questionnaire for traumatic experiences	Davidson JRT, et al. [28]	List of Traumatic experiences for traumatic life event screening	<ul style="list-style-type: none"> • Baseline data • Post evaluation • 3, 6 and 12 months follow-up
DTS: Davidson Trauma Scale, DTS	Davidson JRT, et al. [30]	Traumatic stress symptomatology, frequency and intensity	<ul style="list-style-type: none"> • Baseline data • Post evaluation • 3, 6 and 12 months follow-up
HAD: Hospital depression and anxiety scale, HAD	Zigmond AS, et al. [31]	Assess anxiety and depression in the hospital setting and in the general population.	<ul style="list-style-type: none"> • Baseline data • Post evaluation • 3, 6 and 12 months follow-up
EuroQoL-5D, EQ-5D	Rabin R, et al. [33]	Health-related quality of life scale that is used both in the general population and in patients with different pathologies	<ul style="list-style-type: none"> • Baseline data • Post evaluation • 3, 6 and 12 months follow-up
CRES-4: Scale of Satisfaction with the treatment received	Feixas G, et al. [40]	Scale of satisfaction with the therapeutic intervention	<ul style="list-style-type: none"> • Post evaluation • 6 and 12 months follow-up

reflecting depression. Of these seven depression items, five reflect aspects of reduction in pleasure response. Items are rated on a 4-point (0-3) response category, so the possible scores range from 0 to 21 for anxiety and 0 to 21 for depression. Scores from 0 to 7 for either subscale are considered in the normal range, a score of 11 or higher indicating probable presence of the mood disorder and a score of 8 to 10 being just suggestive of the presence of the respective state. Both subscales, anxiety and depression, are independent measures the corresponding internal consistency [31]. The Spanish validation was used in this study [32].

Health-related quality of life questionnaire (EuroQoL-5D, EQ-5D):

The EQ-5D questionnaire measures health-related quality of life and defines health in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is divided into three levels: no problems, some or moderate problems and extreme problems. The second part of the EQ-5D is a self-rating on a 20-cm vertical scale with endpoints of 'best imaginable health state' set at 100 and 'worst imaginable health state' set at 0. The individual must mark the point on the vertical line that best reflects the assessment of their global health status today [33]. The Spanish validation was used in this study [34].

Scale of satisfaction with the treatment received (CRES-4): The CRES is a four-item scale designed to evaluate whether patients are satisfied with the therapy they have received and whether or not it has been perceived as effective. Its global score is intended to reflect treatment effectiveness as perceived by the patient. Existing studies suggest that the CRES-4 is a good complementary tool to judge, in particular, satisfaction with treatment received, and the corresponding internal consistency measured with traditional Cronbach's alpha was 0.63 [35].

Data analysis

In order to analyze the data, descriptive statistics of basal and follow-up variables were calculated. Mean, standard deviation, frequency tables were calculated. Fischer's exact test was used to compare categorical variables. The Friedman Test, the non-parametric for repeated measures, was then used for the follow-up of the variables in order to analyze the symptoms' evolution across the follow-up. A non-parametric test was used because of the limited sample size. SPSS, version 20 for Windows, was used for all analyses.

Results

From among the total of 26 patients recruited, 16 finally concluded the study: 10 patients participated in the Hospital (HUVH) group and 6 in the MNAC, considering adherence criteria when the attendance percentage of the sessions was equal to or greater than 60%. There were no statistically significant differences in attendance in terms of the assigned group (HUVH 76.9% vs. MNAC 46.2%, $p=0.107$). However, there was a higher percentage of participation in the hospital group.

Regarding the number of traumatic events throughout life, measured with the TQ scale at the beginning of treatment, an average of 4.9 traumatic events throughout life is observed in both groups (minimum 1 and maximum 10). No statistically significant differences were observed between the groups when comparing the number of these events ($Z=0.417$; $p=0.689$)

The results in Table 2 describe the socio-demographic characteristics of the 26 patients recruited, while Table 3 shows the data of the 16 patients included throughout the group intervention.

Demographic variables

The following Table 2 shows the socio-demographic data of the preliminary evaluation carried out of the 26 people who were candidates to participate in the Pilot study and who were randomized.

The most significant data have been chosen in relation to their social and economic status, as well as their cultural origin.

As previously indicated in the inclusion criteria, women should have a medium level of understanding of the Spanish language. Those of South American origin presented a high level of shared cultural bases with the native population, but in women from other origins, it was relevant to perform a language assessment to ensure that they could fully participate in the psychological intervention.

In relation to information on residence and work permit, in Spain there are various formulas. Some facilitate combining residence and authorization to work and, in other cases, they only facilitate residence but not permission to work. The status of "asylum seeker" allows you to reside and, after six months of residence, to acquire work authorization.

Psychological variables

The following Table 3 shows the evolution of the different psychological variables, measures collected in the assessment prior to group assignment, as well as the post-intervention follow-up: immediately upon completion and 3, 6, and 12 months after treatment closure, from the 16 who completed the group approach.

Regarding the evolution of anxiety and depression symptoms, evaluated using the HAD scale, it was found that the differences between the measurements taken during the follow-up were statistically significant. Regarding traumatic stress, DTS mean scores were significantly different across the follow-up. Regarding the health-related quality of life, the EuroQoL shows significantly higher scores in the last measurements than in the first. The CRES scores did not show significant differences in the measurements throughout the study in terms of satisfaction level, that is, the satisfaction level did not vary significantly during the intervention. When observing the scores for the two groups, it is observed that the one carried out in the hospital presented better scores; however no statistical comparisons could be made.

Table 2. Sociodemographic variables.

Variables	Total	MNAC	HUVH
TQ, average of traumatic events	n=26 (100%) 4.9 (2.2)	n=13 (50.0%) 4.9 (2.2)	n=13 (50.0%) 4.9 (2.2)
Origin	From rural areas	9(34.6)	3(23.1)
	From urban areas	17(65.4)	10(76.9)
Place of birth	Latin America	11(42.3)	7(53.8)
	Africa	10(38.5)	6(46.2)
	Europe	5(19.2)	0(0.0)
Mother tongue	Spanish (South America)	11(42.3)	7(53.8)
	Arabian	9(34.6)	5(38.5)
	Romanian	1(3.8)	0(0.0)
	Serbian	1(3.8)	0(0.0)
	Mandinka	1(3.8)	1(7.7)
	Portuguese	1(3.8)	0(0.0)
	Russian	2(7.7)	0(0.0)
Education	>16 years old	11(42.3)	7(53.8)
	Up to 16 years old	15(57.7)	6(46.2)
Marital Status	Single	4(16.0)	1(8.3)
	Married or partner	9(36.0)	6(50.0)
	Divorced/ Separated	11(44.0)	5(41.7)
	Widowed	1(4.0)	0(0.0)
Perception of Social Network Support	high	13(54.2)	5(45.5)
	low	11(45.8)	6(54.5)
Immigration status	Residence permit	25(100)	12(100)
	Work permit	23(95.8)	11(91.7)
Asylum	Asylum seeker	7(26.9)	2(15.4)
	No income	4(16.0)	2(16.7)
	<€650 per month	9(36.0)	4(33.3)
Economic situation	€650-1200 per month	10(40.0)	4(33.3)
	>€1200 per month	2(8.0)	2(16.7)
Children	With children	19(73.1)	11(91.7)
	Without children	6(24.0)	1(8.3)
Children's residence	All with their mother	12(66.7)	7(63.6)
	All in country of origin	4(22.2)	2(18.2)
	Some with their mother, others in country of origin	2(11.1)	2(18.2)
Living place	Owned	6(24.0)	5(41.7)
	Rented apartment	9(36.0)	2(16.7)
	Shared	4(16.0)	2(16.7)
	Reception centers/shelter	3(12.0)	1(8.3)
	Other	3(12.0)	2(18.2)
Religion	Practicing	14(56.0)	7(58.3)
	Muslim	9(36.0)	5(41.7)
Type of Religion	Christian	16(64.0)	7(58.3)
	Psychiatric history	23(88.5)	12(92.3)
Personal history	Drugs consumed	6(25.0)	3(25.0)

	Better	7(28.0)	4(30.8)	3(25.0)
Change of status with migration	About the same	9(36.0)	4(30.8)	5(41.7)
	Worse	8(32.0)	5(38.5)	3(25.0)
	Does not know	1(4.0)	0(0.0)	1(8.3)
Current job situation	Not active	17(68.0)	10(76.9)	7(58.3)
	Active	8(32.0)	3(23.1)	5(41.7)
	Total	MNAC	HUVH	
	Mean (Standard Deviation)	Mean (Standard Deviation)	Mean (Standard Deviation)	
	Age	43.7(9.8)	47.7(8.5)	45.8(10.9)
	Number of children	1.8(1.4)	1.3(1.2)	2.3(1.6)
	Length of residence (years)	10.3(6.4)	8.5(5.5)	12.1(7.0)
Group Attendance	Number of sessions Attended (6-10)	7.7	7.5	7.8
	Number Excused absence	4.6	8.3	52.5(47.0)
	Number Unexcused absence	3.2	6.5	1.1
	Psychopharmacology %	Anxiolytics (baseline)	7(43.8)	2(33.3)
	Anxiolytics (12 months)	12(92.3)	4(80.0)	8(100)
	Antidepressant (baseline)	14(87.5)	5(83.3)	9(90.0)
	Antidepressant (12 months)	12(92.3)	4(80.0)	8(100)
	Antipsychotic Basal	5(31.3)	1(16.7)	4(40.0)
	Antipsychotic (12 months)	2(15.4)	0(0.0)	2(25.0)

Ref: MNAC, Catalonia National Museum of Arts; HUVH: Vall d'Hebron University Hospital, HAD, Hospital Anxiety and Depression Scale; DTS, Davidson Trauma Scale; EuroQol-5, Quality of Life; Cres: treatment satisfaction

Discussion

The first two aims of the study were: (1) design a pilot study based on a group psychotherapeutic intervention strategy, for women from cultural diversity who present symptoms of complex post-traumatic and/or affective stress, at a mild-moderate level, (2) translate to Spanish and culturally adapt the STAIR Modular approach for these group interventions, apply in two different settings and use methodologies appropriate to the context: group therapy following the STAIR model in the hospital and the same therapy adapted to the context of a public art museum (MNAC).

Linked to the first aim, to the best of our knowledge this is the first study that has applied the STAIR modular Program, a manualized approach, in our country, for people with the diagnosis of Complex PTSD disorder. This new group strategy includes the transcultural adaptation and the comparison of this therapeutic approach in two different contexts and using methodologies appropriate to the context: cognitive behavioral strategies included in the STAIR modular model in the hospital and the same therapy adapted to the context of an art museum, under the conditions of an approach that includes an Arts in Health perspective.

In addition to being the first time that this psychological approach has been applied in our community, this pilot study presents a series of special characteristics, among them: applying the STAIR Modular intervention in the Spanish healthcare environment and adding the condition of working on mental

Table 3. Evolution of anxiety symptoms, depressive symptoms, post-traumatic stress disorder (PTSD) symptoms, health-related quality of life and satisfaction with the treatment.

Symptoms		Pre	Post	3 m	6 m	12 m	Statistic	P value
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Anxiety symptoms (HAD)		14.3 (4.3)	13.8 (4.3)	9.2 (4.6)	9.9 (4.2)	8.9 (3.6)	29.2	<0.0001
	HUVH	16.1 (3.4)	14.4 (4.6)	9.6 (4.3)	9.6 (3.3)	9.2 (3.8)		
	MNAC	12.8 (4.4)	12.6 (4)	8.4 (5.5)	10.6 (6)	8.2 (3.5)		
Depressive symptoms (HAD)		13.3 (3.7)	11 (4.7)	6.5 (5)	8.4 (5)	6.9 (4.7)	17.7	0.001
	HUVH	14.5 (3.4)	10.6 (4.6)	7.4 (5)	7.6 (3.7)	7.6 (5.2)		
	MNAC	11.3 (3.6)	11.6 (5.4)	4.5 (4.8)	10.5 (7.6)	5.8 (3.8)		
	DTS Frequency	33.1 (16)	41.4 (13)	14.6 (8)	13.6 (7)	15.7 (6.8)		
	DTS Severity	33.1 (16)	41.5 (13)	14.6 (8)	13.6 (7)	15.7 (6.8)	24.9	<0.0001
DTS Total		54.2 (33.9)	81.2 (23.9)	31.4 (16.2)	23.4 (15.2)	31 (11.8)	26.3	<0.0001
	HUVH	70.5 (36.5)	80.6 (27.4)	35.2 (17.1)	28.2 (12.4)	33.2 (10.7)		
	MNAC	41.1 (26.1)	82.8 (16.4)	24.6 (13.6)	15.3 (17.2)	27 (13.8)		
Health-related quality of life		0.5 (0.2)	0.4 (0.2)	0.6 (0.3)	0.6 (0.3)	0.6 (0.2)	12.1	0.017
	HUVH	0.4 (0.3)	0.3 (0.2)	0.3 (0.2)	0.6 (0.3)	0.5 (0.2)		
	MNAC	0.6 (0.2)	0.5 (0.3)	0.8 (0.2)	0.6 (0.3)	0.7 (0.2)		
Cres Satisfaction			236.2 (43)		228 (29.9)	236 (35.7)	6.6	0.156
	HUVH		246.6 (47.6)		228.5 (22.9)	251 (31.7)		
	MNAC		217 (28.2)		227 (44.2)	206.9 (23)		

Ref: MNAC, Catalonia National Museum of Arts; HUVH: Vall d'Hebron University Hospital, HAD, Hospital Anxiety and Depression Scale; DTS, Davidson Trauma Scale; EuroQol-5, Quality of Life; CRES: treatment satisfaction

health under an Arts in Health framework, and monitoring the participating women, all non-native and presenting the symptomatology of Complex PTSD, for 12 months after the intervention.

In relation to the application and cross-cultural adaptation of the STAIR modular program, the training received and the experience of the professionals, experts in traumatic stress, facilitated its administration for this proposal. In the Hospital group, the interventions adhered to the original model in its group format, which included the module of four sessions of emotional regulation and the four of the improvement of interpersonal relationships. As described in other studies [16,18,19,36], the STAIR modular approach showed several advantages in group format: it is focused on the complex features of Complex PTSD, demonstrated efficacy on reducing CORE PTSD and affective symptoms, allowed participants to normalize symptoms, receive social support and facilitate, explore and work with others perceived to be in a similar situation, and it is effective and efficient in time and economic cost [19].

In relation to the second aim of the Pilot study, focused on applying the psychological treatment, the randomization of the group and the application of the STAIR psychological intervention, it was observed that adherence to the sessions and satisfaction in the Museum group were lower than in the HUVH group. In the initial hypotheses, it was argued that carrying out these clinical activities in the Museum could bring more satisfaction to the clinical population, considering the Museum as a community device, not stigmatizing and where an environment designed for the enjoyment and use of free time would facilitate that satisfaction. Intergroup changes are also observed, which could be attributed to the conditions in which the Pilot project was developed, in one environment unknown to the participants (MNAC setting) and another (General Hospital) already considered habitual and to which positive characteristics are attributed, in terms of test results. At MNAC, less satisfaction with the intervention was shown by the participants.

It has become clear that MNAC as a "non-healthcare", community and open space, where we suppose the possibilities of interaction and generating positive stimuli are highly enhanced, it wasn't perceived the same in this clinical population, perhaps because of several factors as we mentioned before.

After the psychological intervention, a third objective was analyzed: the results in the development of the intervention, as a whole group confirmed the first hypothesis: two STAIR groups had an improvement in the traumatic stress symptoms, in the levels of affectivity, anxiety and quality of life, but those that develop the therapeutic program at MNAC, could show more intervention (satisfaction).

As regards the results obtained, at the global level, considering all the participants, an improvement is identified in the entire symptomatic sphere: anxiety and depression, PTSD symptoms, and perceived quality of life. The possibility of measuring this variability over 12 months allows us to observe changes, some linked to the participants' circumstances, since from the second follow-up the population in Spain was under strict lockdown.

In this way, it was possible to observe and collect some comments from the participants, in relation to the difficulties to focus on the therapeutic meaning of the proposal, some elements that, from museum interventions, like the spaces used, were not sufficient and needed to be accompanied by more previous visits and adaptation to a new framework.

The museum was not previously known to the women and, despite having been accompanied in a preparatory session, it was a new space and perhaps not entirely safe, as a hospital could be, from their perception. Probably the fact that they were women with complicated life experiences and seeking help and assistance from professionals contributed to their perception that the intervention in the hospital is more tailored to their needs. The hospital could have been understood as a more reliable place to receive psychological care than a museum, since this environment is usually associated with more recreational aspects than psychological care. These aspects, collected in the final assessment, are important to improve the intervention proposal in non-healthcare spaces.

Limitation and Future Research

Regarding the third aim, assessment and follow-up of the women participants and comparing the results, we recruited the patients from a Specialized Psychiatry Transcultural Programme, where they were assessed beforehand by a clinical criterion of Complex PTSD disorder, not with structured and standardized tools. It should be noted that the structure with which it was designed could be improved in terms of the robustness of the results, with a structured interview for prior evaluation of the candidates, as would be the case with the CAPS Interview [37].

Another aspect to be discussed in this pilot project would be to reinforce the strategies of evaluation before and after the group intervention. In the original design, with the instruments used, it was only possible to evaluate the level of symptoms, of traumatic stress and anxiety, depression and quality of life. For traumatic stress, the use of DTS, which identifies the symptoms of intrusiveness and re-experience and avoidance, excluding other symptoms

also core to Complex PTSD disorders, has been sensitive to changes, but has not allowed us to know the evolution of all concomitant symptoms. At present, there are more instruments validated in Spanish, for example the ITQ [38-40], which with the ICD-11 criteria allow the inclusion of the other specific characteristics of complex disorders, such as emotional dysregulation, difficulties in interpersonal relationships and negative self-concept. Therefore, with the group strategy applied, we could only talk about changes in symptoms but not aspects related to overcoming.

During the pre-group assessment, the various traumatic events that people had previously experienced were considered, using the TQ scale. This information was expanded in each re-test, and in this case, coinciding with the SARS-CoV-2 pandemic, added factors along with changes in the economic status of worsening. These factors could also be influencing the participants' perception of change and/or improvement, after the end of the group intervention. The possibility of conducting post-psychological intervention follow-ups was well-accepted by the participants. However, from the second re-test, the other three (3, 6 and 12 months after the closure of the intervention) were all carried out under the SARS-CoV-2 pandemic. These extreme conditions, with lockdown and limitations for face-to-face visits, determined that they were all carried out by telephone, with the women in their homes, many of them with a precarious status, and moreover their economic condition had worsened and relatives had also died from the coronavirus and others had suffered the disease in a serious way. Also, some variations can be attributed to the characteristics of the family and economic difficulties, under the COVID-19 pandemic.

Regarding psychopharmacological treatments, which the patients had before joining the study, it can be observed that there was a reduction in the use of antipsychotic and antidepressant treatments, and an increase in treatments with anxiolytics. A possible interpretation of these data guides us to think that the symptomatic improvement could exert this shift towards more structured treatment reduction guidelines, towards anxiety management guidelines, especially considering that the follow-up was carried out under, again, the influence of the COVID pandemic, where an increase in the use of these drugs was also observed in the general population.

Being a pilot project, the inclusion of this number of participants was initially appropriate, but the generalizability of the results is limited since it is a group of only 16 people, observing intragroup differences. It would be necessary to be able to replicate this study with more groups and adjust the intervention with the adapted STAIR Model, depending on the results obtained. We found symptomatic improvement in the participants of the two groups, but the satisfaction and improvement of quality of life were better in the healthcare setting, as we mentioned before in the text.

Conclusion

This is the first study to apply the STAIR Modular approach in our country. The design of the pilot study seeks to provide a treatment with scientific evidence to be able to offer it to women with cultural diversity who presented a diagnosis of Complex PTSD disorder. It was a great challenge to transculturally adapt the STAIR modular program to Spanish, for women of cultural diversity and applies it in a group format in two different settings: a General Hospital and at Art Museum, based on the Arts in Health perspective.

The 16 patients, from the 26 originally recruited, who completed the program in 10 consecutive weekly sessions, with a pre- and post-evaluation, and follow-up during the first year, showed, as a whole group, a significant improvement in anxiety, depressive and post-traumatic stress symptoms, and quality of life. Overall symptomatic improvement was identified in the participants of both groups, despite the fact that satisfaction with the treatment was lower in the museum group.

We can assess that, in this pilot study, the adaptation of the STAIR was effective for this symptomatic improvement, with satisfaction with the therapeutic proposal, but it would be important to be able to carry out more studies, with similar populations and with other clinical and socio-demographic

characteristics, to validate the therapeutic model. Furthermore, the inclusion of the Arts in Health strategies in the museum should be reviewed and improved, as their effectiveness has also been proven in other studies.

Disclosure Statement

No potential competing interest was reported by the authors.

Ethics Statement

This procedure was presented to the Research Ethics Committee of Vall d'Hebron University Hospital and approval was obtained on the official authorization, identified with the following record: PR(AG)115/2019 RE: Evaluación proyecto "Tratamiento grupal de la sintomatología de estrés traumático en una población de mujeres de origen cultural diverso -Estudio comparativo".

Conflict of Interest

J.A.R.Q was on the speakers' bureau and/or acted as consultant for Janssen-Cilag, Novartis, Shire, Takeda, Bial, Shionogi, Sincrolab, Novartis, BMS, Medice, Rubió, Uriach, Technofarma and Raffo in the last 3 years. He also received travel awards (air tickets + hotel) for taking part in psychiatric meetings from Janssen-Cilag, Rubió, Shire, Takeda, Shionogi, Bial and Medice. The Department of Psychiatry chaired by him received unrestricted educational and research support from the following companies in the last 3 years: Janssen-Cilag, Shire, Oryzon, Roche, Psious, and Rubió.

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