Online cognitive behavioural therapy as a psychological vaccine against stress during the COVID-19 pandemic in pregnant women: A randomised controlled trial

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ABSTRACT

The COVID-19 pandemic has affected the population's levels of stress and anxiety due to its contagious nature and the uncertainties generated by its novelty. One population that is especially vulnerable to these psychological consequences are pregnant women. This is why the objective of this study was to test the efficacy of an online stress management programme of a cognitive behavioural nature on pregnant women during the COVID-19 pandemic, in Spain. The trial was controlled and randomised, with a total of 207 pregnant women divided into three groups: the Online Cognitive Behavioural Therapy group (o-CBT) (N = 70); the Online Psychological Support group (o-PS) (N = 69); and the Usual Care group (UC) (N = 68). To test the therapy's efficacy, the women's resilience, perceived stress, pregnancy-specific stress and psychopathological symptoms were assessed before and after the intervention. The o-CBT and o-PS consisted of a programme of 8 group sessions (one per week). The results showed that pregnant women who participated in the o-CBT group presented lower rates of pregnancy-specific stress and perceived stress, as well as greater resilience and lower anxiety, depression and obsessions-compulsions symptoms. These data show the efficacy of the treatment programme and thus confirm the importance of implementing these types of interventions during a woman's pregnancy, especially over periods of major stress, such as during a pandemic.

1. Introduction

In March 2020, the World Health Organisation declared the outbreak of a new pandemic triggered by the international spread of a coronavirus disease (COVID-19) (World Health Organization, 2020). Its highly contagious nature and the resulting lockdown measures led to an increase in anxiety and depressive symptomatology (Wang et al., 2020).

A particularly vulnerable group within the population are pregnant women, as they are more likely to suffer, due to their very pregnancy, from psychological stress, anxiety and depression, symptoms which have been aggravated by the pandemic and concerns about their personal health and foetal health (Woody et al., 2017; Wu et al., 2020). In fact, different studies have shown that women who were pregnant during the COVID-19 pandemic presented higher levels of stress, depression, anxiety, phobic symptomatology and thoughts of self-harm,

than women who were pregnant before the pandemic (Liu et al., 2021; Mariño-Narvaez et al., 2021; Puertas-Gonzalez et al., 2021a; Wu et al., 2020). These results reflect a possibly negative pandemic impact on maternal mental health, which in turn has a significant effect on their babies (Liu et al., 2021; Puertas-Gonzalez et al., 2021a; Wu et al., 2020).

In order to reduce the negative consequences of stress during pregnancy, various intervention techniques have been developed and brought to light by Cognitive Behavioural Therapy (CBT). Such a therapy is based on scientific evidence and treatment efficacy with respect to various psychopathologies, as well as stress reduction (Butler et al., 2006). Specifically, a recent study showed a reduction in the level of pregnancy-specific stress, perceived stress, cortisol in hair, together with lower general psychopathological symptomatology in women who followed stress-management CBT during their pregnancy (Romero-Gonzalez et al., 2020).

As the pandemic has unfolded, there has been a boom in telemedicine, providing evidence that online CBT is a viable method for the symptomatic reduction of certain mental disorders, such as somatic disorders, major depressive disorder, panic disorder or post-traumatic stress disorder (Carlbring et al., 2018; Chipps et al., 2020). Particularly during the pandemic, Wahlund, et al. (2021) studied whether a brief self-guided online cognitive behavioural intervention could reduce the degree of dysfunctional worry related to the COVID-19, in a sample of the general adult population in Sweden. They found that the sample group that received the intervention showed a significant reduction in COVID-19-related worry. In Germany, Heckendorf et al. (2022) also investigated the benefits of an Internet-based, unguided cognitive behavioural self-help intervention in the general population. They reported that the intervention group showed significantly less worrying after the interventions than controls. Finally, Bryant et al. (2022) found that a brief group psychological intervention delivered via videoconferencing to adults in Australia distressed by the pandemic reduced symptoms of depression and anxiety and fears related to COVID-19. The programme used included strategies on management of pandemic-related concerns, compensation for limited access to positive activities, and access to social supports during closure (Bryant et al., 2022).

As for the online health modality during the perinatal period, it has generated promising results for the reduction of maternal mental health problems (Ashford et al., 2016). Nevertheless, not all the studies developed meet the requirements of randomised and controlled trials (RCTs), since most lack a control group or have not been randomised (González-Blanch et al., 2018). Furthermore, to our knowledge, no study has been conducted during the pandemic to evaluate the efficacy of an online psychological intervention aimed at reducing stress in pregnant women in Spain.

Given the importance of a psychological approach to pregnant women during a pandemic and the need to adapt the psychological intervention to an online format (because of the characteristics of the pandemic itself), the objective of this study was to test the efficacy of online cognitive behavioural therapy in pregnant women in managing stress during the COVID-19 pandemic through a randomised controlled study. Three groups of participants were included: pregnant women who received online cognitive-behavioural therapy; pregnant women who received online psychological support; and pregnant women who received the usual care.

2. Methods

2.1. Participants

The study was constituted by 207 pregnant women. Information sheets and posters were produced with the information, objective and contact (phone number and email) to participate in the study and different means of recruitment were used, such as: dissemination in hospitals and health centres, city councils, radio programmes and, finally, through different social networks by sending the study information to pregnant women's groups on WhatsApp and Facebook. Women interested in participating contacted a study researcher, through the contact provided on the information sheets, who checked that they met the criteria for participation in the study and enrolled them. Once enrolled, they were sent a study informed consent form to sign and return to the researchers. Recruitment was conducted from September 2020 to June 2021, during the COVID-19 state of alert. Participants were randomly divided into three groups: the online cognitive behavioural therapy group (o-CBT) (N = 70); the psychological support group (o-PS) (N = 69); and the usual care group (UC) (N = 68).

The inclusion criteria were as follow: pregnant women between the twelfth and twenty-eighth week of gestation; with a good command of the Spanish language (oral and written comprehension); and having an internet connection. The weeks selected as inclusion criterion were chosen considering that from the twelfth week, the probability of having a spontaneous abortion decreases (Regan and Rai, 2000). The twenty-eighth week was also selected to ensure that the participants could finish the treatment.

The exclusion criteria were as follow: having a medical condition; suffering from a diagnosed psychiatric disorder; using of psychiatric medication; and receiving psychotherapy.

All participants, after reading the study information sheet, signed the informed consent document, in which they undertook to participate in the study voluntarily. They were assigned a code to guarantee their anonymity.

The study's protocol was reviewed and approved by the Biomedical Ethics Research Committee of the Junta de Andalucía (internal code 0401- M1-17). In addition, the present work followed the guidelines of the Declaration of Helsinki (WMA, 2008) and the Directive on Good Clinical Practice (Directive, 2005/28/EC) of the European Union. The study was registered as a single-blind randomised controlled trial with the code: NCT03404141. The trial is reported according to CONSORT guidelines.

2.2. Instruments

First, the pregnant women completed the entire evaluation using *Google-Forms*, which asked questions about sociodemographic variables (age, weeks of pregnancy, nationality, level of education, marital status, among others) and obstetric information (whether they were primiparous or not, method of gestation, whether it was a planned pregnancy or a high-risk pregnancy). For the psychological evaluation, the participants completed several instruments, divided into primary outcomes and secondary outcomes. The primary outcomes were those that were focus of the intervention: stress (perceived stress, pregnancy-specific stress and vulnerability to stress) and resilience, which is defined as the ability to cope with stressful situations. In addition to being the main target of the therapy, stress and resilience have been showed to be highly associated before and throughout the pandemic in pregnancy (Puertas-Gonzalez et al., 2022). On the other hand, the secondary outcomes were psychopathological symptoms, which were not a direct target of therapy but they could be reduced by increasing resilience and reducing stress levels (Lupien et al., 2022; Puertas-Gonzalez et al., 2022).

2.2.1. Primary outcome: stress and resilience

Perceived Stress Scale (PSS-14) (Cohen et al., 1983; Remor, 2006). The PSS-14 provides information on the perception of general stress during the preceding month. It consists of 14 items scores on a 5-point Likert scale (0 = never, 1 = almost never, 2 = once in a while, 3 = often, 4 = very often). Scores range from 0 to 56 (higher scores represent higher levels of stress). Cronbach's alpha was 0.90 in this study.

Prenatal Distress Questionnaire (PDQ) (Yali and Lobel, 1999; Caparros-Gonzalez et al., 2019a). This is a 12-item scale that measures pregnancy-specific stress related to maternal concerns about pregnancy, such as medical problems, labor and delivery, physical symptoms, bodily changes and the baby's health. Responses are given using a 5-point Likert-type scale where 0 = not at all and 4 = very much. Cronbach's alpha was 0.75 in this study.

Stress Vulnerability Inventory (IVE) (Beech et al., 1986; Robles-Ortega et al., 2006). It consists of 22 items that evaluate the person's predisposition to feel affected by perceived stress. It has a Yes/No answer format. Items receiving an affirmative answer add 1 point. The range of scores on the scale is 0–22, higher scores corresponding to greater vulnerability to stress. Cronbach's alpha was 0.87 in this study.

Connor Davidson Resilience Scale (CD-RISC) (Connor and Davidson, 2003; García-León et al., 2019) in its abridged Spanish version (Notario-Pacheco et al., 2014). This instrument assesses resilience, understood as the ability to cope with stressful situations such as changes, personal problems, illness, pressure, failure and feelings of pain. The CD-RISC-10 consists of 10 items, and a Likert scale with 5 response

options ranging from 0 ("almost never") to 4 ("almost always"), which had a single dimension. Some of the items it presents are: " I think of myself as a strong person when dealing with life's challenges and difficulties, " or " I am able to adapt when changes occur ". The scale provides a total score ranging from 0 to 40, and higher scores indicate a higher level of resilience. Moreover, the instrument has high construct, divergent and convergent validity, and the Cronbach's alpha was 0.87 in this study.

2.2.2. Secondary outcome: psychopathological symptoms

The Symptom Checklist-90-Revised (SCL-90-R) (Caparrós-Caparrós et al., 2007; Derogatis, 1994). As psychopathological symptoms were not the main focus of the intervention, this scale was used to assess secondary treatment outcomes. The nine main dimensions of this instrument have been used in this research: somatization, obsession–compulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism. This instrument is a 90-item scale with 5 points, ranging from 0 (never) to 4 (extremely). The scores are converted to percentiles (0–100) according to the author's instructions. Percentiles 75 represent clinical symptoms in any of the subscales of this instrument. Cronbach's alpha ranged between 0.68 and 0.87 for the nine dimensions in this study.

2.3. Procedure

The participants were gathered online following the method described above. They were informed that an online group therapy (delivered by synchronous videoconferencing in groups of 8–10 participants) was being conducted based on the Gestastress-Childstress projects, to control stress in pregnant women during the pandemic.

Furthermore, they were explained that the programme included 8 weekly sessions lasting approximately 1.5–2 h each, in both the o-CBT and the o-PS groups. An email address was provided for further information and to enrol in the programme.

Participants were randomly divided into three groups: o-CBT, o-PS and UC. Randomisation was applied using the Statistical Package for Social Sciences (SPSS) version 25.0 for Windows (SPSS, Armonk, New York), via a computer-generated random number sequence in which participants were randomly assigned (1:1:1) to the o-CBT, o-PS or UC. The data management system automatically assigned numbers from the list of random numbers to the study participants. Randomisation sequences, participant registration, and treatment assignments were performed by a research assistant who was unaware of the participants' data.

Before starting the programme, an email was sent to the participants with a link to the session during which they would be assessed using the questionnaires described in the instruments section. A psychologist answered the questions raised during the evaluation session and checked that all the instruments were completed.

The participants assigned to the therapy group attended 8 consecutive weekly sessions of online cognitive behavioural therapy, lasting 1.5–2 h each, imparted by two professionals with extensive training and experience in psychological therapy. These psychologists were licensed psychotherapists and they had conducted the programme in face-to-face settings before the pandemic. The structure of each session was as follows: after an initial welcome, the participants told how the week had gone for them and they were given feedback regarding what they had recorded in the behavioural self-records; they were then taught a new skill which they subsequently practiced through role-play; questions were answered, and to finish, they were given homework. They were given a behavioural self-record by email each week with the aim of writing down the day and time of the week when they put into practice the technique they had worked on that week in the therapy session, the thoughts they had and the difficulties they had found in putting them into practice. The same steps were followed for the online psychological support group, but therapy was replaced with psychoeducation and had

no homework because they had not worked on coping skills to practice them. The treatment was based on the adaptation of a programme backed by extensive scientific evidence: the Program for Stress Management (Robles-Ortega and AuthorAnonymous, 2010), with demonstrated effectiveness in pregnant women (Romero-Gonzalez et al., 2020). It was given online. The programme consists of 8 sessions that cover the following contents: 1) psychoeducation: what is stress, its characteristics, identification of stressors, responses and consequences; 2) deactivation techniques (diaphragmatic breathing and thematic imagination); 3) cognitive restructuring: cognitive distortions; 4) cognitive restructuring: irrational beliefs; 5) other complementary strategies: self-instructional training and time organisation; 6) training in social skills: assertiveness, basic assertive rights, saying no and how to request a change of behaviour; 7) relationship between anger and stress and emotional self-regulation; 8) good mood and optimism: summary. The summary of the modules and themes of the sessions can be found in Table 1. During the first session, the definition and consequences of pregnancy-specific stress were explained, as well as examples and main characteristics and differences between stress and pregnancy-specific stress were shown. In addition, all the stress management techniques presented in the programme were aimed at being applied to both stress and pregnancy-specific stress. Finally, the psychologists in charge of implementing the intervention programme, at the beginning of each session allowed the participants to talk about their fears regarding the pandemic that week (e.g., fear of contagion, concerns about facing medical appointment without relatives or partners, loss of social contact, etc.). Moreover, all the concepts and techniques learned during the sessions were related through examples to the fears that pregnant women showed during the previous months in Spain associated with the COVID-19 pandemic (Chaves et al., 2021; Puertas-Gonzalez et al., 2021a; Romero-Gonzalez et al., 2021), with the objective of being implemented in order to deal with them.

Table 1
Summary of the content of the sessions of the cognitive behavioural therapy group and the psychological support group.

Session number	Cognitive Behavioural Therapy Group		Psychological Support Group	
	Module	Session topic	Module	Session topic
1	Psycho-education	Psychoeducation: what is stress, its characteristics, identification of stressors, responses and consequences	Psycho-education	What stress is and types of stressors
2	Relaxation	Diaphragmatic breathing and thematic imagination	Psycho-education	Physiological stress response
3	Cognitive restructuring	Cognitive distortions	Psycho-education	Stress in pregnancy
4	Cognitive restructuring	Irrational beliefs	Psycho-education	Anxiety and depression as consequences of stress
5	Alternative thought control techniques	Self-instructional training and time organisation	Psycho-education	Physical consequences of stress
6	Training in social skills	Assertiveness, basic assertive rights, saying no and how to request a change of behaviour;	Psycho-education	Stress, sleep and memory
7	Emotional self-regulation	Relationship between anger and stress	Psycho-education	Types of attachment and their importance
8	Good mood and optimism	Humour's benefits and summary	Psycho-education	Optimism and summary

Participants assigned to the online psychological support group received psychoeducation in stress and pregnancy-specific stress. This group was carried out online and the aim was to offer a credible therapeutic alternative. In this way, non-specific therapeutic factors could be controlled for, so that the possible psychological improvements of o-CBT could be attributed to its therapeutic components beyond the benefits of emotional support provided by group therapy with people in the same life situation. The session contents were mainly linked to: the use of empathy and active listening as emotional drainage strategies; psychoeducation, both in stress and pregnancy-specific stress; psychoeducation based on the information obtained from the book "Un villano llamado estrés" (Peralta-Ramírez, 2019). The topics addressed in the 8 sessions were: 1) What stress is and types of stressors; 2) Physiological stress response; 3) Stress in pregnancy; 4) Anxiety and depression as consequences of stress; 5) Physical consequences of stress; 6) Stress, sleep and memory; 7) Type of attachment; 8) Optimism and summary. The summary of topics covered in the psychological support group sessions can be found in Table 1. The psychologists who conducted the psychological support groups were the same psychologists who ran the therapy groups.

A total of 8 groups per arm (o-CBT, o-PS and UC) with 8–10 participants each were constituted at different times. The online sessions for o-CBT and o-PS were conducted in synchronous videoconferences between the therapists and the group participants using a camera and microphone via the Google Meet platform; before the sessions started, participants received an email with a link to connect to the Google Meet room.

In parallel, participants in the usual care group followed their standard routine care, which consisted of regular medical visits to their midwives throughout their pregnancy.

At the end of the sessions, all the participants were summoned to a new session and the questionnaires described in the instruments section were administered once more.

2.4. Statistical analysis

First, a factorial ANOVA (continuous variables) and Chi-square (categorical variables) analysis were performed to verify whether the groups (o-CBT, o-PS and UC) were even regarding the main sociodemographic and obstetric variables.

In addition, to check the efficacy of online cognitive behavioural therapy against online psychological support and the usual care group, a linear mixed model for repeated-measures data was performed, with group (o-CBT, o-PS and UC) and time (pre-intervention and post-intervention) as main effects, and a group x time interaction. The dependent variables were the scores obtained in the primary and secondary outcomes: PDQ, PSS-14, IVE, CD-RISC and SCL-90-R. In addition, we specified participant as a random effect to account for the repeated-measures nature of the data. Deviation tables were performed and reported with F statistics and p-values. Subsequently, a multiple-comparison post hoc analysis was performed for the variables in which the interaction was found, using Tukey post hoc test in order to check whether any differences existed between the pre- and post-scores in the three groups.

Finally, the partial eta squared (η^2p) was calculated for the models to know the effect size, taking as a criterion 0.01 as a small effect size, 0.05 as a moderate effect size, and 0.08 as a large effect size (Cohen, 1969). Moreover, to check the size of the effect of the therapy, Cohen's *d* was calculated: $d \leq 0.20$ low effect size, $d \leq 0.50$ medium size and $d \leq 0.80$ large effect size (Cohen, 1988).

According to the intention-to-treat analysis and following the recommendations made by other researchers (Garcia-Silva et al., 2018; Montori and Guyatt, 2001), the transfer method of the last observation was used to impute the missing values, i.e., loss of subjects throughout the study. All the results presented were based on the intention-to-treat imputed data. The linear mixed models were undertaken using the R 4.1.3 software (R Core Team, 2022) using the *lme4* package (Douglas

et al., 2015).

2.4.1. Sample size

The G*Power software (version 3.1.9.7, Universität Düsseldorf, Düsseldorf, Germany, 2007) was used to estimate the sample size. This programme was used to ensure that the number of participants was suitable to guarantee 95% power and $\alpha \leq 0.05$ for all analyses; the need to compare data at two different moments in time was taken into account, considering the existence of three groups (o-CBT, o-PS and UC), G*Power determined that the total number of required participants was 189 (effect size f = 0.25-mean).

3. Results

3.1. Sample description and adherence to treatment

A total of 219 women were interested in participating in the study. Of these, 207 met the inclusion criteria. The remaining 12 were therefore excluded from the study. Of the 207 women who participated in the study, 70 belonged to o-CBT with a mean age of 35.11 years (SD = 3.60) (M = 19.04 weeks of gestation), 69 belonged to the o-PS with a mean age of 35.59 years (SD = 4.41) (M = 21.28 weeks gestation), and, finally, 68 belonged to the UC with a mean age of 34.31 (SD = 4.85) (M = 20.56 weeks of gestation). In relation to treatment adherence, the average attendance of the o-CBT participants for the 8 sessions was 6.93 (SD = 0.95) and that of the o-PS participants was 6.60 (SD = 1.23). In addition, 82.86% and 85.29% of o-CBT and o-PS participants completed treatment, respectively. Finally, 57.97% of UC participants completed the post-evaluation. The flow of participants across the various moments of the study, as well as the motives for exclusion from the total sample can be consulted in the CONSORT flowchart in Fig. 1.

The groups were even regarding the main sociodemographic, habits and obstetric history variables, as shown in Table 2.

3.2. Efficacy of online stress management CBT during the COVID-19 pandemic in reducing stress and increasing resilience

The linear mixed models showed interaction in pregnancy-specific stress scores (PDQ) (F (2, 197.48) = 6.27; p $\leq$ .002; η^2 = 0.06) and perceived stress scores (PSS-14) (F (2, 192.78) = 5.02; p $\leq$ .007; η^2 = 0.05) between the pre- and post-treatment. With respect to the PDQ, the three groups reduced their scores in the post-treatment, the o-CBT notably presenting a median effect size (d = 0.62), while the remaining two showed a small effect size. As for the PSS-14, the o-CBT presented a medium, almost large change effect size (d = 0.76) in stress reduction, while the o-PS and UC showed a small effect size. No interaction was found for the vulnerability to stress variable. These results can be found in Table 3.

Fig. 2 below shows the main differences between pre- and post-stress intervention.

In addition, a linear mixed model presented interaction in the resilience variable (CD-RISC) (*F* (2, 192.78) = 7.08, *p* $\leq$ .001; η^2 = 0.07). In this way, the o-CBT increased its post-treatment scores. The o-PS and HC showed no improvement in relation to their scores between the first and second evaluation. These results can be found in Table 3 and Fig. 2.

3.3. Efficacy of online stress management CBT during the COVID-19 pandemic in reducing psychopathological symptoms

As far as the psychopathological symptoms are concerned, interaction was found via the linear mixed models in the symptom scores of obsession-compulsions (OBS), depressives (DEP) and anxious (ANX) between pre- and post-treatment. As observable in Table 3, the scores decreased after treatment for the variables: anxiety, depression and obsession-compulsion, all variables presenting a medium effect size.

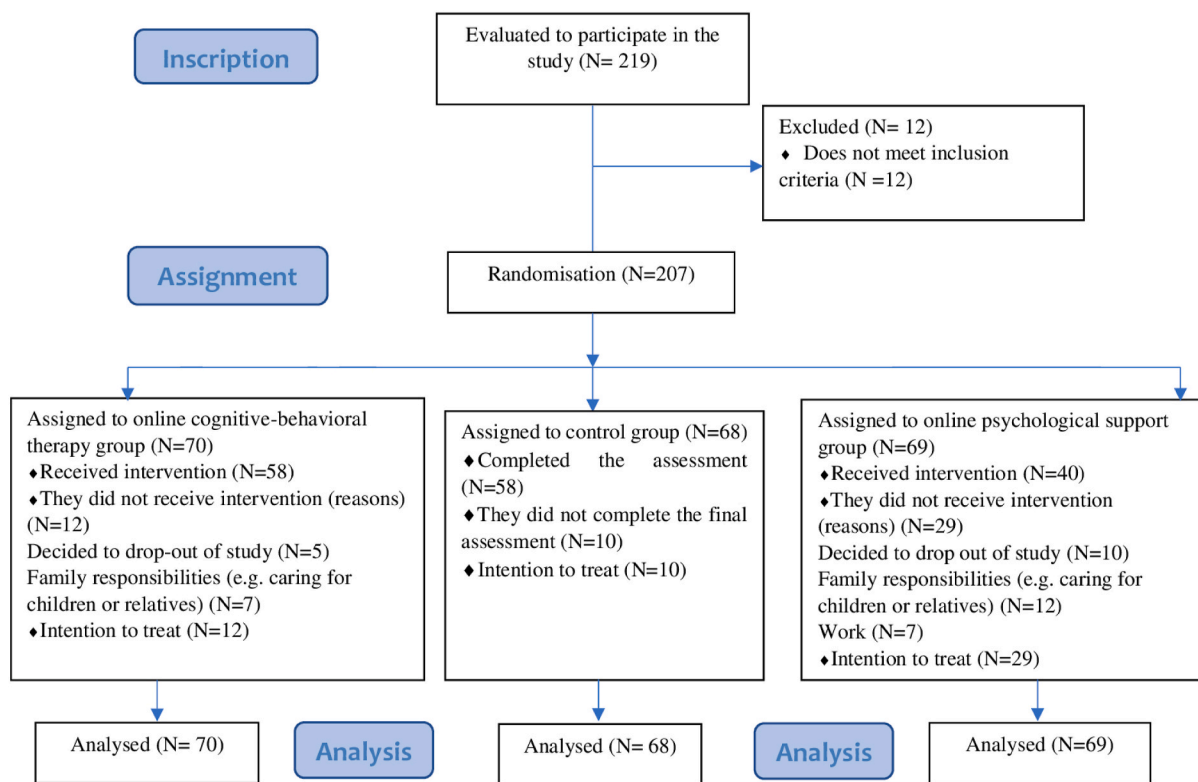For its part, o-PS presented a drop in depressive symptomatology and

Fig. 1. CONSORT flow chart.

Table 2

Differences in sociodemographic, habit and obstetric variables between the online therapy group, the online psychological support group and the usual care group.

Variables		Online therapy group (n = 70) M(SD)/%	Online psychological support group (n = 69) M(SD)/%	Usual care group (n = 68) M (SD)/%	F// $\chi 2$	p
Sociodemographic variables						
Age		35.11(3.60)	35.59(4.41)	34.31(4.85)	1.554	.214
Married/cohabiting	Yes	69(98.6%)	63(91.3%)	62(91.2%)	4.231	.121
	No	1(1.4%)	6(8.7%)	6(8.8%)		
Nationality	Spanish	67(95.7%)	61(88.4%)	61(89.7%)	2.664	.264
	Other	3(4.3%)	8(11.6%)	7(10.30%)		
Level of Education	High school	7(10%)	10(14.5%)	15(22.1%)	6.128	.190
	University	63(90%)	59(85.5%)	52(76.5%)		
Employment situation	Unemployed	8(12.5%)	7(10.9%)	11(17.5%)	4.143	.387
	Part-time employment	4(6.3%)	9(14.1%)	4(6.3%)		
	Full-time employment	52(81.3%)	48(75%)	48(76.2%)		
Smoking	Yes	1(1.4%)	4(5.8%)	2(2.9%)	2.090	.352
	No	69(98.6%)	65(94.2%)	66(97.1%)		
Alcohol	Yes	2(2.9%)	1(1.4%)	2(2.9%)	.308	.857
	No	68(97.1%)	68(9.6%)	66(97.1%)		
Obstetric variables						
Gestational age (weeks)	T_0	19.04(7.40)	21.28(7.19)	20.56(7.43)	1.679	.189
	T_1	27.26(7.45)	29.61(7.30)	29.13(7.12)	2.042	.132
Primiparous	Yes	30(42.9%)	35(50.7%)	29(42.6%)	1.180	.554
	No	40(57.1%)	34(49.3%)	39(57.4%)		
Type of pregnancy	Spontaneous	63(90%)	52(75.4%)	57(83.8%)	4.612	.100
	Fertility treatment	7(10%)	17(24.6%)	11(16.2%)		
High-risk pregnancy	Yes	13(18.6%)	12(17.4%)	11(16.2%)	.138	.933
	No	57(81.4%)	57(82.6%)	57(83.8%)		
Wanted pregnancy	Yes	60(85.7%)	64(92.8%)	61(89.7%)	1.825	.402
	No	10(14.3%)	5(7.2%)	7(10.3%)		

Note: (*) = statistically significant difference; T_0 = pre-intervention; T_1 = post-intervention.

anxiety, with an effect size that does not reach the cut-off point to be considered a small effect size (<0.20) (see Table 3).

To finish, Fig. 3 shows the main pre- and post-intervention differences in obsession-compulsion, depression and anxiety symptomatology.

Table 3
Linear mixed models and mean differences after intervention in the three groups on the main measures of stress, resilience and psychopathology.

Results				Linear Mixed Models			Tukey post hoc test	
	Group	T_0 M(SD)	T_1 M(SD)	F(df)	p	η^2	p	d
PDQ				6.27(2, 197.48)	.002**	.06		0.62
	o-CBT	19.81(6.23)	15.70(6.95)				.001**	
	o-PS	18.78(6.80)	16.79(6.48)				.001**	0.15
	UC	17.93(6.17)	16.59(6.86)				.022*	0.20
PSS-14				5.02(2, 197.61)	.007**	.05		
	o-CBT	27.7(7.67)	21.54(8.65)				.001**	0.76
	o-PS	25.25(9.06)	22.59(8.47)				.003**	0.15
	UC	26.31(9.09)	23.57(9.55)				.002**	0.29
CD-RISC		7.08(2, 192.78)	.001**			.07		
	o-CBT	23.87(5.96)	26.90(6.24)				.001**	0.24
	o-PS	26.52(6.26)	27.65(6.62)				.050	0.09
	UC	27.97(7.04)	28.07(6.78)				.852	0.01
SCL-90-R								
OBS				8.13(2, 197.49)	.001**	.08		
	o-CBT	84.93(17.3)	73.81(25.2)				.001**	0.51
	o-PS	78.12(23.5)	75.40(26.4)				.483	0.05
	UC	74.34(26.7)	75.54(24.8)				.597	0.02
DEP				6.23(2, 197.46)	.002**	.06		
	o-CBT	75.23(23.4)	59.00(29.5)				.001**	0.61
	o-PS	70.03(28.4)	65.06(29.9)				.036*	0.17
	UC	71.54(26.6)	66.53(28.2)				.049*	0.19
ANX				7.05(2, 197.34)	.001**	.07		
	o-CBT	77.43(18.9)	66.06(23.1)				.001**	0.54
	o-PS	75.93(22.5)	71.40(26.2)				.039*	0.18
	UC	71.81(28.2)	71.47(26.2)				.873	0.01

Note: *p <,05; **p < ,01; T_0 = pre-intervention; T_1 = post-intervention; PDQ= Pregnancy Distress Questionnaire; PSS-14 = Perceived Stress Scale-14; CD-RISC = Connor Davidson Resilience Scale; SCL-90-R = The Symptom Checklist-90-Revised; OBS = obsession-compulsion; DEP = depression; ANX = anxiety; o-CBT = online cognitive-behavioural therapy group; o-PS = online psychological support group; UC = usual care group.
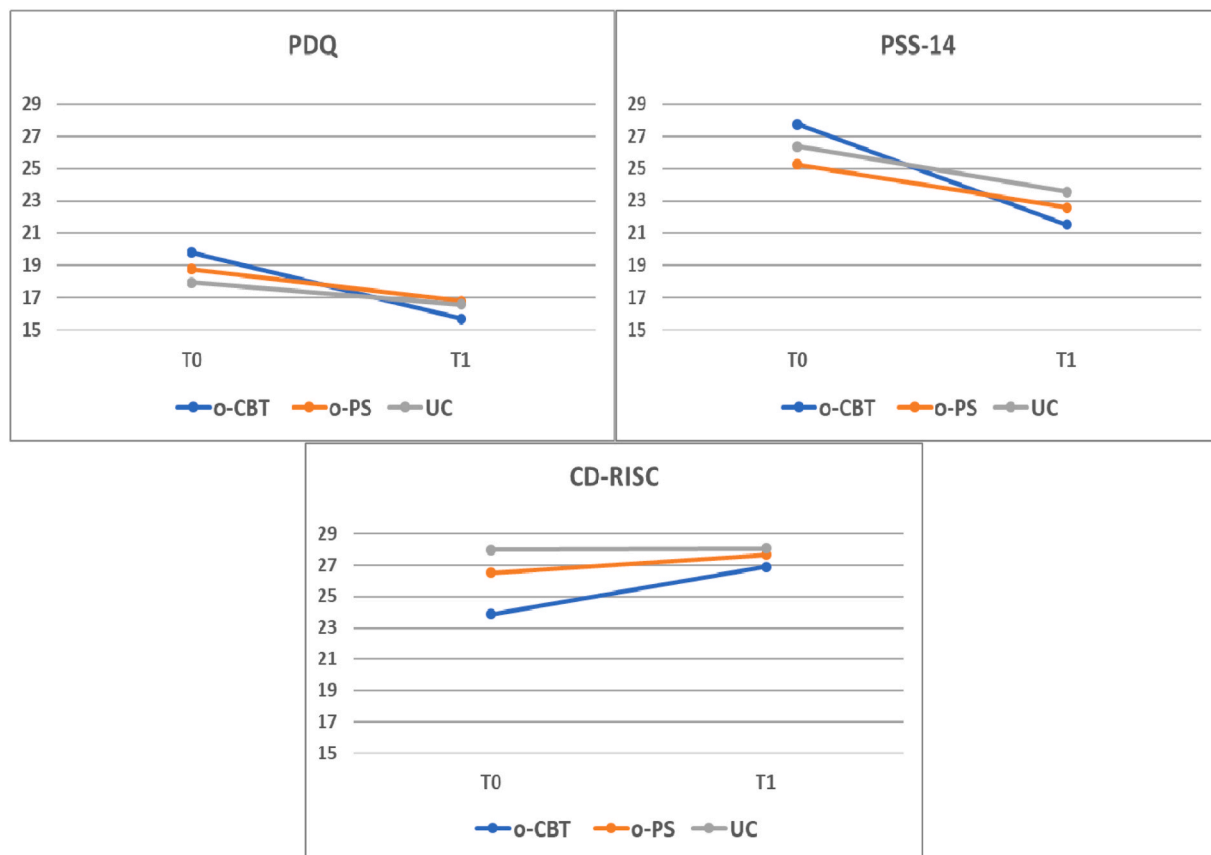

Fig. 2. *Perceived stress, pregnancy-specific stress and resilience scores before and after the intervention of the three groups.Note*: T_0 = pre-intervention; T_1 = post-intervention; o-CBT = online cognitive-behavioural therapy group; o-PS = online psychological support group; UC = usual care group; PDQ= Pregnancy Distress Questionnaire; PSS-14 = Perceived Stress Scale-14; CD-RISC = Connor Davidson Resilience Scale.
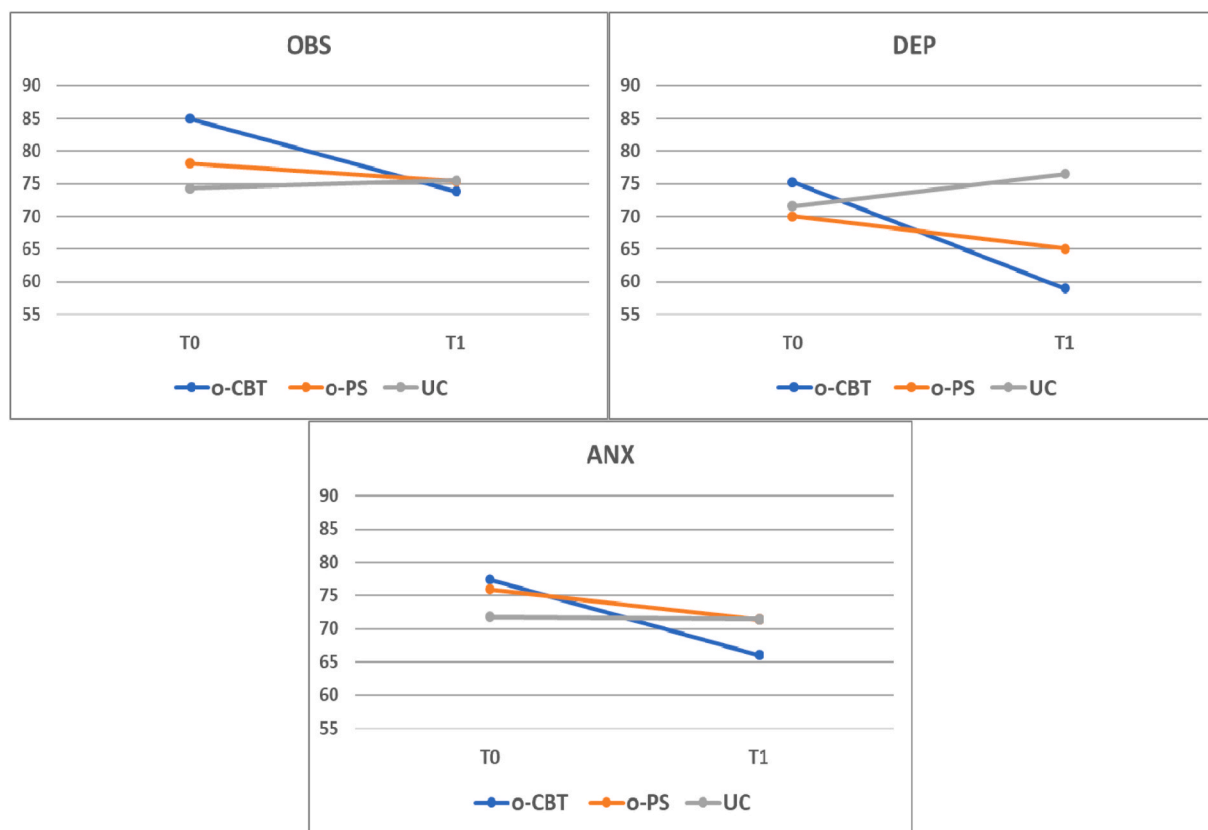
Fig. 3. *Obsession-compulsion, depression and anxiety scores before and after the intervention of the three groups. Note*: T_0 = pre-intervention; T_1 = post-intervention; o-CBT = online cognitive-behavioural therapy group; o-PS = online psychological support group; UC = usual care group; OBS = obsession-compulsion; DEP = depression; ANX = anxiety.

4. Discussion

The objective of this study was to test the efficacy of an online cognitive behavioural stress management therapy in pregnant women during the COVID-19 pandemic in Spain. In order to achieve this goal, three groups of pregnant women were compared, one group that attended online stress management therapy, another group of online psychological support and another that received standard medical care.

The results showed that pregnancy-specific stress levels and perceived stress levels significantly decreased after treatment to a greater extent in the o-CBT group than in the other groups. There was no evidence of improvement in any of the groups regarding vulnerability to stress, understood as a person's predisposition to be influenced by perceived stress. These results are in line with that of previous studies that examined the efficacy of this therapy in a presential modality before the pandemic (Romero-Gonzalez et al., 2020), and which found a reduction in both pregnancy-specific stress and perceived stress in the therapy group. These data also support that of other authors who found a decrease in perceived stress in pregnant women who had gestational diabetes (Zaheri et al., 2017).

Improvements in coping with stress are critical for this population, as they are vulnerable to stress due to their pregnancy (Romero-Gonzalez et al., 2020). It is also particularly relevant due to the current pandemic situation where the symptomatology associated with stress is aggravated (Puertas-Gonzalez et al., 2021a). Thus, training in deactivation techniques (diaphragmatic breathing and thematic imagination), as well as training in detecting and transforming distortions and irrational thoughts, together with training in social skills and time management, have probably provided participants with key tools to cope with the psychological stress related to the COVID-19 pandemic. In this way, participants had a wider range of ways of coping with direct (e.g. fear of

infection) and indirect (e.g. confinement, lack of social contact, etc.) fears and concerns caused by the pandemic. These results have major clinical implications, since prenatal stress can negatively affect a baby's cognitive and motor neurodevelopment (Caparros-Gonzalez et al., 2019b). Improving maternal mental health would therefore be a protective factor regarding potential neurodevelopmental problems in babies.

On the other hand, it is worth noting that the participants who attended online therapy considerably improved their resilience, while no change was observed with respect to this variable in the psychological support group or in the usual care group. These results support the findings of Puertas-González et al., which also reflected the improved resilience of pregnant women who attended therapy (Puertas-Gonzalez et al., 2021b). Resilience is an ability to cope with adverse situations (Connor and Davidson, 2003), which is why, in the current situation of pandemic and the vulnerability entailed by gestation, an increase in resilience represents a key buffer against negative psychological effects during this critical period of life (Puertas-Gonzalez et al., 2021b). The increase in resilience in the treatment group may be due to the stress coping techniques taught during the sessions. Indeed, women are trained in cognitive distortions and irrational beliefs, which strengthens their resilience. This increase was not found in the psychological support group who were only trained in psychoeducation and active listening. In this sense, stress management learning techniques can increase the ability to cope with adverse situations.

With respect to psychopathology, the o-CBT group showed a significant reduction in anxiety, depression and obsessions after treatment. These data are in line with those found by several studies that showed a decrease in psychopathology symptomatology after conducting a presential intervention for stress reduction in different fields (Bradbury et al., 2008; Linares-Ortiz et al., 2014; Romero-Gonzalez et al., 2020;

Santos-Ruiz et al., 2017). In this way, reducing psychological stress and increasing resilience is expected to lead to a reduction in anxiety, depression and obsessions, thus improving the psychological state of pregnant women in a highly threatening situation such as living through a global pandemic, both for women and for their babies. In addition, these data are also consistent with a study conducted before the pandemic, which found that internet-based cognitive behavioural therapy for prenatal depression reduced levels of depression in pregnant women (Forsell et al., 2017).

Added to the above, it is worth noting that many changes in the body during pregnancy can bring about poor psychological adaptation (Nayak et al., 2015). Therapy could thus be a protective factor by reducing symptoms, considering that greater participation in healthy practices affects women's general well-being (Alhusen et al., 2016); in this line, psychological support produces an improvement in psychopathological symptoms, although not as significantly as therapy, active listening and the use of empathy being notably relevant factors to consider in interventions. There is clear evidence, however, of the importance of learning specific stress control techniques during therapy and the reduction of associated psychopathological symptomatology that comes with it.

Despite the findings, this study presented various limitations. A major limitation was the fact that the variables were measured at two different moments in time without any follow-up. A long-term follow-up of participants could provide us with data on the progression of changes found in the participants. In addition, the trimester in which the participants found themselves at the time of joining the study is significant, because depending on the pregnancy trimester, the woman's stress levels, their origin and biological manifestation may differ (Nayak et al., 2015). It is important to take this data into account when recruiting participants in future works. On the other hand, although the intervention groups were led by two different psychologists with extensive experience, there was not fidelity monitoring to assess deviation from the protocol. Another limitation is that although the instrument used in order to assess pregnancy-specific stress (Prenatal Distress Questionnaire; PDQ) is robust and widely used, there is a new version of this questionnaire (Prenatal Distress Questionnaire Revised; NuPDQ). This new version seems to have conceptual and methodological advantages (Ibrahim and Lobel, 2020), but when we designed the study, the Spanish validation had not yet been published. For this reason, we encourage the use of the new version in future similar research.

To conclude, clear evidence was obtained that online cognitive-behavioural intervention during the COVID-19 pandemic brings about positive results for pregnant women: improvements took place regarding pregnancy-specific stress and perceived stress, psychopathological symptomatology was reduced, and resilience increased. These factors are of vital importance in coping with crises. Therefore, cognitive behavioural therapy for stress management in pregnant women could prevent increased stress and psychopathological symptoms resulting from a pandemic, acting as a "psychological vaccine" or buffer, in a metaphorical sense.

Lastly, it is important to understand the psychological impact of pregnancy on the well-being of both the mother and child, pregnancy often being considered as the golden stage of a woman's life. Yet pregnancy entails a series of physical and mental challenges that often go unnoticed, added to the knowledge that the gestation period can affect the child's mental and physical health in the long term. Despite awareness of these data, psychological aspects are often overlooked during pregnancy and the vast majority of women are not conscious of the consequences that mental health problems can have during the period of gestation, childbirth, lactation and even the baby's neurodevelopment (Caparros-Gonzalez et al., 2017; Caparros-Gonzalez et al., 2019b, 2019c; Kumar-Nayak et al., 2015).

These data thus highlight the importance of implementing intervention programmes during pregnancy, not only to facilitate adequate maternal mental health during the gestation period, but also as a long-term protective factor of good public health.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpsychires.2022.07.016.

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