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Effects of cognitive-behavioural therapy for stress management on stress and hair cortisol levels in pregnant women: A randomised controlled trial

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ABSTRACT

Objective: To demonstrate the effectiveness of a cognitive behavioural therapy for stress management in pregnant women in the reduction of psychological stress and hair cortisol levels.
Methods: The trial was controlled and randomised, with a total of 78 pregnant women: control group (n-39) and Cognitive Behavioural Therapy group (n-39). To test the therapy's efficacy, an evaluation of the primary outcome (hair cortisol levels) and secondary outcomes (psychological stress, psychopathological symptomatology and resilience) was conducted before and after the treatment. The therapy was conducted during 8 sessions (one per week) in a group setting. The study was registered as a Randomised Controlled Trial with the code NCT03404141.
Results: The results showed a group time interaction between hair cortisol levels, psychological stress (perceived and pregnancy-specific), and in the exacerbation and severity of psychopathological symptoms. These variables presented reductions after treatment only in the Cognitive Behavioural Therapy group.
Conclusions: Using a novel way of assessing chronic stress (psychological and objective measures as hair cortisol levels), this is the first study that has shown a decrease in both the levels of cortisol in hair and in psychological stress. This decline could have implications for maternal and fetal health.

1. Introduction

Despite being regarded as a positive stage, pregnancy is a stressful process that involves numerous changes affecting pregnant women's psychological status, physiological health and social relationships [1,2]. Pregnancy-specific stress, evaluated and considered differently from general stress, is characterised by particular concerns proper to the pregnancy, such as physical symptoms, stress in intimate relationships, family responsibilities and concern for foetal health [2,3]. It is estimated that around 6% of the pregnant population experiences high levels of prenatal stress, which are related to problems such as pregnancy depression and postpartum depression, increased risk of pre-eclampsia and hypertension, higher risk of miscarriage, low foetal weight and premature birth [1,4–6]. In addition to the consequences previously described, it is necessary to consider the effect of the mother's psychological state in the final stages of pregnancy, and the likelihood that childbirth will require instrumented or surgical attention. In this line, a recent study presented surprising results according to which mothers with high levels of stress or psychopathological symptoms during pregnancy were more likely to need instrumented delivery (forceps, vacuum, emergency c-sections) [7].

Similarly, the effects that stress has on pregnant women has an impact on their babies. Maternal stress levels are responsible for the deregulation of the pituitary adrenal hypothalamus axis in the newborn, thus babies had lower cortisol levels at birth when maternal cortisol levels during pregnancy were high [8]. In this way, prenatal stress plays a major role in maternal and foetal health, but it also has a major impact on the baby's health and subsequent neurodevelopment. Maternal stress and cortisol levels in hair have been found to be linked to inferior motor and cognitive neurodevelopment at 6 months of age [9,10].

Given the consequences of suffering stress, many interventions and therapies have emerged with the aim of reducing or alleviating stress. In recent years, guidance and training of health workers (nurses and

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midwives) have played a substantial role in preventing stress during pregnancy and childbirth [5]. Other alternatives such as third-generation therapies (e.g. mindfulness) [11–13], and sports such as yoga or relaxation training [14,15] have also been used to reduce stress levels and improve pregnant women's quality of life. However, within evidence-based medicine, Cognitive-Behavioural Therapy (CBT) stands out for the treatment of many disorders [16]. Particularly worthy of note is the favourable data regarding its efficacy to treat anxiety and depression in gestational women [17–19], women with recurrent miscarriages [20] and women with pre-eclampsia [21].

In addition to psychological stress, cortisol appears as a potential stress biomarker. As a result, the evaluation of chronic and physiological stress by extracting cortisol in hair has gained further significance due to its negative impact on the pregnancy and the baby's neurodevelopment [4,8]. Due to the key role that stress plays in maternal and foetal health, it is crucial to measure hair cortisol levels as they are thought to be a reflection of psychological stress. This analysis of hair cortisol level serves as testament to the effectiveness of therapies and interventions in the reduction of stress. To the best of our knowledge, there is no evidence regarding the effect that CBT can have on reducing cortisol levels in hair in pregnant women, as most studies are based only on self-informed stress measures [21–24]. The inclusion of physiological measures of chronic stress, such as cortisol in hair, would provide information previously unknown about the efficacy of therapy. Furthermore, psychological stress is thought to increase risk of suffering psychopathological disorders [25]. For that reason, it could be interesting to test if by reducing psychological stress, it would be possible to reduce psychopathological symptoms as well. Moreover, resilience could play an important role in the reduction of psychological stress [26], so its assessment is vital in order to check any possible alterations in resilience levels as consequence of a psychological intervention. The main objective of this study was to check the effectiveness of a cognitive-behavioural therapy for stress management in reducing psychological stress and hair cortisol levels in low-risk pregnant women. As a consequence of reducing stress levels (psychological and hair cortisol levels), a second objective has been to check if there is a reduction in psychopathology using a CBT in pregnant women.

2. Methodology

2.1. Trial design

The study was an individual level randomised controlled trial (RCT) with single blind RCT.

2.2. Participants

Participants were recruited at the Góngora and Mirasierra Health Centres in the province of Granada during September 2017 and May 2019.

The inclusion criteria consisted of: pregnant women, to be in the second trimester of pregnancy (between weeks 12 and 28 of gestation), with a good grasp of the Spanish language (oral and written understanding). The 12th week was selected because at this stage of the pregnancy, the patient is at less risk of suffering an abortion. The 28th week of gestation was selected because when the patient completes the intervention, she will still have some weeks remaining before the onset of labor.

Exclusion criteria included suffering from a medical illness, have been diagnosed with any mental disorders (i.e. schizophrenia, bipolar disorders…), or following a corticosteroid treatment.

Participation was voluntary, and an informed written consent document was read and signed by every participant. This study was approved by the Human Ethics Research Committee of the University of Granada (reference 881), the Biomedical Ethics Research Committee and the Ethics Research Committee of the Health Centres, and the hospital where this study was implemented. Moreover, this study followed the guidelines of the Helsinki Declaration (AMM, 2008) and the Good Clinical Practice Directive (Directive 2005/28/EC) of the European Union. The study was registered as a Randomised Controlled Trial with the code NCT03404141.

2.3. Outcomes measures

2.3.1. Primary outcome: hair cortisol levels

The cortisol evaluation consisted in taking a lock of hair containing approximately 150 strands from the rear corner of the skull, as close as possible to the scalp [27]. A maximum length of 3 cm was set for each sample to reflect cortisol levels during the preceding 3 months [28]. The samples were wrapped in aluminium foil to be adequately protected from light and humidity and were kept at room temperature until further analysis by the Department of Pharmacology of the Faculty of Pharmacy of the University of Granada. The analysis protocol was published in several studies [4,8].

2.3.2. Secondary outcomes: psychological assessment

Perceived Stress Scale (PSS) [29,30]. The PSS 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). Spanish reliability alpha's Cronbach coefficient is 0,81.

Pregnancy Distress Questionnaire (PDQ) [31,32]: this is a 12-item scale that measures pregnancy-specific stress related to maternal concerns about pregnancy, such as medical problems, labour 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. The Cronbach's alpha reliability coefficient is 0.71.

The Symptom Checklist-90-Revised (SCL-90-R) [33,34]: This is a 90-item scale scored using a 5-point Likert scale from 0 (never) to 4 (extremely). This instrument is used to assess 9 dimensions: Somatization, Obsession-compulsion, Interpersonal sensitivity, Depression, Anxiety, Hostility, Phobic anxiety, Paranoid ideation, and Psychoticism. The scale also has 7 extra items distributed among 3 global indexes of distress: the GSI, which measures overall psychological distress; the PSDI, which is used to measure the intensity of symptoms; and Positive Symptom Total, used to measure the number of self-reported symptoms. Using the author's instructions, the scores are transformed to percentiles ($0-100$). Percentiles ≥ 75 represent clinical symptoms in any of the subscale of this instrument. The nine dimensions show an acceptable reliability, with a Cronbach's alpha for internal consistency of 0.81.

Connor Davidson Resilience Scale (CD-RISC) [35,36]. It reflects the capacity to tolerate experiences such as change, personal problems, illness, pressure, failure, and feelings of pain. The CD-RISC-10 consists of 10 items Likert scale with 5 response options ranging from 0 (“almost never”) to 4 (“almost always”). It has a Cronbach's alpha reliability coefficient of 0.86.

2.4. Procedure

Participants were recruited by their midwife at their health centre as they attended their quarterly pregnancy visit. At this time, they were informed of the study and provided with a phone number to call if they wished to participate. Subsequently, interested participants were provided with the study information sheet and the informed consent document was signed.

Participants were randomly divided into two groups, a control group (CG) and a CBT group (CBTg). Randomisation was performed by using a computer-generated random number sequence in which patients were randomly assigned (1:1) to either the CBTg or the CG. The data management system automatically allocated numbers from the

random number list to study participants. Random allocation sequences, participants' registration and intervention assignments were carried out by a research assistant who was unaware of the participants' data. Patients assigned to the CG received standard care during their pregnancy. Patients assigned to the CBTg attended 8 weekly CBT sessions of 1.5 to 2 h with two trained psychologists. Each group was composed of 4 to 5 participants and 8 groups were thus formed.

The evaluation instruments described in the previous paragraph were delivered to both the CBTg and CG members at the same time. In addition, a hair sample was taken for the retrospective removal of cortisol. Those assigned to the CBTg were informed of the starting date and time of their therapy. Participants of the CG were told to follow their standard routine care, which consists of three medical visits during the entire pregnancy with their midwifes. Information about whether they followed their standard routine care or not was obtained from the Pregnancy Health Document [37].

The intervention was adapted from a pre-existing treatment programme [38] and was taught in the Multipurpose Room of the Zaidin Sur Health Centre. It consisted of a cognitive behavioural programme that had demonstrated to be highly effective in stress management. Its main objective was to provide participants with psychological tools that gave them greater control over the different stressful situations they confront throughout their pregnancy. The programme teaches them strategies to face stress in an optimal way [39–42]. The sessions were composed as follows: (1) psychoeducation: what stress is, characteristics, identification of stressors, responses and consequences; (2) deactivation techniques (thematic imagination along with diaphragmatic breathing); (3) cognitive restructuring: cognitive distortions; (4) cognitive restructuring: irrational beliefs; (5) Alternative thought control strategies - self-instructional training and time organisation; (6) training in social skills: assertiveness, basic assertive rights, saying no and asking for a change of behavior; (7) Relationship between anger and stress: emotional self-regulation; (8) optimism and good humour – recapitulation.

At the end of the therapy, the assessment tools described above were re-administered to participants in both groups. During this second extraction of hair, only the two centimetres closest to the root were used to avoid overlap between pre and post-treatment samples. At that moment, participants of the CG were offered to take part in the therapy whenever they wished.

2.5. Data analysis

First, descriptive information is presented using mean and standard deviation for continuous variables and percentage of qualitative variables.

According to the intention-to-treat analysis, and following the recommendations established by other researchers [43,44], using the last observation carry forward method, missing values were imputed, and all participants initially randomised were included in a mixed repeated measures ANOVA 2*2 the variable between groups having two levels (CG and CBTg), and the intrasubject variable two temporary moments (pre and post). These analyses are performed in order to know whether or not the participant completed intervention, indicated a differentiating factor of confounding that may bias the results [43,44].

As some authors have stated, it is important not to single report intention-to-treat analysis alone [45], then, to check the effectiveness of cognitive behavioural therapy, only participants who completed the study were included in a mixed repeated measures ANOVA 2*2, the variable between groups having two levels (CG and CBTg), and the intrasubject variable having two temporal times (pre and post). The Greenhouse-Geisser correction was applied in these ANOVAs. The dependent variables were scores in PSS, PDQ, CD-RISC, the SCL-90-R subscales and cortisol levels in hair. For ANOVAS, effect size partial eta square (η_p^2) was calculated based on the recommendations of taking a $\eta_p^2 = 0.01$ as the effect's low size, $\eta_p^2 = 0.05$ as the average size, and $\eta_p^2 = 0.08$ as a large effect size [46].

Subsequently, a comparison of means using the student's *t*-test was also performed, the group being the independent variable (control vs experimental) and the dependent variables being the scores in the PSS, PDQ, CD-RISC, the SCL-90R subscales and cortisol in hair. To check the effect size on the contrast between groups, Cohen's d was calculated using the equation of "Effect Size Estimate Using Pooled Pretest *SD*" based on Morris' recommendations [47] and taking a d = 0.20 as the effect's low size, d = 0.50 as the average size, and d = 0.80 as a large effect size [48].

Then, dependent *t*-tests analyses were performed on the variables presenting group*time interaction, applying Bonferroni correction to check whether there were pre and post intervention changes in both the CG and the CBTg.

For hair cortisol, we performed a log transformation (natural log; ln base e) in order to obtain a normal distribution. Analyses were performed using the Statistical Package for the Social Sciences 20.0 for Windows, version 8.1 (SPSS, Armonk, New York).

Statistical approaches were performed according to the recommendations of the ICH E9 statistical principles for clinical trials [49,50].

2.6. Sample size estimation

G*Power (version 3.1.9.2, Universität Düsseldorf, Düsseldorf, Germany, 2007) was used to confirm that the number of participants was high enough to secure 95% power and $\alpha \leq 0.05$ for all analyses. Taking into consideration the existence of 2 groups (experimental and control group) and the need to compare data from 2 different times, G*Power determined that the total number of participants required was 54 (effect size f = 0.25 – medium).

3. Results

3.1. Sample description

A total of 108 pregnant women were interested in participating in the study. Of these, 93 met the inclusion criteria, the remaining 15 were thus discarded from the study. Participants were randomly divided into two groups: a control group (n = 47) and an experimental group (n = 46). Within the experimental group, a total of 7 women were excluded from the total sample because they did not complete the therapy. In addition, another 8 women were excluded from the control group for the reasons described in the flowchart (Fig. 1). Finally, 78 pregnant women (M = 23.94 weeks of gestation; SD = 4.40) with an average age of 33.07 years (SD = 4.63) participated in the study. These women were divided into two groups: a CBTg (n = 39) with an average age of 34 years (SD = 4.99) and a CG (n = 39) with an average age of 32.03 years (*SD* = 4.01). Fig. 1 shows the CONSORT flow diagram corresponding to the sample.

Main sociodemographic variables and obstetric information are presented in Table 1.

3.2. Intention-to-treat analysis

The mixed repeated measures ANOVA 2*2 analysis performed with the initially randomised group showed that there was statistically significant group*time interaction in primary outcome: hair cortisol levels [F (1,91) = 1.48; p = .04; $\eta_p^2 = 0.049$], and secondary outcomes: PDQ scores [F (1,91) = 9.18; p = .003; $\eta_p^2 = 0.092$], PSS scores [F (1,91) = 13.44; p = .001; $\eta_p^2 = 0.130$], and the general scales of the SCL-90-R, GSI [F (1,91) = 4.51; p = .003; $\eta_p^2 = 0.048$] and PSDI [F (1,91) = 8.31; p = .005; $\eta_p^2 = 0.085$]. However, resilience scores were not statistically significant [F (1,91) = 0.93; p = .33; $\eta_p^2 = 0.012$].

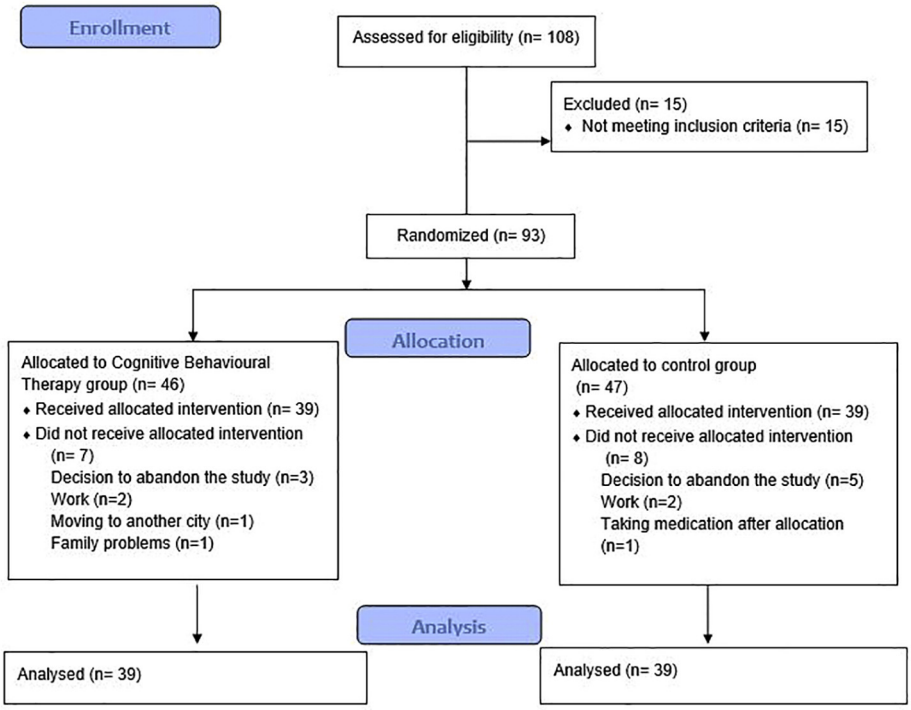

Fig. 1. CONSORT flow diagram of participants.

Table 1
Sociodemographic variables and obstetric information in control and experimental group.

		Control group (n = 39) M(SD)/n(%)	CBT group (n = 39) M(SD)/n(%)
Sociodemographic variables			
Age		32.03(4.01)	34(4.99)
Nationality	Spanish	36(92.3%)	37(94.9%)
	Inmigrant	3(7.7%)	2(5.1%)
Marital status	Married/cohabitant	39(100%)	39(100%)
Employment situation	Employed	8(13.9%)	10(25.6%)
	Unemployed	31(86.1%)	29(74.4%)
Education	Primary school	1(2.6%)	–
	High school	11(28.2%)	10(25.6%)
	University	27(69.2%)	29(74.4%)
Sport	Yes	20(51.3%)	22(56.4%)
	No	19(48.7%)	17(46.6%)
Smoking	Yes	3(7.7%)	–
	No	36(92.3%)	39(100%)
Alcohol	Yes	–	–
	No	39(100%)	39(100%)
Hair	Natural	18(46.2%)	17(46.6%)
	Dyed	21(53.8%)	22(54.4%)
Hair	Straight	23(59%)	22(56.4%)
	Curly	16(41%)	17(43.6%)
Obstetric information			
Weeks of gestation	T_0	23.85(3.20)	24.03(5.37)
	T_1	33.34(2.27)	31.58(5.59)
Wanted pregnancy	Yes	36(92.3%)	31(79.5%)
	No	3(7.7%)	8(20.5%)
Type of pregnancy	Spontaneous	33(84.6%)	34(87.2%)
	Fertility treatment	6(15.4%)	5(12.8%)
Previous miscarriages	0	26(67%)	19(48.7%)
	≥1	13(33%)	20(51.3%)
Primiparous	Yes	20(51.3%)	17(43.6%)
	No	19(48.7%)	22(56.4%)

Note: CBT = Cognitive Behavioural Therapy.

3.3. Efficacy of cognitive behavioural therapy in controlling stress during pregnancy: hair cortisol levels, pregnancy-specific stress, perceived stress, resilience and psychopathological symptoms. Results from Per Protocol Analyses

With regard to the participants who completed the study (n = 39 for CG; n = 39 for CBGg), the ANOVA results showed a statistically significant group*time interaction in the primary outcome: hair cortisol levels [F (1,74) = 14.05; p = .004; η_p^2 = 0.051], and secondary outcomes: PDQ scores [F (1,74) = 11.00; p = .001; η_p^2 = 0.129], PSS scores [F (1,74) = 4.04; p = .001; η_p^2 = 0.160], as well as the GSI SCL-90-R general scales [F (1,74) = 4.86; p = .030; η_p^2 = 0.059] and PSDI [F (1,74) = 8.90; p = .004; η_p^2 = 0.104]. Resilience scores were not statistically significant [F (1,74) = 1.02; p = .31 η_p^2 = 0.016].

The average scores of the variables showing group*time interaction and resilience scores in both groups in the pre and post are shown in Table 2. Subsequent between-group analyses revealed differences between CG and CBTg after stress therapy.

3.4. Pre and post-intervention changes in CG and CBTg

Dependent t-tests were performed to detect changes in pre and post intervention. There were not statistically pre-post intervention changes in CG in hair cortisol levels [t (38) = −0.84; p = .40] nor the secondary outcomes: PDQ scores [t (38) = 0.35; p = .72], PSS [t (38) = −0.84; p = .40], and on the overall scales of the GSI SCL-90-R [t (38) = −0.25; p = .80] and PSDI [t (38) = −0.77; p = .44], and resilience [t (38) = −0.98; p = .33]. As for the CBTg, significant statistically changes were found in the hair cortisol levels [t (38) = 1.95; p = .04] and the secondary outcomes: PDQ scores [t (38) = 4.54; p = .001], PSS [t (38) = 3.75; p = .001], and on the overall scales of the GSI SCL-90-R [t (38) = 2.47; p = .018] and PSDI [t (38) = 3.27; p = .002]. The mean scores of the CBTg in these variables being higher before the therapy than after. As for resilience, significant statistically changes differences were found [t (38) = −2.13; p = .038], being scores after treatment higher than before. Those results are shown in Supplementary Table 1.

Table 2
Differences in post intervention scores between control and experimental group.

Outcomes			Group	T_0	T_1	test	*p*	d
Primary		**HCC**						
			CG	5.50(0.91)	5.62(0.86)	5.59	0.005	0.45
			CBTg	4.78(0.97)	4.47(0.94)			
		PDQ						
			CG	13.04(4.68)	12.93(5.24)	−0.71	0.47	0.83
	Stress		CBTg	18.18(5.38)	13.82(5.75)			
		PSS						
			CG	26.12(2.78)	26.43(1.34)	3.70	0.001	2.43
			CBTg	26.72(7.41)	21.87(7.56)			
Secondary		**GSI**						
			CG	49.37(28.58)	50.10(29.30)	−1.53	0.12	0.44
	SCL-90-R		CBTg	71.33(25.56)	60.05(28.97)			
		PSDI						
			CG	39.35(24.32)	41.88(22.91)	−0.30	0.76	0.65
			CBTg	57.95(26.56)	43.59(27.26)			
			CG	28.16(5.74)	27.61(5.41)	−0.429	0.295	0.38
	CD-RISC							
			CBTg	26.44(6.25)	28.21(5.76)			

Note: PDQ = Pregnancy Distress Questionnaire; PSS = Perceived Stress Scale; HCC = Hair Cortisol Concentrations; GSI = Global Severity Index; PSDI = Positive Symptom Distress Index; CD-RISC = Connor Davidson Resilience Scale; CG = Control Group; CBTg = Experimental Group; T_0 = Pre-intervention; T_1 = Post intervention.

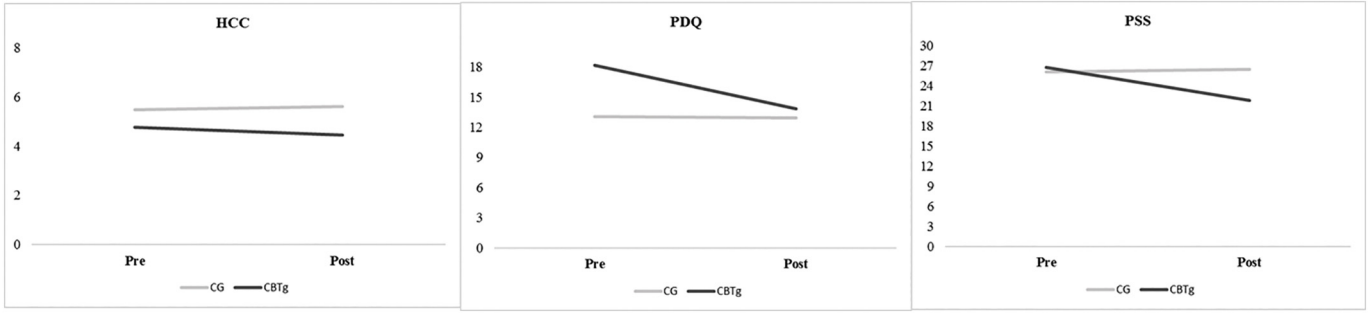

Fig. 2. Pre and post-intervention scores in CG (n = 39) and CBTg (n = 39) in main stress measures.
Note: PDQ = Pregnancy Distress Questionnaire; PSS = Perceived Stress Scale; HCC = Hair Cortisol Concentrations; CG = Control Group; CBTg = Experimental Group.

Fig. 2 shows the evolution of pre and post intervention scores in both groups in the main stress measures.

4. Discussion

The objective of this study was to test the effectiveness of a cognitive-behavioural therapy for stress management in healthy pregnant women. Among the variables to be modified were the pregnancy-specific stress, perceived stress, cortisol levels in hair, psychopathological symptomatology and resilience. To this end, two groups of pregnant women were compared, a group that participated in a cognitive-behavioural therapy for stress management (CBTg) and another group that received standard medical care (CG). The results showed that the therapy used could be effective, as reductions in specific pregnancy stress levels, perceived stress, cortisol in hair, and in positive indices of discomfort and overall severity were found.

It is first worth noting that the result of the reduction of perceived stress levels in women who participated in the therapy is compatible with that of a previous study that found a decrease in perceived stress levels in pregnant women with gestational diabetes [51]. Perceived stress is a type of stress that is present in both pregnant women and the general population, as it involves aspects such as work, daily tasks, etc. [30]. The intervention we performed on healthy pregnant women succeeded in alleviating this type of general stress. However, the most exciting result we obtained was the decrease in pregnancy-specific stress. Pregnancy-specific stress is a powerful predictor of negative outcomes in maternal and child health [3], even more important than perceived stress. Other authors have found it to have been reduced following interventions based on counselling and diseases such as pre-eclampsia [5,52]. However, our study is the first to find a reduction during healthy pregnancy, working on the concerns experienced by pregnant women. The results showed that it could be possible to diminish the concerns that pregnant women try to normalise, but that can have negative consequences for them. Overall, the decrease in perceived stress and pregnancy-specific stress in a population of healthy pregnant women may be a step towards implementing this therapy as a health-promoting measure.

Second, in regard to the chronic stress biomarker used, cortisol levels in hair, a reduction in levels was found after intervention, as a result of reduced activation of the HPA axis. This reduction in cortisol levels leads to positive health benefits. Some authors have affirmed the importance and usefulness to include the evaluation of cortisol in hair

to check the efficacy of therapies, also finding lower levels after the intervention [53,54]. A recent study showed the relationship between maternal and child cortisol, as women with high stress levels had newborns with lower levels, posing a risk to their health [8]. It is important to address this fact, in accordance with the "hypothesis of foetal programming", which suggests the possibility that the intrauterine environment, dependent on the mother and her living habits, significantly conditions child and adult health [55]. Lowering maternal cortisol levels through therapy may lead to further prevention of diseases in adulthood caused by prenatal stress. Thus, the intervention's effectiveness goes beyond the management of psychological stress, allowing the physiological reduction of cortisol in healthy pregnant women and the previously mentioned implications for themselves and for their babies.

In relation to psychopathological symptomatology during pregnancy, lower levels were found after intervention on the general discomfort scales, which indicates an average degree of severity of symptoms, and on the positive discomfort scale, which reflects a pregnant woman's tendency to exacerbate psychopathological symptoms. Some authors had found a reduction in a wide range of psychopathological symptoms by conducting the intervention in different domains [39,42,56]. Our results indicate that general psychopathological symptoms could decrease in this population following the therapy, implying that the tendency to exacerbate symptoms and the very perception of the severity of symptoms decrease after therapy. These results are significant in a pregnant population as gestation involves a psychological and hormonal adaptation that does not apply to the general population [57]. In addition, during pregnancy, many changes take place in the body, changes in blood circulation, glandular functions and in the process of feeding gestation-related tissues, which can lead to pain and even psychological maladaptation [58]. Furthermore, it is worth noting the significant role that cognitions play in this programme: a major objective is that participants manage to identify the maladaptive cognitive processes underlying their thoughts and to learn new ways of perceiving and thinking about what they are going through. These aspects can be key to reducing their own symptoms, which are indicators of psychological well-being, by leading the pregnant woman to avoid regarding her symptoms as more serious than they truly are and to focus less on their severity [59].

The implications of these results are of great significance: they reflect the effectiveness of a stress management therapy directed towards healthy pregnant women, that succeeded in reducing levels of psychological, physiological stress and certain psychopathological symptoms. Since the population is healthy and has no medical or psychological pathology, this model of therapy is based on promoting mental health in pregnant women: its effectiveness lies in lowering the probability of suffering a large number of stress-associated psychological and obstetric problems [4,7,8].

Nevertheless, there were some limitations to the present study. The experimental group started with higher levels of stress and a weaker psychological state. The latter, however, does not overshadow the fact that notable reductions were found after the intervention in all the variables under study. Indeed, the effect sizes revealed a substantial change in the women having taken part in the therapy, that were not found in the control group. Therefore, despite the groups not having been equal, the therapy effect was visible in the group. Despite the fact that psychopathological symptoms were not clinical in pre-treatment moment in any group (more than percentile 75), these differences between groups might be significant, so it is worth considering to take them into account in future research. Another possible limitation was the measurement of variables at only two moments in time: a follow-up could have provided relevant data regarding the maintenance of the effect of the therapy long-term, after birth. Additionally, the range of recruiting participants could be too large, so, it is worth considering for future research, as stress levels, origin of stress and biological manifestation of stress could differ dramatically between trimesters.

To conclude, these findings have major implications for the field of research and at the clinical level, as a number of stress-related psychological/psychopathological variables shown in pregnant women could be reduced through psychological intervention. Evaluating these variables can provide relevant data to health professionals on the problems affecting women during the gestation period and the consequent implementation of treatments adapted to this population. It is essential to raise the awareness of health workers and beneficiaries both about the role of psychological health and its impact on pregnant women and their children [4,60], as well as the need for interventions aimed at improving psychological health during such a vital stage of life, pregnancy.

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Declaration of Competing Interest

The authors have no competing interests to report.

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Appendix A. Supplementary data

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