The SMART Moms Program: A Randomized Trial of the Impact of Stress Management on Perceived Stress and Cortisol in Low-Income Pregnant Women

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A B S T R A C T

Background: Dysregulations in maternal hypothalamus-pituitary-adrenal function and the end product, cortisol, have been associated with a heightened risk for stress-related health complications during pregnancy and post partum. Given the adverse health impact that maternal cortisol may have on expectant mothers and their infants, empirically-based prenatal interventions are needed to target optimal management of stress and its biological effects in at-risk pregnant women, a primary example of which is cognitive behavioral stress management (CBSM). This randomized-controlled trial examined the effects of a prenatal CBSM intervention on reduction in perceived stress and regulation of salivary cortisol patterns [i.e., overall cortisol output (area under the curve), cortisol awakening response (CAR), diurnal slope] during pregnancy and the early postpartum period, as compared to a control group.
Methods: One hundred low-income pregnant women (71% Latina; 76% annual income < $20 K) with low or high anxiety during pregnancy were randomized (stratified by anxiety) to either an eight-week CBSM group intervention ($n = 55$) or a control group ($n = 45$). They provided seven salivary cortisol samples (four am samples, 12 pm, 4 pm, and 8 pm samples on one collection day) at baseline (1st trimester; < 17 weeks of gestation), after their prenatal program (2nd trimester), and also in the third trimester and at three months post partum.
Results: Women receiving CBSM had lower perceived stress levels throughout pregnancy and early post partum compared to women in the control group ($p = .020$). Among women with high prenatal anxiety, those in CBSM showed a steeper decline in their diurnal cortisol at three months post partum compared to those in the control group ($p = .015$). Further, non-Latina women in CBSM had a lower CAR at three months post partum compared to non-Latina women in the control group ($p = .025$); these randomization group differences on the CAR were not observed among Latina women.
Conclusions: These findings provide preliminary support for the efficacy of prenatal CBSM interventions in improving stress outcomes among low-income pregnant women and suggest the need to test the effects of these interventions on a larger scale for improving maternal and infant health outcomes long-term.

1. Introduction

1.1. Prenatal stress effects on maternal and infant health

Stress is generally considered an adaptive response to challenges in the environment, but chronic dysregulations in biological stress-related systems have been associated with adverse health outcomes (Chrousos, 2009). Stress during pregnancy has been associated with a range of health problems for women, including increased anxiety and postpartum depressive symptoms (Dunkel Schetter et al., 2016; Yim et al., 2015). It has also been linked to adverse birth outcomes, namely preterm birth and low birthweight, which are associated with long-term neurodevelopmental impairments in children (Van den Bergh et al., 2017). Of particular concern are low-income women, who are prone to

experiencing psychosocial stressors during pregnancy such as poverty, little or no prenatal health education, single parenthood, and are at greater risk for prenatal health complications and adverse birth outcomes (Lefmann et al., 2017; Reynolds et al., 2013). Therefore, studies examining biological mechanisms underlying the impact of prenatal stress on maternal and infant health in low income populations are needed.

1.2. Cortisol during pregnancy

The stress hormone cortisol has been associated with a heightened risk for stress-related health complications during pregnancy and the postpartum period (Hodyl et al., 2017; Zijlmans et al., 2015). Cortisol is the end-product of the hypothalamus-pituitary-adrenal (HPA) axis, is released by the adrenal glands, and is considered one of the main markers of the biological stress response (Fries et al., 2009). A dramatic change in HPA axis regulation and cortisol secretion occurs during pregnancy with cortisol levels rising throughout pregnancy, which plays an important role in fetal organ development, and returning to pre-pregnancy levels after childbirth (Mastorakos & Ilias, 2003). Diurnal variation is still observed during pregnancy, though reduced, with cortisol levels being highest in the morning and lowest at the end of the day (Mastorakos & Ilias, 2003). Although the rise in cortisol during pregnancy is normative, studies show that higher concentrations of maternal cortisol during pregnancy are related to adverse birth outcomes, including increased rates of preterm births, a higher need for infant resuscitation assistance at birth, and infant brain cell damage (Hodyl et al., 2017; Zijlmans et al., 2015). In addition to overall cortisol secretion, researchers have examined women's cortisol awakening response (CAR), a normative increase in salivary cortisol from the time of awakening to 30 min after waking (Pruessner et al. 1997). A higher CAR during pregnancy has been associated with shorter gestational periods (Buss et al., 2009) and a blunted or flat CAR with increased risk for postpartum depression (Scheyer & Urizar, 2016). Furthermore, flatter diurnal cortisol slopes (i.e., smaller decrease in cortisol levels across the day) during pregnancy have been associated with increased anxiety and impaired sleep in mothers and with low birthweight in infants (Bublitz et al., 2018; Kivlighan et al., 2008). Although low-income and ethnic minority women experience unique stressors (e.g., unemployment, racial discrimination) that place them at greater risk for prenatal health complications and poor birth outcomes (Lefmann et al., 2017; Reynolds et al., 2013), fewer studies have examined income/ethnicity differences in cortisol patterns and their relation to adverse health outcomes for mothers and their infants. Pregnancy studies show that African American women (regardless of income level) demonstrate a more blunted CAR and flatter diurnal cortisol patterns compared to non-Hispanic whites, which in turn have been associated with a greater risk for preterm birth in this population (Glynn et al., 2007; Simon et al., 2016). Collectively, these findings suggest that altered cortisol patterns (i.e., higher cortisol concentrations, higher/flat CAR, flatter diurnal cortisol slope) negatively affect mothers and their infants, and highlight the pressing need to develop and test prenatal interventions that target optimal management of stress during this critical period.

1.3. Cognitive behavioral interventions and stress outcomes

Health providers of pre- and postnatal care are becoming more aware of the need to create clear guidelines for the management of stress during pregnancy (ACOG, 2006). The Institute of Medicine (IOM) Report on Preventing Mental Disorders prominently states the need for research on preventive interventions and has endorsed group cognitive behaviorally-based interventions as one of the best methods and empirically-supported modalities for helping to prevent stress-related disorders (National Research Council & Institute of Medicine, 2009). Over the past 15 years, there has been some progress in examining the

effectiveness of cognitive behavioral stress management (CBSM) interventions (i.e., combination of cognitive coping and relaxation training) on regulating biological markers of stress, such as cortisol. Previous randomized studies have shown group-based CBSM interventions to be effective in producing short-term reductions (i.e., 2 to 10 week follow-up period) in stress and cortisol levels in patients with stressful medical conditions, such as HIV and breast cancer (Antoni, 2013; Antoni et al., 2005). One of the few studies to examine the effects of a prenatal CBSM intervention on cortisol demonstrated lower cortisol levels among mothers at high risk for depression at 18 months post partum (Urizar & Muñoz, 2011). Despite these promising results, limited resources and training have precluded the translation of the IOM's recommendations for systematically evaluating the effectiveness of group-based CBSM interventions in regulating stress and cortisol levels among low-income pregnant women who are in most need of these programs. In fact, despite the disproportionate number of premature births and low birth-weight babies observed among low-income mothers, less than one quarter of these women report actively engaging in stress management during pregnancy due mainly to a lack of awareness of how important managing one's stress levels can be for the health of the mother and her baby (Birdee et al., 2014). Given these disparities in birth outcomes and dissemination of preventive interventions, studies are needed to reach underserved women during pregnancy and provide them with the necessary skills and knowledge to facilitate stress management.

1.4. Present study

The current randomized-controlled trial examined whether a prenatal CBSM intervention, in comparison to a control group, was effective in reducing perceived stress levels and regulating salivary cortisol patterns among low-income pregnant women prospectively assessed throughout pregnancy and the early postpartum period. CBSM effects on perceived stress and cortisol were examined by ethnicity and prenatal anxiety levels.

2. Method

2.1. Participants and study design

Women were recruited from six public-sector prenatal centers in southern California during their first to second trimester of pregnancy between 2011 and 2013. These prenatal centers serve a predominantly low-income population representative of the surrounding neighborhoods (38% below poverty level; U.S. Census Bureau, 2014). Women were recruited by research staff who approached them in the waiting room during their prenatal clinic visits, through print-based advertising (brochures, flyers), or by referrals from their health care provider. They signed a consent form to determine their study eligibility, with eligible women then signing a second consent form to participate in the study. Eligibility criteria included being 18 years of age or older, less than 17 weeks pregnant, fluent in either Spanish or English, free of any major medical problems (i.e., gestational diabetes, diagnosed psychiatric disorder such as major depression, high risk pregnancy), and free of any medications that may interfere with their cortisol levels (i.e., asthma inhaler, antidepressants). Women who smoked or used illicit substances were excluded from the study.

The Consolidated Standards of Reporting Trials (CONSORT) diagram of study recruitment, enrollment, and retention is provided in Fig. 1. Of 1072 women recruited for the study, 807 were ineligible (69% > 17 weeks gestation, 13% not available to attend CBSM class, 9% with a major medical problem, 6% not pregnant, 2% not fluent in Spanish/English, 1% underage) and 80 were lost to contact. Of the remaining 185 women, 85 were not randomized (65% did not complete their baseline assessments and therefore were no longer eligible for the study, 24% completed their baseline assessment but were lost to contact, 7% had a miscarriage or were later diagnosed with gestational
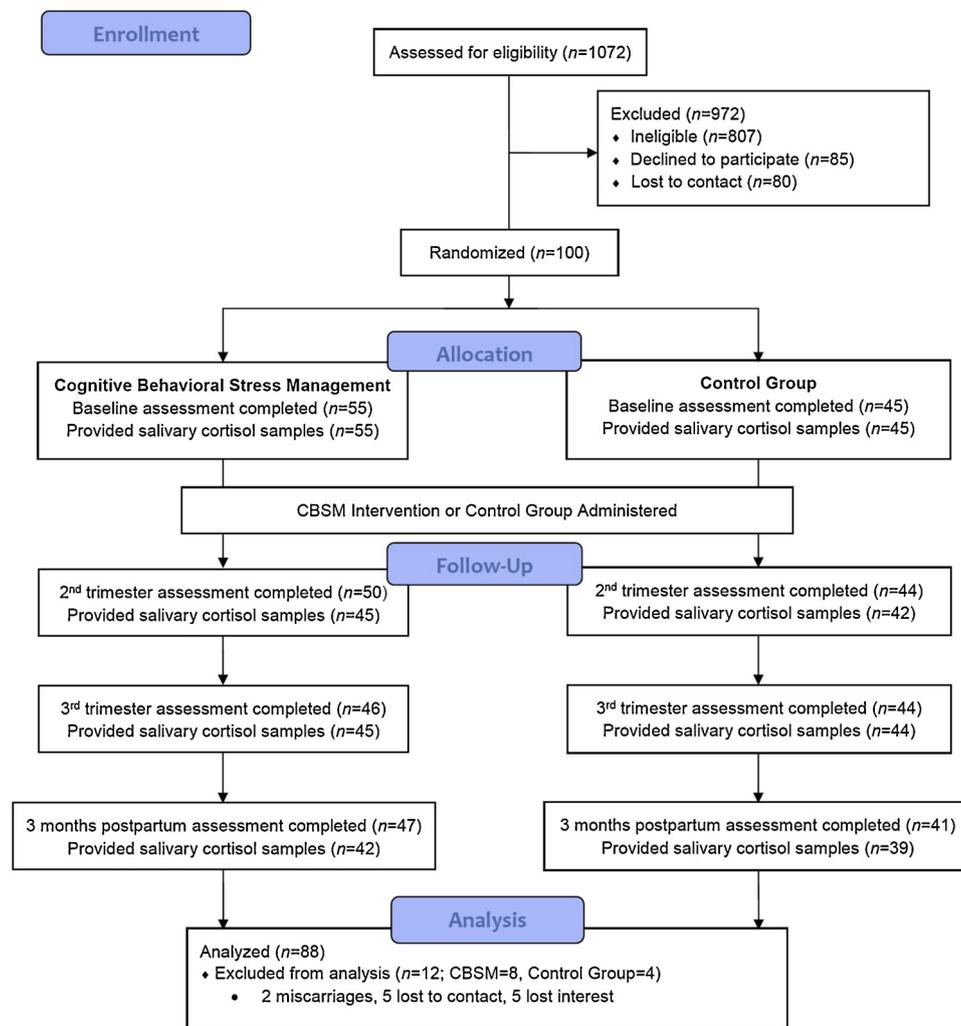
Enrollment

Assessed for eligibility (*n*=1072)

Excluded (*n*=972)
- Ineligible (*n*=807)
- Declined to participate (*n*=85)
- Lost to contact (*n*=80)

Randomized (*n*=100)

Allocation

Cognitive Behavioral Stress Management
Baseline assessment completed (*n*=55)
Provided salivary cortisol samples (*n*=55)

Control Group
Baseline assessment completed (*n*=45)
Provided salivary cortisol samples (*n*=45)

CBSM Intervention or Control Group Administered

Follow-Up

2nd trimester assessment completed (*n*=50)
Provided salivary cortisol samples (*n*=45)

2nd trimester assessment completed (*n*=44)
Provided salivary cortisol samples (*n*=42)

3rd trimester assessment completed (*n*=46)
Provided salivary cortisol samples (*n*=45)

3rd trimester assessment completed (*n*=44)
Provided salivary cortisol samples (*n*=44)

3 months postpartum assessment completed (*n*=47)
Provided salivary cortisol samples (*n*=42)

3 months postpartum assessment completed (*n*=41)
Provided salivary cortisol samples (*n*=39)

Analysis

Analyzed (*n*=88)
- Excluded from analysis (*n*=12; CBSM=8, Control Group=4)
  - 2 miscarriages, 5 lost to contact, 5 lost interest

Fig. 1. CONSORT Statement.

diabetes, and 4% were no longer available for the CBSM class/moved from the area). Women who were not randomized to the study were more likely to have gestational diabetes ($\chi^2 = 5.39$, $p = .02$) and were not available for the CBSM class ($\chi^2 = 7.57$, $p = .01$) compared to women who were randomized; these groups were not significantly different on any other study characteristics. The remaining 100 women were randomized to either an eight-week prenatal CBSM intervention ($n = 55$) or a control group ($n = 45$) using a stratified randomized procedure. This procedure helped to ensure that women identified as having low or high pregnancy anxiety at baseline (a total score < 17 or ≥17 on the Prenatal Anxiety Scale, Rini et al., 1999) were equally distributed between the two randomization groups given that it has been associated with adverse stress-related health outcomes in infants more so than other psychological states during pregnancy (Dunkel Schetter & Tanner, 2012).

Follow-up assessments were also conducted (using a prospective, pre-test post-test, experimental control group design) for women randomized to the CBSM and control group with participant retention rates of 94%, 90%, and 88% for second trimester, third trimester, and three months postpartum time points, respectively. Retention rates by randomization group were similar at all but one time point. At three months post partum, there was greater missing data for women in CBSM ($n = 9$) vs. the control group ($n = 1$; $\chi^2 = 5.50$, $p = .02$) due to miscarriage ($n = 2$) and loss of participant contact ($n = 7$; see Fig. 1).

Participants were approximately 27 years of age ($SD = 6.26$; range = 18–40 years) and 10 weeks pregnant when they entered the

study ($SD = 4.25$; range = 2–17 weeks). The majority of our sample were Latina women (71%), followed by African American (18%), Asian-American (4%), non-Hispanic white (4%) and mixed ethnicity (3%). For the purpose of the present study, ethnicity was dichotomized into Latina (71%) and non-Latina (29%) women. Exploratory analyses were also conducted between African American (18%) and non-African American women (82%; see note in Analyses Section 2.5 for a brief summary of these results). Participants were mostly born outside the U.S. (57%; 70% from Mexico), were single (51%), unemployed (70%), and had an annual family income of less than $20,000 per year (76%). In addition, most women had a high school education or less (71%) and had at least one other child prior to their current pregnancy (63%). Approximately 47% of women demonstrated high levels of pregnancy anxiety at baseline (PAS score ≥17; Rini et al., 1999) and were equally distributed by randomization group (CBSM: Low Anxiety $n = 29$, High Anxiety $n = 26$; Control group: Low Anxiety $n = 24$, High Anxiety $n = 21$).

2.2. Procedures

Women completed a health interview administered by research staff in Spanish or English that assessed their baseline stress and anxiety levels. They were then given a saliva collection kit that included seven cryovials with saliva collection aids and instructions to collect saliva at home via passive drool at seven times on one collection day (immediately upon waking, 30, 45, and 60 min after waking, 12 pm, 4 pm

and 8 pm). They were also provided a personal digital assistant (PDA) device and collection log to date and time stamp their saliva collection times. Participants practiced collecting saliva and using the PDA device in front of research staff to help answer any questions and to increase protocol adherence (Stalder et al., 2016). They were instructed to collect saliva on a weekday within the next two days, making sure to abstain from behaviors known to interfere with the cortisol assay (e.g., brushing teeth) or to change cortisol concentrations (e.g., eating, exercising) for at least 60 min before sample collection (Gröschl et al., 2001). Upon collecting each sample, participants used the electronic PDA device and a log to record their collection times and report any behaviors they believed may have interfered with saliva sampling. Participants stored the samples in their freezer until a research staff member came to pick up and review the saliva samples, PDA device, and collection log to confirm protocol adherence. If participants reported collecting any of their saliva samples outside of the instructed times, they were asked to repeat the collection protocol for the seven saliva samples on a new collection day to get the most comparable diurnal cortisol levels across participants (only occurred 4% of the time across all study time points).

After completing the baseline assessments (perceived stress and salivary cortisol), participants were randomized to either the CBSM intervention or the control group using a parallel assignment design. Randomization was computer-generated, with group allocation concealed by opaque, sequentially numbered sealed envelopes (research staff were blinded to group assignment) to prevent selection bias. A 1.2 to 1 (CBSM to Control group) randomization ratio was used to slightly oversample for the CBSM intervention to account for expected differences in class attendance within this group. Group facilitators documented the number of classes attended by each participant receiving the CBSM intervention. Post-intervention assessments (perceived stress and salivary cortisol) were conducted during the second trimester (i.e., upon completing the eight-week program), third trimester (between 30–32 weeks of pregnancy), and at three months post partum. Participants received up to $200 in gift cards for completing all four study assessments ($100 after completing the first and second assessments and their prenatal program, $25 after the third assessment, and $75 after the fourth assessment). All study procedures were approved by the Institutional Review Board at California State University, Long Beach (National Institutes of Health, Clinical Trial NCT03627247).

Adherence to Salivary Cortisol Collection. At baseline, 98% of participants recorded their collection times on the saliva collection log and collected all seven saliva samples. Similar adherence rates were observed during the second trimester (99%), third trimester (98%), and at three months postpartum (99%). There was less participant adherence to using the electronic PDA device to time stamp collection dates and times (range of missing PDA data = 39%–62%) due to devices malfunctioning and participants forgetting to use the device. However, for those who did use the PDA, self-reported collection times on the saliva collection log were significantly correlated with the PDA's time stamp across all study time points ($r = 0.61$, $p = .04$). There were no randomization group differences (CBSM vs. Control group) on cortisol collection times across all four study time points with the exception of the waking collection time at baseline, with women in the control group collecting saliva 34 min earlier on average compared to those in the CBSM group (see Table 1 for average baseline collection times).

2.3. Randomization groups

CBSM Intervention. Women randomized to CBSM participated in an eight-week prenatal course called SMART Moms (Stress Management and Relaxation Training for Moms) aimed at teaching coping and relaxation skills that address stressors and daily challenges experienced during pregnancy and motherhood. This course (offered in Spanish and English) was taught by one or two clinically-trained facilitators to twelve separate groups of three to eight pregnant women at a local

Table 1
Baseline sociodemographic, perceived stress, and salivary cortisol characteristics for low-income pregnant women in SMART Moms Program by group condition (CBSM versus Control Group).

	CBSM $n = 55$	Control Group $n = 45$
Sociodemographic		
Age *[M (SE)]*	26.3 (+ 0.9)	26.8 (+ 0.9)
Number of weeks pregnant *[M (SE)]*	10.3 (+ 0.6)	9.5 (+ 0.6)
Multiparous (%)	61.8	64.4
High school education or less (%)	67.3	75.6
Annual family combined income < $20,000 (%)	79.6	71.1
Unemployed (%)	72.7	66.7
Single (%)	52.7	48.9
Latina (%)	69.1	72.7
Country of birth, Outside of US (%)	58.2	55.6
Baseline perceived stress levels		
Perceived Stress Scale *[M (SE)]*	24.2 (+ 0.9)	23.6 (+ 1.2)
Baseline salivary cortisol levels		
Overall cortisol output (nmol/L) *[M (SE)]*	143.5 (+ 7.3)	166.6 (+ 16.8)
Cortisol Awakening Response (% increase) *[M (SE)]*	13.4 (+ 10.6)	38.2 (+ 12.9)
Diurnal Cortisol Slope (log scores) *[M (SE)]*	− 0.05 (+ 0.005)	− 0.04 (+ 0.004)
Baseline salivary cortisol collection times		
Waking [hour:minutes (minutes)] *[M (SE)]**	8:10 (+ 0:11)	7:36 (+ 0:11)
30 minutes post-waking [hour:mins (mins)] *[M (SE)]*	8:39 (+ 0:11)	8:08 (+ 0:11)
45 minutes post-waking [hour:mins (mins)] *[M (SE)]*	9:00 (+ 0:10)	8:31 (+ 0:11)
60 minutes post-waking [hour:mins (mins)] *[M (SE)]*	9:22 (+ 0:10)	8:55 (+ 0:12)
12 pm [hour:minutes (minutes)] *[M (SE)]*	12:06 (+ 0:02)	12:06 (+ 0:03)
4 pm [hour:minutes (minutes)] *[M (SE)]*	4:07 (+ 0:02)	4:10 (+ 0:03)
8 pm [hour:minutes (minutes)] *[M (SE)]*	8:09 (+ 0:03)	8:07 (+ 0:02)

Note. Pearson's χ^2 and Independent samples t tests were conducted to examine for between group differences among categorical and continuous variables, respectively. * $p < .05$.

prenatal clinic where most women received prenatal services. The course was offered during the day to accommodate the operating hours of the clinic. Transportation to the clinic was provided upon request. Interactive activities (e.g., role-playing, use of physical props to introduce concepts related to coping and stress) were designed for each class to optimize participant engagement and understanding of the course material while tailoring class content to the stressors commonly reported by participants. Each week, participants were given coping and relaxation skills to practice at home (e.g., cognitive reappraisal, diaphragmatic breathing) and were asked to record their experiences on an activity log that was collected and discussed in class the following week. Course content was taught from a detailed training manual (Urizar & Kofman, 2012; see Table 2 for description of course content) and was based on the B-SMART Program for women with breast cancer (Antoni, 2003) and the Mothers and Babies Depression Prevention Course for pregnant women (Muñoz et al., 2007). Key concepts from these programs were used for teaching women cognitive behavioral strategies to manage their stress. These strategies have been effective in regulating cortisol among patients with breast cancer and HIV, and in low-income mothers (Antoni, 2013; Antoni et al., 2005; Urizar & Muñoz, 2011).

Control Group. Women randomized to the control group participated in an eight-week program where they received printed materials (offered in Spanish and English) by mail once per week, on common prenatal health information topics (e.g., common discomforts of pregnancy, labor and delivery) chosen from the March of Dimes Foundation's "Becoming a Mom" handouts (March of Dimes, 2011). A

Table 2

Cognitive Behavioral Stress Management (CBSM) Intervention Topics & Aims[1].

Intervention Topic	Aims
Class 1: Stress Awareness	• Increase awareness of different stress responses • Learn diaphragmatic breathing
Class 2: Thought Awareness	• Recognize how thoughts affect our emotions • Learn mindfulness
Class 3: Thought Replacement	• Learn how to balance overly negative/positive self-talk • Learn guided imagery
Class 4: Coping Awareness	• Define different types of coping • Learn progressive muscle relaxation
Class 5: Matching Coping	• Identify steps to matching coping strategies to stressors • Learn 'letting go of tension'
Class 6: Social Support	• Recognize how our interactions with others affect our emotions • Learn 'supportive imagery'
Class 7: Communication	• Define different types of communication • Learn 'therapeutic touch'
Class 8: Review of Coping & Relaxation Skills	• Identify coping and relaxation skills learned • Use of skills learned in postpartum

[1] *The SMART Moms (Stress Management and Relaxation Training for Moms) Course: A Prenatal Stress Management Program* (Urizar & Kofman, 2012). Based on the B-SMART Program for women with breast cancer (Antoni, 2003) and the Mothers and Babies Depression Prevention Course for pregnant women (Muñoz et al., 2007).

research staff member called participants once per week to make sure that they received and read their weekly handout and to ask if they had any questions about the content received.

2.4. Measures

2.4.1. Sociodemographics

A sociodemographic questionnaire assessed for maternal characteristics such as age, ethnicity (Latina vs. non-Latina), number of weeks pregnant (based on participant self-report at time of prenatal care visit with their health care provider), parity, total years of education, annual household income, and marital status.

2.4.2. Pregnancy anxiety

Pregnancy anxiety was assessed using the 10-item Prenatal Anxiety Scale (PAS; Rini et al., 1999). The PAS assesses the frequency with which pregnant women worry or feel concerned about their health, their baby's health, labor and delivery, and caring for a baby. Each item is rated on a 4-point scale (range = 10–40), with higher scores reflecting greater levels of pregnancy anxiety. A median cut-off score of ≥17 was used in the current study to identify women with low vs. high pregnancy anxiety. The PAS has good internal consistency in both English and Spanish and has been well-validated in pregnancy samples, with higher pregnancy anxiety being associated with adverse birth outcomes (Guardino et al., 2014; Rini et al., 1999; current study α = 0.74, English-speakers α = 0.76, Spanish-speakers α = 0.71).

2.4.3. Perceived stress

Perceived stress was assessed using the 14-item version of the Perceived Stress Scale (PSS-14; Cohen & Williamson, 1988). The PSS-14 measures the degree to which situations in one's life over the past

month were appraised as stressful, with higher scores (range = 0–56) reflecting higher stress levels. The PSS-14 has shown good test-retest reliability and internal consistency in both general and pregnancy populations (Huizink et al., 2002) and has demonstrated sensitivity to changes in the perceived stress levels of pregnant women receiving a relaxation intervention (Bastani et al., 2005). The PSS-14 demonstrated good internal consistency across the four time points in the current study (α range = 0.74-0.75; English-speakers α = 0.79, Spanish-speakers α = 0.78).

2.4.4. Salivary cortisol

After being thawed for biochemical analysis, saliva samples were centrifuged and salivary cortisol was analyzed using a time-resolved immunoassay with fluorescence detection. Intra- and inter-assay variability were both under 10%. Three cortisol summary scores were computed: the overall amount of cortisol secreted throughout the day (area under the curve; AUC), cortisol awakening response (CAR), and diurnal cortisol slope. AUC was calculated using the trapezoidal rule and represents the AUC with respect to ground (Pruessner et al., 2003) taking into account individual collection time: AUC = $[(Waking_{cort} + 12\,pm_{cort})/2$ x Time elapsed between Waking and 12 pm] + $[(12\,pm_{cort} + 4\,pm_{cort})/2$ x Time between 12 pm and 4 pm] + $[(4\,pm_{cort} + 8\,pm_{cort})/2$ x Time between 4 pm and 8 pm]. Larger numbers represent a greater amount of cortisol produced throughout the day. CAR measures the acute rise in cortisol typically seen after waking in the morning and was calculated by subtracting the waking cortisol value from the 30 min post-waking cortisol value and dividing this number by the waking cortisol value: CAR = $[(30\,min\ post\text{-}waking_{cort} - Waking_{cort})/(Waking_{cort}) \times 100]$. Larger numbers represent a greater percent increase in cortisol from waking to 30 min after waking. Diurnal cortisol slope was estimated by calculating the change in cortisol from waking to 8 pm while taking into account individual collection time: Diurnal cortisol slope = $[(8\,pm_{cort} - Waking_{cort})/Time$ elapsed between Waking and 8 pm], with larger numbers representing a flatter diurnal cortisol slope (i.e., smaller decrease in cortisol levels across the day). Previous findings have emphasized the importance of examining all three of these cortisol indices as altered cortisol patterns (i.e., higher cortisol concentrations, higher/flat CAR, flatter diurnal cortisol slope) have been associated with distinct adverse pre- and postnatal health outcomes for both mothers and their infants (e.g., Bublitz et al., 2018; Hodyl et al., 2017; Scheyer & Urizar, 2016).

2.5. Statistical analyses

A priori power analyses (using G Power software, Erdfelder et al., 1996) indicated that 100 participants are needed to obtain statistical power to detect meaningful associations among study variables with a medium effect size (.25) at the recommended .80 level. Pearson's chi-squared and independent samples t-tests were conducted for categorical and continuous variables, respectively, to assess for between group differences (i.e., CBSM and Control groups) on study characteristics. Pearson product-moment correlations and repeated measures ANOVA analyses were used to identify possible covariates (i.e., ethnicity, gestational age, number of children, pregnancy anxiety, number of classes attended, CBSM class size, country of birth, immigration status) on study outcomes. Only ethnicity (Latina vs. non-Latina), and pregnancy anxiety (low vs. high) were significantly associated with stress outcomes and were included as covariates in subsequent analyses. Exploratory analyses were also conducted between African American and non-African American women on stress outcomes by randomization group. However, given the small sample of African American women in the study (n = 18), African American ethnicity was not associated with any of our stress outcomes (all p > .05); therefore, African American women were grouped with the other non-Latina women in the sample to conduct all subsequent exploratory analyses by Latina vs. non-Latina ethnicity.

Mixed effect linear models were used to test for between group differences (CBSM vs. Control group) in perceived stress and salivary cortisol (AUC, CAR, diurnal slope) over the four study time points (baseline, 2ⁿᵈ trimester, 3ʳᵈ trimester, three months post partum). Mixed models were estimated by maximum likelihood using SAS PROC MIXED (SAS Institute, Cary, NC, USA). Simple effect analyses testing average differences across groups and covariate-adjusted analyses that additionally controlled for ethnicity (Latina vs. non-Latina) and pregnancy anxiety (low vs. high) were conducted. The effect sizes for time and group effects were presented as partial eta squared (η_p^2) and Cohen's D (d), respectively, as is recommended for mixed models (Baguley, 2009).

Exploratory mixed effect linear models were also performed to test for significant two way (ethnicity by time, pregnancy anxiety by time) and three way interactions (i.e., randomization group by ethnicity by time, randomization group by pregnancy anxiety by time) that could influence intervention effects on perceived stress and salivary cortisol, respectively. Interaction terms of $p < .02$ were considered to be significant. The least-squares means method was used to compare group means for all significant effects. Casewise deletion of missing data was used in all analyses.

3. Results

### 3.1. Participant characteristics

A description of the study sample by randomization group is shown in Table 1. Women in both groups were similar on all sociodemographic characteristics, including gestational age, as well as baseline levels of perceived stress and cortisol (all $p > .05$). On average, women in CBSM attended five out of eight classes (63%), with 56% attending at least half of the classes (range = 1-8 classes). The most common reasons for women missing a CBSM class included having competing time demands, having a conflicting medical appointment, or not feeling well. Women in the control group reported reading six out of eight prenatal topics mailed to them.

3.2. Correlations between perceived stress and salivary cortisol

Approximately 20% of women demonstrated high levels of perceived stress at baseline (PSS score ≥ 30; Silveira et al., 2013). Pearson correlations showed that women with higher perceived stress had a more pronounced CAR during the 3ʳᵈ trimester of pregnancy ($r = 0.26$, $p = .02$) and a flatter diurnal cortisol slope (i.e., less decrease in cortisol throughout the day) at three months post partum ($r = 0.34$, $p = .002$), respectively. Perceived stress was not significantly associated with salivary cortisol (i.e., AUC, CAR, diurnal slope) at any of the other study time points ($p > .05$).

3.3. Group differences in perceived stress

Mixed effect linear model analyses of change revealed a significant linear decrease in perceived stress levels from baseline (first/second trimester of pregnancy) to three months post partum [$F(92) = 7.70$, $p = .007$, $\eta_p^2 = .09$]. There was a significant main effect of randomization group on perceived stress levels such that women randomized to CBSM showed a decrease in their perceived stress levels over time relative to women randomized to the control group whose perceived stress levels remained constant [$t(92) = -2.35$, $p = .02$, $d = -0.60$, $CI_{.95} = -0.89, -0.30$; see Fig. 2]. There were no significant main effects found for ethnicity [$t(92) = -1.63$, $p = .18$] or pregnancy anxiety [$t(92) = -1.09$, $p = .43$] on perceived stress. Similarly, there were no significant three-way interactions found for randomization group by ethnicity (Time x Randomization Group x Ethnicity; $t(92) = -1.01$, $p = .32$) or randomization group by pregnancy anxiety (Time x Randomization Group x Pregnancy Anxiety; $t(92) = -0.78$, $p = .43$) on
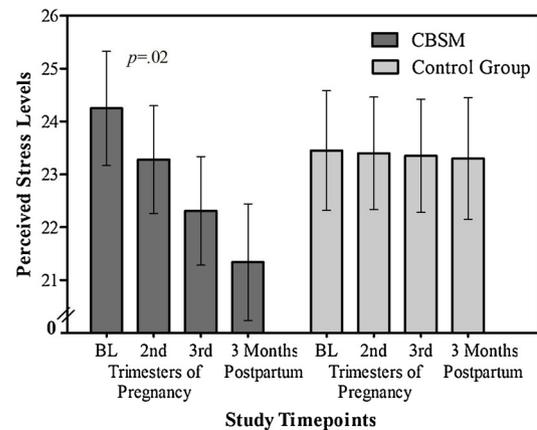
Fig. 2. Changes in Pre– and Postnatal Perceived Stress Levels over Time for Women Randomized to Cognitive Behavioral Stress Management (CBSM) vs. Control Group.

perceived stress levels over time.

3.4. Group differences in salivary cortisol

Overall Cortisol Output (Area Under the Curve; AUC). As expected, there was a significant increase in overall cortisol output (AUC) from the first to third trimester of pregnancy, followed by a drop at three months post partum [$F(88) = 22.24$, $p < .001$, $\eta_p^2 = .22$]. There were no significant main effects found for randomization group [$t(88) = 1.04$, $p = .31$], ethnicity [$t(88) = 1.39$, $p = .17$], or pregnancy anxiety [$t(88) = 0.89$, $p = .35$] on overall cortisol output. Similarly, there were no significant three-way interactions found for randomization group by ethnicity (Time x Randomization Group x Ethnicity; $t(88) = 1.48$, $p = .23$) or randomization group by pregnancy anxiety (Time x Randomization Group x Pregnancy Anxiety; $t(88) = 1.22$, $p = .27$) on overall cortisol output. However, a significant three-way interaction of ethnicity by pregnancy anxiety (Time x Ethnicity x Anxiety) on overall cortisol output was found such that non-Latina women high in pregnancy anxiety demonstrated a greater increase in cortisol throughout pregnancy and a larger drop in cortisol at post partum compared to non-Latina women low in pregnancy anxiety [$t(87) = 3.03$, $p = .003$, $d = -0.81$, $CI_{.95} = -1.38, -0.24$; see Fig. 3].

Cortisol Awakening Response (CAR). A significant decrease in CAR magnitude (i.e., smaller awakening response) from the first to third trimester of pregnancy was found, followed by an increase in CAR magnitude (i.e., larger awakening response) at three months post
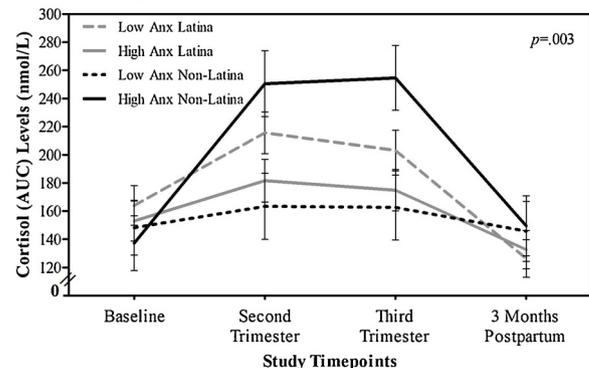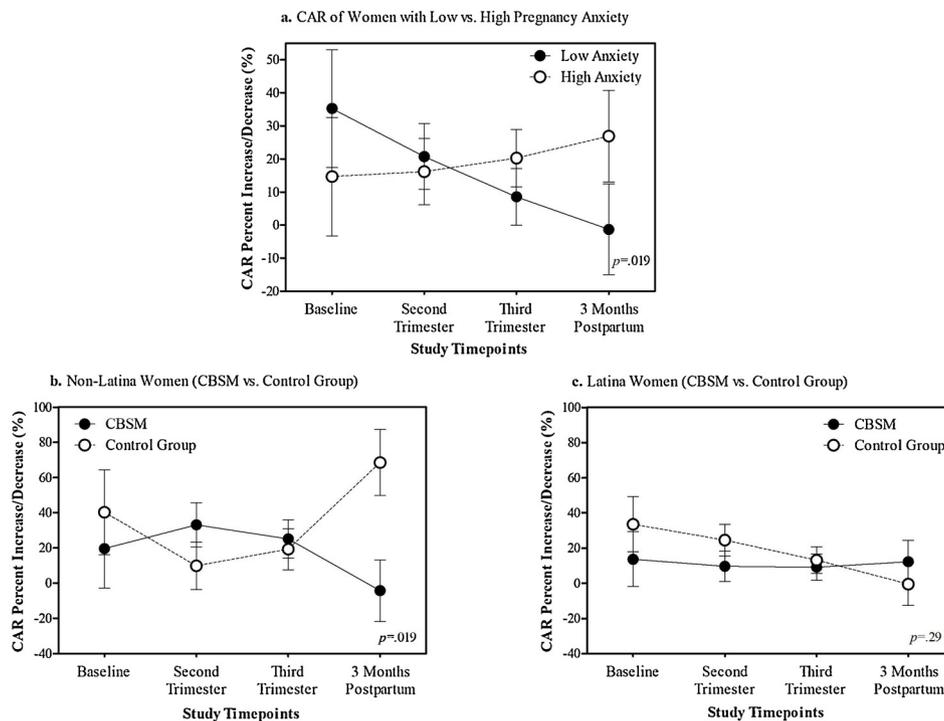

Fig. 3. Group Differences in Pre– and Postnatal Cortisol Levels (Area Under the Curve; AUC) by Pregnancy Anxiety Level (Low vs. High) and Ethnicity (Latina vs. Non-Latina).

Fig. 4. Group Differences in Pre– and Postnatal Cortisol Awakening Response (CAR) by Pregnancy Anxiety, Ethnicity (Latina vs. Non-Latina) and Randomization Group [Cognitive Behavioral Stress Management (CBSM) vs. Control Group].

partum [$t(87) = 2.18$, $p = .032$, $\eta_p^2 = .13$]. There were no significant main effects found for randomization group [$t(87) = 1.84$, $p = .07$] or ethnicity [$t(87) = 1.23$, $p = .22$] on the CAR. However, there was a significant main effect for pregnancy anxiety on the CAR over time such that women low in pregnancy anxiety demonstrated a significant decrease in the CAR from baseline to three months post partum, whereas women high in pregnancy anxiety showed a steady increase in the CAR over this time period, with their highest CAR at three months post partum [$t(87) = 2.39$, $p = .019$, $d = -0.50$, CI$_{.95}$ = -0.74, 0.11; see Fig. 4a]. Moreover, a significant three-way interaction of randomization group by ethnicity (Time x Randomization Group x Ethnicity) on the CAR over time was found. Specifically, non-Latina women receiving the CBSM intervention showed a significant decrease in CAR from the second trimester of pregnancy to three months post partum, compared to non-Latina women in the control group who showed a significant increase in CAR over this time period, with their highest CAR at three months post partum [$t(87) = 2.28$, $p = .019$, $d = 0.90$, CI$_{.95}$ = 0.24, 1.37; see Fig. 4b]. These randomization group differences on the CAR were not observed among Latina women (see Fig. 4c). Finally, there was no significant three-way interaction found for randomization group by pregnancy anxiety on the CAR over time (Time x Randomization Group x Pregnancy Anxiety; $t(87) = 0.96$, $p = .33$).

Diurnal Cortisol Slope. Women's diurnal cortisol slope showed the expected decrease in cortisol throughout the day at baseline. This decrease became flatter during the second and third trimesters of pregnancy before returning to the expected decrease in cortisol throughout the day at three months post partum [$t(90) = -3.96$, $p < .001$, $\eta_p^2 = .15$]. There was a significant main effect found for randomization group on diurnal cortisol slope such that women randomized to CBSM showed a steeper decrease in cortisol throughout the day at three months post partum compared to the flatter diurnal cortisol patterns observed in this group during the second and third trimesters of pregnancy [$t(89) = -2.11$, $p = .038$, $d = 0.68$, CI$_{.95}$ = 0.27, 1.10; see Fig. 5a]. In contrast, women randomized to the control group showed diurnal cortisol slope patterns that remained relatively constant over time. A significant main effect was also found for pregnancy anxiety on

diurnal cortisol slope such that women low in pregnancy anxiety demonstrated a steeper decrease in cortisol throughout the day during the third trimester of pregnancy and at three months post partum compared to women high in pregnancy anxiety [$t(88) = 2.94$, $p = .004$, $d = 0.62$, CI$_{.95}$ = -0.91, -0.07; see Fig. 5b]. There was no significant main effect of ethnicity on diurnal cortisol slope [$t(87) = -0.85$, $p = .40$]. However, a significant three-way interaction of randomization group by pregnancy anxiety (Time x Randomization Group x Anxiety) on diurnal cortisol slope was found. Specifically, women high in pregnancy anxiety who received the CBSM intervention showed a steeper decrease in their cortisol levels throughout the day at three months post partum compared to women high in pregnancy anxiety in the control group [F (89) = 6.14, $p = .015$, $d = 0.56$, CI$_{.95}$ = -0.07, 1.20; see Fig. 5c]. These randomization group differences in diurnal cortisol slope were not observed among women low in pregnancy anxiety (see Fig. 5d). Finally, there was no significant three-way interaction found for randomization group by ethnicity on diurnal cortisol slope over time (Time x Randomization Group x Ethnicity; $t(87) = 0.97$, $p = .33$).

4. Discussion

The goal of this randomized controlled trial was to examine the effects of a prenatal CBSM intervention, compared to a control group, in reducing perceived stress and regulating salivary cortisol patterns (i.e., overall cortisol output, CAR, diurnal slope) in low-income pregnant women during pregnancy and the early postpartum period. Findings showed that women receiving CBSM had lower perceived stress levels during pregnancy and early post partum compared to women in the control group. Although there were no main effects found for CBSM on cortisol, significant treatment effects were observed by ethnicity and pregnancy anxiety level. Specifically, non-Latina women in CBSM had a lower CAR at three months post partum compared to non-Latina women in the control group. Among women with high pregnancy anxiety, those in CBSM showed a steeper decline in their cortisol levels throughout the day at three months post partum compared to those in the control group. Collectively, these results demonstrate that the
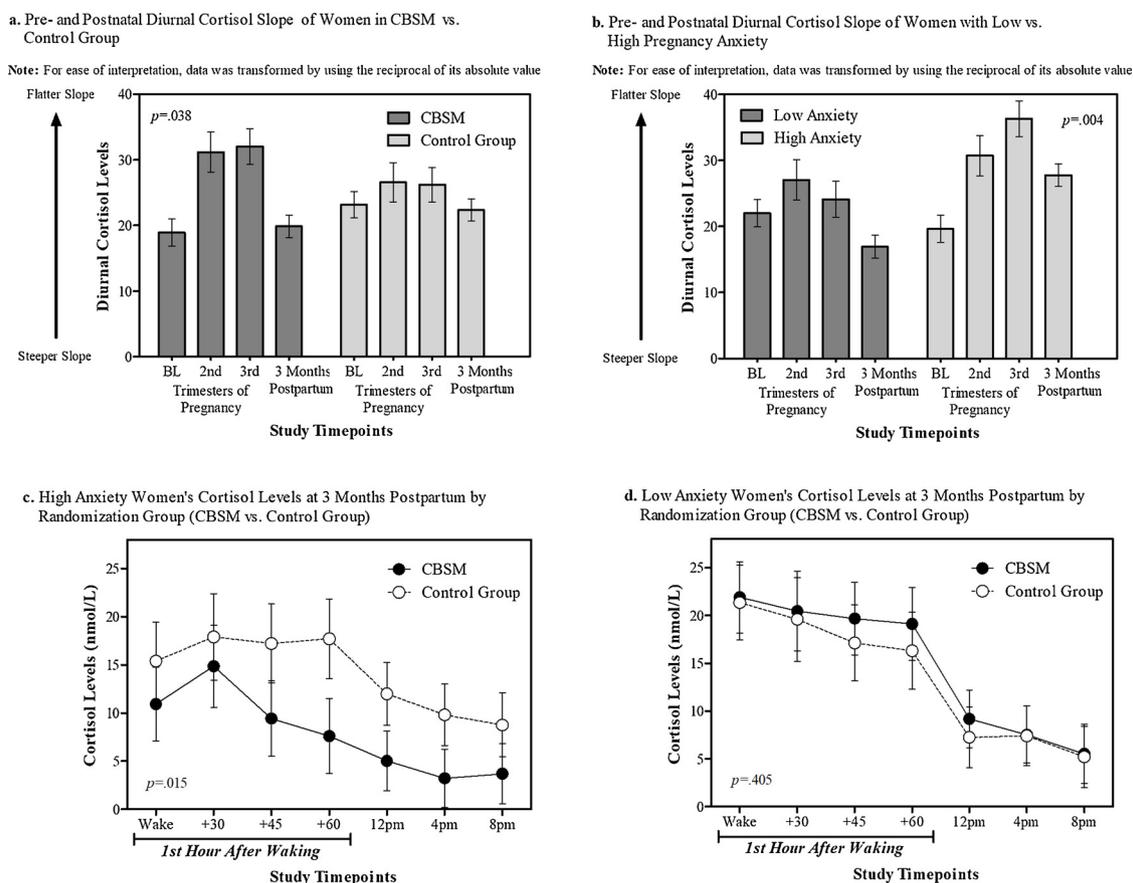
Fig. 5. Diurnal Cortisol Slopes for Women Randomized to Cognitive Behavioral Stress Management (CBSM) vs. Control Group by Preganancy Anxiety Level (Low vs. High Anxiety).

prenatal CBSM intervention was particularly effective in reducing perceived stress and regulating cortisol at post partum and for specific subgroups of pregnant women (i.e. non-Latina and high pregnancy anxiety women).

4.1. CBSM intervention effects on perceived stress

The CBSM effects on perceived stress in this study are consistent with that of other randomized studies implemented during the second trimester of pregnancy that taught women relaxation skills, such as breathing and progressive muscle relaxation exercises (Bastani et al., 2005; Tragea et al. 2014), or a combination of cognitive coping and relaxation training (CBSM; Zaheri et al., 2017). These studies showed reductions in women's perceived stress levels by the third trimester of pregnancy relative to women in a control group. The findings from the current study are important because prior studies demonstrated that although perceived stress levels generally decline throughout pregnancy (Glynn et al., 2008; Silveira et al., 2013; Woods et al., 2010), the stress levels of low-income and ethnic minority women are at risk of remaining elevated over this time period (Silveira et al., 2013). In turn, increases in perceived stress during pregnancy have been found to predict postpartum depression (Scheyer & Urizar, 2016) and, in at least one study, predict preterm birth after controlling for factors such as obstetric risk and parity status (Glynn et al., 2008). Therefore, the results of the current study have potential implications for improving long-term maternal and infant health outcomes in low-income populations.

4.2. CBSM intervention effects on salivary cortisol

CBSM effects on CAR were found for non-Latina, but not Latina

women, with non-Latina women randomized to CBSM having a lower CAR at three months post partum relative to those in the control group. Of our non-Latina sample (n = 29), 62% were African American women who in previous studies have been shown to be at risk for lower CAR and flatter diurnal cortisol slopes due to chronic stress related to racial discrimination (Adam et al., 2015; Simon et al., 2016). In turn, these cortisol patterns have been associated with a greater risk for preterm birth among African American women compared to other ethnic groups in two studies (Austin & Leader, 2000; Glynn et al., 2007). Although the current study was underpowered to determine differences in CBSM effects between African American and non-African American women on stress outcomes, our results suggest the need to further examine CBSM effects on cortisol patterns and birth outcomes by ethnicity. In this and other studies, ethnicity may be a proxy for individual differences in stress exposure, stress regulation, social support, and coping resources that merit further investigation. Therefore, additional studies are needed to examine the type of coping and relaxation strategies that may be effective and culturally responsive to the stressors experienced by Latina women during pregnancy and at post partum.

This is one of the few studies to examine intervention effects on CAR at multiple times in pregnancy and in the early postpartum period, and to compare ethnic groups. One previous study demonstrated pregnant women randomized to CBSM to have a lower CAR by their second trimester of pregnancy relative to those in a control group; however, these intervention effects did not persist at three months post partum (Richter et al., 2012). The CAR is an important stress biomarker during pregnancy as higher levels have been associated with shorter gestational periods (Buss et al., 2009) and lower CAR patterns have been associated with increased risk for postpartum depression (Scheyer & Urizar, 2016). These findings are consistent with that of previous studies in non-pregnant women with a higher CAR found among those

facing greater stress and anxiety and a blunted or flat CAR found among those experiencing chronic fatigue or depression (Fries et al., 2009). Consistent with the results of these past studies, we found that women with higher perceived stress and anxiety during pregnancy had a higher CAR.

Results also showed that women high in anxiety when randomized to CBSM had a steeper decrease in diurnal cortisol at three months post partum compared to those in the control group. Only two studies to our knowledge have investigated CBSM effects on diurnal cortisol at more than one time in pregnancy and in the early postpartum period showing mixed results. Richter and colleagues (2012) examined the effect of an 8-week prenatal CBSM intervention on diurnal cortisol among women with elevated stress, anxiety, or depression during pregnancy but found no intervention effects when compared to a control group. In contrast, Urizar & Muñoz (2011) tested the efficacy of a 12-week prenatal CBSM intervention on diurnal cortisol among low-income women with elevated depressive symptoms during pregnancy. Results showed that women randomized to CBSM demonstrated a steeper decrease in their diurnal cortisol at six and 18 months post partum relative to those in a control group. Similar to the results by Urizar & Muñoz, steeper decreases in diurnal cortisol for the current study were a result of significantly lower cortisol levels in the afternoon for women in CBSM relative to those in the control group and support the need to offer CBSM interventions for at-risk populations. As shown in Fig. 5b, women with high pregnancy anxiety are at particular risk for having flatter diurnal cortisol patterns, especially at three months postpartum, compared to women with low pregnancy anxiety. These differences in diurnal cortisol patterns may be due to greater degree of concerns or fears experienced by high anxiety women during pregnancy about the health and well being of their baby, the impending childbirth, and the responsibilities associated with being a mother that carry over to the postpartum period. Therefore, the coping and relaxation strategies taught in the CBSM intervention may have been particularly salient in balancing these fears and regulating cortisol levels in this at-risk group. These findings have possible significant implications for the health of mothers and their infants. A meta-analytic review of chronic stress and HPA functioning in general shows that chronic stress, particularly uncontrollable stress experienced over longer periods of time, is associated with flatter diurnal cortisol slopes, with lower morning and higher evening cortisol levels throughout the day among adults (Miller et al., 2007). These flatter diurnal cortisol slopes have been associated with increased anxiety and impaired sleep in mothers and low birth weight of their infants (Bublitz et al., 2018; Kivlighan et al., 2008).

Finally, there were no CBSM effects found for overall cortisol output. The absence of these effects is consistent with the few existing studies examining intervention effects on reducing overall cortisol levels during pregnancy. In these studies, pregnant women in their second to third trimester participated in a laboratory experiment where they were randomized to an active relaxation group (i.e., progressive muscle relaxation, guided imagery) or a control group (i.e., sitting quietly for 10 to 45 minutes). Results showed no between-group differences in cortisol reduction over time, however, cortisol did decline in both groups immediately following the experiment (Teixeira et al., 2005; Urech et al., 2010). Our findings highlight the need to examine intervention effects over a longer time period and in a more naturalistic setting (i.e., home-based cortisol collection) in order to investigate the impact of CBSM on different cortisol patterns and other stress biomarkers in this population.

4.3. Study limitations and strengths

There are a number of limitations and strengths of the current study that merit mention. Our sample consisted of pregnant women who were able to attend a CBSM intervention offered during the day at the prenatal clinic where the majority of women were receiving prenatal services. Therefore, the results may not be generalizable to pregnant women who are unable to participate in CBSM because of competing time demands (e.g., work, caring for multiple children at home). Future studies should address barriers that may preclude low-income women from participating in CBSM (e.g., offering classes after work hours, providing childcare and transportation). Second, although women in each randomization group did not significantly differ by gestational age at baseline, there was some variability in women's gestational age at the start of the study (based on participant self-report at the time of their prenatal care visit with their health care provider). Specifically, 75% of women were in their first trimester of pregnancy (range = 2–12 weeks of gestation) when they completed their baseline assessment with an additional 25% of women in the beginning of their second trimester of pregnancy (range = 13–17 weeks of gestation). This wider range in gestational age at enrollment was necessary given the challenges of recruiting a large enough sample of low-income women who met all of the study eligibility criteria and completed their baseline assessments before they reached 17 weeks of gestation. Given these challenges, future studies may want to stratify their randomization groups by gestational age, since variability in this factor at baseline can potentially affect prenatal cortisol, although no such effects were observed in the current study. Third, our analyses by ethnicity are underpowered and limited by the greater number of Latina women in our sample (71%) compared to non-Latina women (29%). Therefore, these results are exploratory in nature and provide preliminary findings for future studies examining ethnicity differences in CBSM effects.

Finally, given that our protocol adherence measures for salivary cortisol collection were largely based on self-report, it is difficult to accurately determine how adherent participants were with saliva collection. There was less participant adherence to using the electronic PDA device to time stamp collection dates and times due to devices malfunctioning and participants forgetting to use the device and for those who did use the PDA, self-reported collection times on the saliva collection log were moderately correlated with the PDA's time stamp ($r = 0.61$, $p = .04$). Therefore, the cortisol results, particularly those related to the CAR, should be interpreted with caution. To address these concerns, a focus group was conducted prior to study recruitment to gather feedback from low-income pregnant women regarding the number of saliva samples collected, the manner by which to deliver instructions, and incentives to promote adherence. This feedback was instrumental in how we designed our saliva collection materials and how we discussed the importance of saliva collection adherence with participants, resulting in the majority of women reporting that they collected their salivary cortisol at the designated times (96%–99% adherence rates; 0%–2% missing data).

Strengths of the study include the representation of ethnic minority women, with the majority consisting of low-income Latina (71%) and African American women (18%). Relatedly, the CBSM intervention was offered in both Spanish and English to address language barriers that may preclude Latina women from participating in stress management. Moreover, despite the barriers and competing time demands that low-income pregnant women may face (e.g., caring for children, financial stressors), the current study had high retention and participation rates (i.e., 94%, 90%, and 88% for 2nd trimester, 3rd trimester, and 3 months postpartum time points, respectively).

4.4. Conclusions and implications

In summary, these findings suggest that teaching low-income women CBSM strategies during pregnancy is effective in reducing perceived stress. While CBSM did not appear to affect cortisol patterns during pregnancy, it was effective in influencing cortisol at three months post partum, particularly among non-Latina women and those with high pregnancy anxiety. These delayed intervention effects are similar to those found by Urizar & Muñoz (2011) and may be due to normative pregnancy-related alterations in HPA functioning overshadowing any CBSM effects during this time period. This may also be

due to women's continued practice of the learned coping and relaxation skills over time enhancing intervention effects by the early postpartum period.

These results have potential implications for the health of mothers and their infants in helping to reduce stress-related health complications that have been associated with altered cortisol in pregnancy. Despite the disproportionate number of premature births and low birthweight babies among low-income mothers, less than 25% report actively engaging in stress management during pregnancy (Birdee et al., 2014). Given these disparities in birth outcomes and in access to preventive interventions, community-based research studies are needed to reach underserved women during pregnancy and provide them with the necessary skills and knowledge to facilitate stress management. Results from the current study potentially address existing barriers (limited resources and training) to providing CBSM interventions for English- and Spanish-speaking low-income women by providing a manualized prenatal program that can be delivered by prenatal health care professionals and paraprofessionals (e.g., social workers, OBGYNs, community health workers). More studies are also needed to test different delivery modalities to reach underserved groups (e.g., one-on-one case management, implementation in prenatal clinics) and examine how to culturally tailor these interventions for different at-risk populations. Prenatal CBSM interventions may help women better prepare for the many challenges related to pregnancy, childbirth, and motherhood, and prevent negative health outcomes for mothers and their infants.

Conflict of interest

The authors declare that there are no conflicts of interest.

Acknowledgements

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