



Rationale, formative research, and protocol for Calma, Conversa, y Cría: A pilot mindful parenting intervention with Latina women

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ABSTRACT

Background: Latina mothers' stress is associated with their children's health behaviors and risk for obesity; however, existing pediatric health promotion programs have not focused on maternal stress reduction.

Methods: Herein we describe a study design that will examine the acceptability and feasibility of Calma, Conversa, y Cría (CCC) a 6-week mindful parenting intervention designed to reduce stress. We present the results of qualitative research with Latina mothers and experts in Latinx health and mindfulness who provided culturally-relevant feedback on existing mindful parenting strategies to inform the development of CCC. Fifty Latina mothers of children ages 3–11 years will be randomly assigned to CCC or an enhanced usual care health education intervention. Acceptability will be assessed through participant satisfaction surveys and exit interviews. Feasibility will be determined through detailed tracking of recruitment, retention, and attendance rates. A signal regarding any group differences in maternal stress, health-related parenting practices, child diet, child physical activity, and child quality of life will be explored.

Discussion: The development of interventions that can reduce maternal stress and risk for obesity in Latinx children is critical to significantly reduce negative health impacts in this underserved population. Our approach includes the identification of effective cultural adaptations that should improve the feasibility and acceptability of mindful parenting strategies in Latinx families, ideally reducing maternal stress and improving parenting behaviors related to child health. If successful, CCC will be examined in a larger efficacy trial involving the measurement of objective biomarkers of children's chronic disease risk.

1. Introduction

The Hispanic/Latinx population is the fastest growing population in the United States, expected to comprise 30% of the population by 2060 [1]. There are numerous strengths within this community that are protective of health, including a focus on strong interpersonal relationships, family connectedness, and extended community supports that promote well-being [2]. Despite these protective factors, members of the Latinx community also face adversities in United States society that influence

health and risk for chronic disease [3,4]. One area of health that continues to warrant attention is the rate of obesity among Latinx youth; alarmingly, 22% of Latinx children have obesity [5]. This is problematic as obesity tracks strongly from childhood to adulthood [6], and is comorbid with type 2 diabetes (T2DM) [7] and cardiovascular disease (CVD) [8]. Effective interventions are needed that can reduce Latinx children's risk for obesity and its associated comorbidities.

Research has identified a link between maternal stress and childhood obesity [9,10]. Factors that have been known to create parent stress,

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such as financial insecurity and physical health problems, have each been linked with children's increased risk for obesity [11,12]. For children ages 6 to 8, each additional parent stressor is associated with a 27% increase in risk for obesity [9]. Data suggest that Latinx children are most vulnerable to the association between parent stress and obesity [9, 10]. Ecological momentary assessment data highlight that within-day variations in Latina mothers' stress are associated with fewer home-made meals, provision of less nutritious packaged foods, and less encouragement of physical activity [13,14]. The need to address Latina mothers' stress is particularly timely given increases in parenting-specific stress following the COVID-19 pandemic [15].

Mindfulness-Based Stress Reduction (MBSR) is a widely used, evidence-based strategy to improve the ability to cope with stress [16]. Previous research indicates that mindfulness training can help Latinx adults cope more effectively with stress and improve health outcomes [17,18]. Mindfulness yields positive changes in a variety of psychosocial and health-related outcomes in Latinx samples [18–21], although the majority of mindfulness studies including Latinx participants have not included a control group thereby limiting causal inference [22]. Cultural enhancements can improve Latinx participant retention and satisfaction in mindfulness interventions, including dispelling myths about mindfulness and incorporating testimonials from peers who use mindfulness [18,22]. This is critical as culturally-adapted interventions provided in an individual's native language are more effective than non-adapted interventions [23].

Fostering parent mindfulness can reduce parent stress, and also improve parenting practices and child health outcomes [24,25]. Mindful

parenting programs were developed using a combination of the key MBSR skills (e.g., sitting meditations, yoga, body scans) and an explicit focus on parenting (e.g., responding thoughtfully rather than reacting to difficult child behaviors, parental self-compassion) [26,27]. Mindful parenting programs have shown promise in improving parenting practices and child outcomes in the context of youth ADHD, behavioral health, and developmental disabilities [27,28]. A mindful parenting intervention has the potential to significantly decrease mothers' stress levels and enhance their ability to act with intention and awareness during parenting behaviors related to obesity, such as meal preparation, provision of healthy foods, encouragement of physical activity, maintaining consistency in goals, and role modeling of healthy behaviors. The goal of the present study is to develop and pilot a mindful parenting intervention to assist Latina mothers of children ages 3–11 years to reduce stress and enhance their obesity-related parenting practices.

2. Design and methods

2.1. Primary aims

We will assess the implementation feasibility and acceptability of a mindful parenting intervention called Calma, Conversa, y Cria (CCC, which translates to "Relax, Chat, and Parent"). Fifty Latina mothers of a child between the ages of 3 and 11 years will participate in a pilot randomized controlled trial (RCT) consisting of two arms: 1) CCC, the mindfulness program for Latina mothers (n = 25); and 2) an enhanced usual care control condition consisting of publicly available information

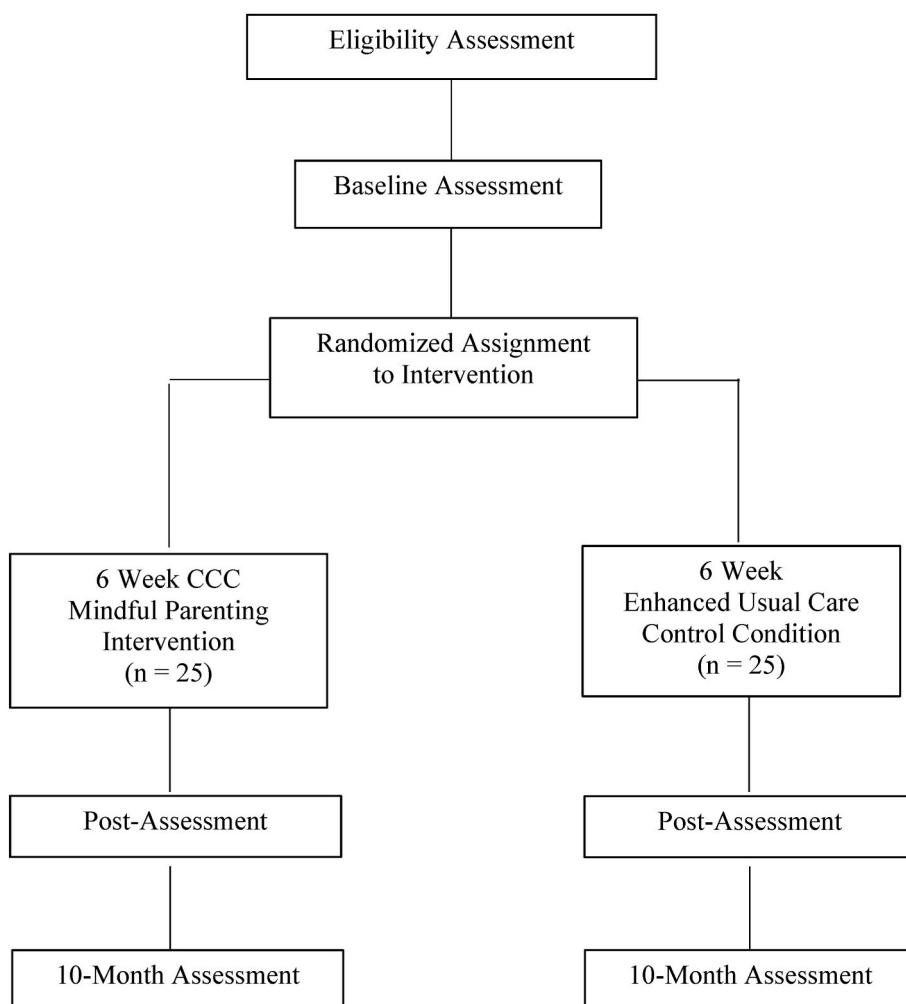


Fig. 1. Study participant flow chart.

from the NHLBI-created ¡Podemos!® [29] that has been used successfully with Latinx families [30] ($n = 25$; see Fig. 1 for study protocol). Feasibility will be determined by examining ability to meet a priori benchmarks for recruitment ($N = 50$ mothers recruited in 12 months), retention (75% at 10 months), and treatment fidelity (90% of the material delivered as intended). Acceptability will be determined via participant scores on the Client Satisfaction Questionnaire [31] (mean scores of >28) and qualitative interview feedback.

Institutional Review Board approval will be received for each aspect of the research. All participants will provide consent/assent prior to beginning any aspect of the research.

2.2. Participant eligibility

We will explore CCC in mothers who identify as female, Hispanic or Latina, Spanish-speaking, and have a child between the ages of 3 and 11 years who primarily resides with them. Parents will be ineligible if they are below age 18 or pregnant or planning on becoming pregnant within the study window. The children of participating mothers who are ages 3–11 years will only take part in the assessment aspects of the study. Children will be ineligible if they have an obesity-associated genetic syndrome (e.g., Prader-Willi), untreated hypothyroidism, or a pervasive developmental disorder. All ineligible participants will receive appropriate referrals.

2.3. Partner recruitment sites

We will recruit participants through established partnerships with health clinics in Washington, DC that provide healthcare services to Latinx families. We will use strategies that have proven effective in recruiting Latinx participants [32], including posting flyers within our partners' waiting rooms, attending programming to share the study with potentially eligible families, accepting referrals from staff members, and accepting participant referrals of friends and family members.

2.4. Description of CCC intervention

The CCC intervention consists of evidence-based MBSR [33], mindful eating [34], and mindful parenting [28] strategies tailored for Latina mothers, based in our formative research described below. CCC consists of 9 h across 6 group-based sessions delivered virtually over Zoom, which is supported by previous research [35]. Parents will be taught a variety of mindfulness skills that encompass the formal meditation components of MBSR, including seated meditation, body scans, and walking meditation. They will discuss mindfulness in the context of eating and parenting, and practice mindful eating exercises.

2.5. Formative research leading to the refinement of the CCC intervention manual

The CCC mindful parenting intervention was developed and refined through qualitative research completed in the summers of 2020 and 2021. Identified experts ($n = 11$) in the fields of Latinx health and mindful parenting provided feedback on CCC through individual key informant interviews. Latina mothers provided feedback on CCC through participation in individual semi-structured interviews ($n = 10$) and focus group discussions ($n = 17$). Participant demographics are presented in Table 1. Key informant interviews were conducted in English; interviews and focus groups with Latina mothers were conducted in Spanish. Each interview was audio recorded, transcribed verbatim, and examined using a thematic analysis approach to determine patterns among responses [36]. All participants received a \$20 incentive for their time.

2.5.1. Summary of key informant interviews

Key informants highlighted the importance of a skilled facilitator

Table 1
Formative research participant demographics.

Key Informant Interviews ($N = 11$)				
Age ($M + SD$)	Gender	Ethnicity	Occupation	
53.10 (± 12.53)	81.81% Women	54.54% Hispanic/ Latinx	Mindfulness Facilitator ($n = 4$) Researcher ($n = 5$) Non-profit Leader ($n = 2$)	
Individual Interviews with Mothers ($N = 10$)				
Age ($M + SD$)	Gender	Ethnicity	Number of Children ($M + SD$)	
32.80 (± 3.85)	100% Women	100% Hispanic/ Latina	2.80 ($\pm .79$)	
Focus Groups with Mothers ($N = 17$)				
Age ($M + SD$)	Gender	Ethnicity	Number of Children ($M + SD$)	Country of Origin*
34.71 (± 5.73)	100% Women	100% Hispanic/ Latina	3.06 (± 1.03)	El Salvador ($n = 12$) Honduras ($n = 3$) Guatemala ($n = 1$) Mexico ($n = 1$)

Note: Country of origin data were only collected from focus group participants.

who can build rapport and comfort amongst the group and create an environment of safety where sharing is welcome. Key informants also noted the importance of focusing on relevant stressors, such as acculturative stress or separation from family for those who have recently immigrated. Other adaptations suggested included the incorporation of humor, incorporating dance as a form of mindful movement and considering check-ins with other household members to gain their support. Key informants suggested framing the program as providing tools that can help with everyday life, such as dealing with stress or becoming closer with one's family.

2.5.2. Summary of individual in-depth interviews with mothers

Individual interviews with Latina moms allowed us to gather in-depth information on mothers' life stressors, their responses to stress and its effects on parenting, and perceptions of mindfulness. The most shared stressors included difficulty balancing time between work and family responsibilities, difficulty maintaining patience as a parent, pandemic-related stress (e.g., having fewer social outlets), and lack of sleep. Mothers described a tendency to hide their stress from others due to the importance of not putting their problems onto other family members. Mothers shared that stress usually manifested in headaches, exhaustion, and feelings of being overwhelmed, angry, or sad. Mothers were most likely to acknowledge impatience when describing how stress influenced their parenting. None of the mothers had heard of the term "mindfulness" or "atención plena," but all mothers responded positively to a brief 60 s mindfulness exercise shared during the interview, stating that it provided relief, clarity, and relaxation. Mothers shared they would be most likely to focus on the present moment while preparing meals, spending time outside with their children, and when they were feeling impatient with their children.

2.5.3. Summary of focus group findings

Seventeen Latina mothers participated in four, 60-min focus groups (n ranged from 3 to 5) to obtain feedback about the proposed content of CCC. Mothers were asked their preference for holding the intervention in-person versus virtually, and most recommended virtual given busy work and parenting schedules. Mothers also suggested incorporating a range of movements beyond traditional yoga, such as dance or Zumba. Mothers provided information on what would motivate them to

participate in such a program, describing the benefits of improving their relationship with their child, reducing their stress, and enhancing other relationships as being most important. Table 2 provides a summary of the recommendations across the formative research and describes how these recommendations were integrated into the CCC intervention manual.

2.6. Description of active control condition

The enhanced usual care arm, consisting of publicly available health education information from ¡Podemos!® [29], includes one 90-min group-based virtual session and then 5 packets of information delivered through WhatsApp to correspond with the remaining 5 sessions of CCC. The program consists of strategies meant to enhance health (e.g., reducing screen time, increasing fruit and vegetable consumption, family-friendly physical activity) but does not include mindfulness as an active ingredient.

2.7. Procedures

Interested mothers will complete a brief eligibility screen through Qualtrics. Eligible participants will be contacted by phone to schedule their baseline assessment. Most assessment measures will be completed by mothers online through Qualtrics; however, participants and their eligible children will come in-person to a centrally-located community center to complete anthropometric measures, a pediatric quality of life measure, and to receive their activity trackers and monetary incentive. After baseline assessment, participants will be randomly assigned to one of the two group-based interventions: CCC or Podemos. At the end of the six-week program, participants will be asked to complete post-program assessment, with mothers completing most measures online through Qualtrics and coming in-person with their enrolled child to complete anthropometrics and the pediatric quality of life measure. Participants will complete the same set of assessments at 10-months from baseline.

2.8. Randomization procedure

The statistical program SAS proc surveyselect will be used to randomly assign all participants who complete an initial baseline assessment to either the CCC or Enhanced Usual Care intervention (1:1). Any resistance to or concerns about randomization will be noted.

2.9. Adequacy of sample size

The main purpose of this pilot is to test the feasibility of conducting CCC to inform a future larger-scale efficacy trial, and thus it is not explicitly powered to assess statistical significance. The selected sample size aligns with sample size recommendations for pilot feasibility trials and is sufficient to estimate recruitment and retention rates in a larger clinical trial [37–40].

2.10. Measures of acceptability and feasibility

2.10.1. Client Satisfaction Questionnaire (CSQ-8) [31]

The CSQ-8 is a brief, 8-item, widely used survey of satisfaction with health-related services available in Spanish. Items are responded to using a 4-point scale, with scores of 1 indicating strong dissatisfaction and scores of 4 indicating strong satisfaction and then responses are totaled with a possible range of 8–32. This survey will be completed at post-assessment only.

2.10.2. Session satisfaction questionnaire

Mothers will complete a brief, 5-min satisfaction survey at the end of each intervention session assessing reactions to the topics discussed and skills reviewed, comfort with the group members and leaders, opinions of the materials used, and overall satisfaction with the intervention at

Table 2
Summary of formative research findings.

Content Area	Participant Recommendations	Enhancements Made to CCC
Parent Stress	<p>Key Informants:</p> <ul style="list-style-type: none"> Relevant stressors discussed included acculturative stress, separation from family, and food insecurity <p>Individual Interviews with Mothers:</p> <ul style="list-style-type: none"> Relevant stressors discussed included difficulty balancing time between work and family, maintaining patience as a parent, and pandemic-related stress (e.g., having fewer social outlets) Mothers described a tendency to hide stress from others so as not to burden them Mothers' stress manifested in headaches; exhaustion; and feelings of overwhelm, anger, and sadness Mothers were most likely to acknowledge impatience when describing how stress influenced their parenting <p>Focus Groups:</p> <ul style="list-style-type: none"> Relevant stressors discussed included managing household chores and routines, not having energy, and not having "me" time 	<ul style="list-style-type: none"> Stress-related content, examples, and images in the manual are directly drawn from the stressors most relevant to Latina mothers
Building Participant Rapport and Engagement	<p>Key Informants:</p> <ul style="list-style-type: none"> Importance of a skilled, culturally congruent facilitator Incorporation of humor to "lighten the mood" Create opportunities for sharing and personal connection Frame the program as providing tools that can help with everyday life, such as dealing with stress or becoming closer with one's family <p>Focus Groups:</p> <ul style="list-style-type: none"> Mothers reported that they would be most motivated to participate if benefits included building a better relationship with their child, reducing stress, improving relationships, and having more energy 	<ul style="list-style-type: none"> The program is led by a skilled, Latina mindfulness facilitator The beginning of each session offers an opportunity for participants to talk in groups of two through brief "charlas" or chats Recruitment and orientation materials frame the goals of the program within the values described as most important to mothers
General Mindfulness Programming Suggestions	<p>Key Informants:</p> <ul style="list-style-type: none"> Informants highlighted that some participants might not have privacy in their home; the importance of naming this and suggesting alternatives <p>Individual Interviews with Mothers:</p> <ul style="list-style-type: none"> Mothers shared they would be most likely to use mindfulness or focus on 	<ul style="list-style-type: none"> The program is offered virtually via Zoom to accommodate mothers' busy schedules Given the virtual format, the program encourages flexibility and creativity in finding a quiet, private space (e.g., taking a walk, sitting in one's car, going to a library basement) for participation

(continued on next page)

Table 2 (continued)

Content Area	Participant Recommendations	Enhancements Made to CCC
Feedback on Yoga Components	<p>the present moment while preparing meals, spending time outside with their children, and when they were feeling impatient with their children</p> <ul style="list-style-type: none"> None of the mothers had heard of the term “mindfulness” or “atención plena” before the interview <p>Focus Groups:</p> <ul style="list-style-type: none"> Regarding platform, the majority of mothers stated they would prefer virtual programming due to scheduling and time constraints 	<ul style="list-style-type: none"> The manual focuses on mindfulness in daily life moments most relevant to moms (e.g., while cooking, when disciplining children) The program will focus on mindful movement more broadly (i.e., “movimientos conscientes”) This can include yoga postures, but can also include movements like mindful dancing, walking, and other energetic movements Given some concerns about religious conflicts, we clarify that the mindfulness approach we will be using is secular and not meant to replace anything in participants’ religious or spiritual practice
	<p>Key Informants:</p> <ul style="list-style-type: none"> Consider dance as a form of mindful movement Explain that the mindfulness approach we will be using is secular (focused on self-care, coping tools for happier lives); however, participants might find ways to integrate mindfulness with their spiritual beliefs if they choose (e.g., repeating a prayer, mindfully using rosary beads) <p>Focus Groups:</p> <ul style="list-style-type: none"> There was a mix of opinions about yoga – some mothers reported enjoying yoga and practicing it regularly; while one mother thought it might conflict with her religious beliefs Other mothers reported wanting to do movements that were more energetic and perceived as aligned with their culture, such as Zumba or other activities paired with Latin music 	
Feedback on Body Scan Components	<p>Key Informants:</p> <ul style="list-style-type: none"> Emphasized the importance of the facilitator being trained in trauma-sensitive mindfulness The facilitator should provide options; participants should not feel like they have to complete an entire body scan <p>Focus Groups:</p> <ul style="list-style-type: none"> Participants generally thought it seemed like a helpful exercise Some mothers didn’t seem to understand the body scan and its purpose 	<ul style="list-style-type: none"> The CCC facilitator is trained to provide trauma sensitive approaches and adapt exercises to the needs of participants (e.g., focusing on sensations in the hands or sounds in the environment, encouraging participants to stand up if they are uncomfortable with a traditional body scan) Participants will have options; they can focus on the body parts that feel most comfortable to them, or they can skip the exercise altogether and do an alternative exercise We provide context in the manual about the purpose and the benefits of the body scan prior to engaging in the exercise At the end of each session, we include “homework”
Role of the Family	<p>Key Informants:</p>	

Table 2 (continued)

Content Area	Participant Recommendations	Enhancements Made to CCC
	<ul style="list-style-type: none"> Clearly link program benefits to participants’ families (“techniques that can bring me closer to my family”) Consider methods to facilitate other household members’ understanding of what’s happening in the program and gain their support <p>Focus Groups:</p> <ul style="list-style-type: none"> Many moms expressed wanting their children to be able to participate in the program Mothers understood the importance of having a space that is just for moms to share and get support, but they also wanted to share this programming with their child in some way 	<p>where moms are asked to share the activities they learn each week with their kids</p> <ul style="list-style-type: none"> The team has also created a brief orientation video that mothers can share with family members to help them understand the program and its potential benefits

that point in time. Items are responded to using a scale of 1–5, with higher scores indicating greater satisfaction. This will be completed via a Qualtrics survey link texted to each participant’s cell phone. Acceptability will be determined by the ability to obtain a mean score ≥ 4 on each item in the survey.

2.10.3. Exit interview

CCC participants will be asked to take part in a 30-min, in-depth qualitative exit interview to share their perceptions of the program, engagement with the material, benefits of and barriers to participation, advice for further cultural refinements, fit of the program for mothers of children in their child’s particular age group, and whether they would recommend the program to another mother.

2.10.4. Feasibility of recruitment

Feasibility of recruitment will be assessed through detailed tracking of recruitment yield via each recruitment strategy (e.g., referrals from physicians, flyer distribution), the number of initial contacts from interested mothers, and the number of families eligible after the initial screening. We will document all cases of ineligibility and the reason for disqualification. Feasibility of recruitment will be determined by the ability to meet the target of 50 mothers within 12 months.

2.10.5. Feasibility of retention

Feasibility of retention will be assessed through detailed tracking of attendance during each assessment period and intervention session. Any enrolled participants who drop out (defined as participants who either explicitly state that they would like to leave the program or who miss two consecutive sessions in a row without contacting the research team) will be contacted by phone to inquire about their reasons for ending the program, as a method of assessing any barriers to intervention completion. Feasibility of retention will be determined through the ability to reach the benchmark of 80% retention of participants through 10-month follow-up. We will utilize strategies intended to enhance retention to help us achieve this goal, including an orientation session intended to defuse ambivalence about participation and enhance “buy-in,” regular reminder calls and multiple attempts at contact, and newsletters with trial updates sent between post and 10-month assessment to maintain engagement.

2.10.6. Feasibility of treatment fidelity

A member of the research team will attend each intervention session and use an observational fidelity tracking sheet to assess whether the interventionist delivered the key concepts and activities and demonstrated appropriate mindfulness techniques. A score will be provided for each session according to interventionist competence and adherence to key components. Feasibility of treatment fidelity will be determined through the ability to achieve the benchmark of fidelity to $\geq 90\%$ of content. The facilitator will also complete a brief survey after each session sent via text through Qualtrics assessing the degree to which participants appeared to like and engage with the content, participant understanding of content, whether the facilitator could deliver all the content as intended, whether any aberrations occurred, and suggestions for improvement.

2.11. Outcome measures completed by mothers

Participating mothers will complete the measures described herein in Spanish at three time points: prior to the start of the intervention, immediately following the 6-week intervention, and 10 months from the start of the intervention. Participants with lower reading levels will have the option to have the items read to them by a member of the research team. Participating mothers will receive a \$40 incentive at baseline and post-intervention assessment, and \$50 at 10-month follow-up.

2.11.1. Mindfulness

Mindfulness will be assessed using the Five Facet Mindfulness Questionnaire (FFMQ; Spanish version) [41]. The FFMQ is a 39-item self-report measure of five facets of mindfulness: observing, describing, acting with awareness, non-judgment, and non-reactivity. It has established psychometric properties in Spanish-speaking clinical, undergraduate, and community samples [41,42].

2.11.2. Perceived stress

Experiences of psychological distress will be measured using the Perceived Stress Scale (PSS), a 10-item, widely used self-report measure that has been translated into Latin American Spanish [43]. It has demonstrated internal consistency and concurrent validity in Spanish-speaking samples [43,44] and is sensitive to pre- and post-intervention changes [45].

2.11.3. Coping strategies

Coping responses will be assessed using the Spanish-language version of the Brief Cope [46], a widely used 28-item measure of coping strategies with demonstrated internal consistency and concurrent validity in Spanish-speaking samples [46,47].

2.11.4. Feeding habits

Parent feeding habits will be assessed using a modified version of the Comprehensive Feeding Practices Questionnaire (CFPQ) [48,49]. The original scale was developed in a primarily European American sample and consists of 49 items and 12 subscales [48]; however, exploratory factor analysis research with Latinx parents indicated a 34-item version with 5 subscales is more appropriate [49]. The 34-item Spanish-language version assesses parental monitoring of child's eating, food restriction, promotion of overconsumption, using food as a reward, providing healthy eating guidance, and healthy eating variety. Research using the Spanish version of the CFPQ indicates it is internally consistent and has convergent validity [49,50].

2.11.5. Family eating and exercise behaviors

Items used in previous work by Neumark-Sztainer et al. [51] will be used to assess eating and weight-related habits of families. Items assess frequency of family meals, fast food consumption, and watching TV during meals; availability of fruits and vegetables and sugar sweetened beverages; and parents' encouragement of healthy food consumption

and physical activity.

2.11.6. Parent-reported child physical activity

Mothers will complete a two-item measure of their child's time spent in moderate to vigorous physical activity [52]. The first item assesses time spent in moderate to vigorous physical activity over the past week. The second item assesses time spent in moderate to vigorous physical activity over a typical week. A composite score is created by averaging the two items. Past research indicates this measure is significantly correlated with child accelerometer data [52].

2.11.7. Parent-reported child dietary intake

Parents will use the Automated Self-administered 24-Hour Dietary Recall (ASA24, Spanish Version) to complete a detailed report of everything consumed in the past 24 h on behalf of their child. Adults will provide a detailed account of the foods and beverages consumed by their child the day prior to data collection. Previous research indicates that parent-reports of child diet using the ASA-24 are feasible [53] and reasonably accurate in comparison to direct observation [54]. Energy intake (kcal) will be the primary dietary outcome.

2.11.8. Anthropometrics

Trained staff will measure height and weight (after a 12hr fast) to the nearest 0.1 cm and 0.1 kg using a precision stadiometer and digital scale, respectively, applying methods outlined in the NHANES Anthropometry Procedures Manual [55]. Two measures will be taken, and the average used, with a third taken if the difference exceeds .1 cm or .1 kg, respectively. BMI will be calculated (kg/m^2).

2.12. Outcome measures completed by participants' children

The enrolled children ages 3–11 years of mothers in the study will complete the measures described below during each of the three assessment time points (baseline, post-intervention, 10-months from baseline). Children will have the option to complete surveys in English or Spanish. Mothers will assist in the completion of measures for younger children.

2.12.1. Quality of life

Children's perceptions of how their health affects their daily life will be assessed using the Pediatric Health-Related Quality of Life (PedsQL4.0) [56]. The PedsQL is a 23-item measure of quality of life in 4 areas: physical, emotional, social, and school. Research indicates this measure is reliable and valid in children ages 3–11 [56]. The PedsQL will be interview administered to child participants by a member of the research team. For children under 5, their enrolled parent will complete the PedsOL Parent Report for Toddlers (Spanish Version) on their child's behalf [57].

2.12.2. Anthropometrics

Similar to parents, trained staff will measure children's height and weight (after a 12hr fast) to the nearest 0.1 cm and 0.1 kg using a precision stadiometer and digital scale, respectively, applying methods outlined in the NHANES Anthropometry Procedures Manual [55]. BMI will be calculated (kg/m^2) and plotted on the CDC Growth Charts to obtain BMI percentile for age and gender [58].

2.12.3. Accelerometry

Accelerometers (Actigraph GT3X) will be worn for 1 week by children on their non-dominant wrist for each assessment period to assess physical activity objectively. Appropriate cut-points will be applied to determine time spent in sedentary, light, moderate and vigorous activities [59]. Total time (min/wk) spent in moderate/vigorous activity and mean total daily physical activity energy expenditure (kcal/d) will be examined.

2.13. Data analytic plan

Frequencies will be used to examine rates of attendance, retention, and satisfaction (primary outcomes). We will use quantitative analyses to explore potential variations in maternal stress, maternal mindfulness, and health-related parenting practices, child diet, child physical activity, and child quality of life. Linear mixed-effects models will be used to evaluate both between and within group effects of intervention group (CCC, Enhanced Usual Care) and time (0, 6 m, 10 m) and the group \times time interactions on the outcome measures to determine if there is a signal that CCC is optimal to the Enhanced Usual Care arm. Analyses will be applied using intent-to-treat [60]. Outcomes will be tested at the $\alpha = 0.05$ threshold. We will do an initial test of potential covariates identified in previous literature (e.g., age, sex, baseline BMI) [61,62] in relation to our outcomes. Any covariates that are significant at the $p < .10$ level will be retained to inform future conceptual models. We anticipate that some families will have multiple participants (e.g., a mother with multiple children in the age range), with each completing their own assessment. If this is the case, then a random effect for family will be included in any statistical models to address nesting. For missing data, we will use the multiple imputation method of Lavori et al. [63], implemented via the MI and MIANALYZE procedures in SAS.

3. Discussion

Mindfulness is a promising tool for reducing Latina mothers' stress and enhancing their ability to create healthier environments for their children. The research described herein will provide a first step in examining this premise through a rigorous feasibility trial, informed by extensive formative work. A strength of our research is our focus on cultural tailoring of existing mindfulness strategies to meet the needs of Latina mothers in Washington, DC. Effective cultural adaptations to evidence-based interventions can take many forms, including delivery in one's preferred language, providing a cultural match between providers and participants, and the integration of culturally relevant concepts and metaphors [23,64,65]. The formative research we completed allowed us to move beyond more surface-level adaptations (such as language translation) to deeper-level adaptations that consider Latinx families' cultural norms, values, goals, stressors, and parenting practices, ideally enhancing the acceptability and effectiveness of CCC [23,66]. This has also allowed our program to capitalize on protective factors within the Latinx community, including social connectedness and strong family relationships, as recommended by Nagy and colleagues to further enhance the efficacy of our program [67].

Our research design has some limitations that should be noted. Given the pilot nature of our study, we are unable to demonstrate the efficacy of CCC. However, we have several measures of feasibility and acceptability aligning with our primary research question and will evaluate efficacy if a signal exists that warrants future investigation in a fully powered trial. Regarding our measures, we are relying on self-report data to assess stress, diet, and parent feeding habits. We are also not assessing certain biomarkers of stress and obesity, such as insulin resistance or inflammatory cytokines. However, promising feasibility results will ideally lead to a large-scale efficacy trial that will involve a broader range of objective measurements of parent behaviors and biomarkers of parental stress and children's risk for chronic disease. We also acknowledge our intervention's limitations to address structural factors that increase risk for pediatric obesity in Latinx youth. For example, the immigration process brings about certain challenges to healthy eating, such as the enhanced affordability and accessibility of processed foods in comparison to fresh meat and produce [68]. The need for some parents to work long hours and/or multiple jobs also necessitates the seeking out of processed, convenience foods [69]. Despite this shortcoming, CCC acknowledges these structural and environmental barriers and seeks to support mothers to focus on controllable, discrete, targeted strategies that can influence health issues of highest relevance

to this population. Pilot RCT data will yield important new information about the association between maternal stress and parenting practices that will be examined in a future efficacy trial designed to improve Latina mothers' well-being and reduce pediatric obesity.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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