Long Protocol Title: Culturally Adapted Cognitive Behavioral Stress and Self-Management (C-CBSM) Intervention for Prostate Cancer
Short Protocol Title: Health Gatherings –For Your Health after Cancer (Encuentros de Salud – Por tu Salud Después del Cáncer) NCT#03344757
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Purpose of the Study:
This 5-year study evaluates the effects of a 10-week group-based linguistically translated and culturally adapted cognitive-behavioral stress and self-management (C-CBSM) intervention on symptom burden and health related quality of life (HRQoL) in Hispanic men treated for localized prostate cancer (PC). About 80% PC cases are diagnosed as early disease and have a 5- and 10-year survival rate of almost 100% and 99%, respectively.[1] Most patients receive active treatment (~70%) leading to prolonged treatment-related side effects and dysfunction persisting well beyond primary treatment.[2, 3, 4] Survival is offset by chronic side effects such as sexual and urinary dysfunction, pain and fatigue that can lead to poor psychosocial functioning, impaired intimacy and social functioning, and masculinity concerns. [5, 6, 7] Hispanic PC survivors report lower physical and social functioning, poorer emotional well-being and greater sexual and urinary dysfunction, even after accounting for SES and disease severity. These sequelae can lead to elevated glucocorticoid release and inflammatory cytokines that have a direct effect on these symptoms and can interfere with physiological pathways necessary for recovery of sexual and urinary functioning. We have shown that CBSM reduces symptom burden and improves HRQoL in bilingual Hispanic PC survivors. In a pilot we showed that a linguistic translation of CBSM with attention to sociocultural processes improved symptom burden and HRQoL in Spanish monolingual PC survivors. We have also shown that CBSM is associated with reduced glucocorticoid resistance and inflammatory gene expression pathways in circulating leukocytes among breast cancer survivors. We propose to (a) deliver a culturally adapted C-CBSM intervention in Spanish that places greater emphasis on salient sociocultural determinants of symptom burden and HRQoL in Hispanics (e.g., fatalistic attitudes, family interdependence, perceived discrimination, machismo), (b) incorporate a neuroimmune model of symptom regulation and management, and (c) test the efficacy of C-CBSM, relative to standard non-culturally adapted CBSM, in two diverse Hispanic communities (Chicago & Miami). We will test our aims in 200 Hispanic men post-treatment for localized PC with elevated symptom burden in a 2 x 4 randomized design with condition (C-CSBM vs. CBSM) as the between groups factors, and time (baseline, post-intervention & 6- and 12-months post intervention) as the within groups factor.
Our **Primary Aim** is to determine whether randomization to C-CBSM, relative to standard CBSM, is associated with reduced symptom burden and improved HRQoL. Our **Secondary Aims** evaluate whether C-CBSM leads to greater improvements in the intervention targets (e.g., stress management, psychological distress & interpersonal disruption), and physiologic adaptation (i.e., glucocorticoid receptor sensitivity & inflammatory gene expression). We will also evaluate psychosocial and physiological mechanisms as mediators of C-CBSM's effects on our primary outcomes. We also **explore** several moderators (e.g., SES, acculturation, treatment, Hispanic origin) of C-CBSM's effect on primary outcomes and the effects of C-CBSM on cardiometabolic health (e.g., lipids, fasting glucose) via reduced inflammation.

Primary Aim:
Aim 1: Determine whether participation in C-CBSM is associated with significantly greater reductions in symptom burden and improvements in HRQoL relative to participation in CBSM.

Secondary Aims:
Aim 2: Determine whether participation in C-CBSM is associated with significantly greater improvements in intervention targets (i.e., improved stress management, and reduced psychological distress and interpersonal disruption) relative to participation in the CBSM condition.

Exploratory Aims:
Aim 3: Explore whether participation in C-CBSM is associated with significantly greater activation of leukocyte glucocorticoid receptor and less inflammatory gene expression profiles relative to CBSM.
Aim 4: Explore whether C-CBSM related improvements in symptom burden and HRQoL are mediated by improvements in intervention targets and gene expression profiles.
Aim 5: Explore moderators of C-CBSM (e.g., SES, treatment type, acculturation, Hispanic ancestry) and C-CBSM's effects on cardiometabolic markers via reduced inflammation.

Integrated Model of Culturally Adapted Cognitive Behavioral Stress Management (C-CBSM) in PC: Our aims are guided by several theoretical frameworks.[8,9,10,11,12,13,14,15,16,17] Our approach is based on three predominant models: (a) psychosocial interventions impact clinically relevant outcomes (e.g., symptoms & HRQoL); (b) effects of psychosocial interventions on clinical outcomes are mediated by improvement in

intervention targets (e.g., stress management skills) that impact psychosocial (e.g., mood, social relations) and physiological (e.g., glucocorticoid resistance & inflammation) adaptation; and (c) cultural adaptation of evidence-based treatments (EBTs) to optimize the effectiveness in a specific population. We also draw from models in cancer survivorship[18,19] suggesting that the influence of ethnicity on HRQoL is mediated by modifiable mechanisms (e.g., knowledge, attitudes), and that HRQoL outcomes must be considered within the cultural and social context. Our approach conceptualizes SES, culture, emotions, cognitions and biology as interrelated underlying mechanisms associated with race/ethnicity, and that individuals are embedded within systems at multiple levels (e.g., context, inter- and intra-personal factors) that impact and interact with these mechanisms to promote health outcomes.[20,21,22,23,24]Based on biobehavioral oncology models [25,108]suggesting stress- induced psychosocial modulation of glucocorticoid receptor sensitivity favors pro-inflammatory states, we propose that stress-related inflammation worsens symptom burden and HRQoL, but that C-CBSM can buffer this pathway.

Model for Test of C-CBSM's Effects on Symptom Burden and HRQoL. Based on our research in chronic disease interventions and health outcomes in PC,[57, ,59,60,98,25] HIV,[26] CFS[27], we hypothesize that C-CBSM vs. a standard non-culturally adapted CBSM will have greater reductions in psychological distress and interpersonal disruption, increased stress management skills and parallel improvements in physiologic adaptation. Based on our CBSM work in BC, and localized and advanced PC[59,60,28] and a C-CBSM pilot, we propose that due to the cultural specificity of C-CBSM based on our adaptation, C- CBSM leads to significantly greater (incremental efficacy) reductions in symptom burden and improvements in HRQoL via its improvements in psychosocial and physiologic targets. All proposed mechanisms are linked to our aims by our prior work or literature documenting such pathways.

First, we test a novel linguistic and culturally adapted, culture-specific CBT-based stress management intervention (C-CBSM) in Spanish bilingual and monolingual PC survivors diverse in regard to SES and Hispanic ancestry in two US cities with a large concentration of Hispanics-Chicago and Miami. Therefore, this study will inform the utility of culturally adapted interventions in diverse Hispanics and provide greater generalizability by surpassing prior limited intervention work with Hispanic cancer survivors, which typically involves homogenous, low SES participants specific to one geographic area with behavioral interventions that have limited or no cultural adaptation. Second, unlike prior work, we test the utility and incremental efficacy of such cultural adaptations by comparing C-CBSM to a standard CBSM intervention that is only linguistically translated. This approach will allow us to address an important and emerging research question—*Do culturally adapted interventions for cancer survivors have incremental efficacy over standard, non-adapted treatments?* This approach addresses the gap in prior work where the few available RCTs involved limited adaptations and inert or inadequate comparison conditions with no opportunity to evaluate the incremental efficacy of the cultural adaptation. Third, we evaluate whether C-CBSM's effects on symptom burden and HRQoL are explained via its effect on physiologic pathways. Evaluating leukocyte gene expression of glucocorticoid and inflammation pathways will elucidate novel molecular signaling pathways by which C-CBSM and culture impact symptom burden and HRQoL. Relating psychosocial modulation of inflammation to PC symptom burden (i.e., sexual & urinary dysfunction) is highly innovative.

Background and Significance:
Almost 2.8 million men are living with Prostate Cancer (PC) accounting for 40% of all male cancer survivors. About 80% of PC cases are diagnosed as non-metastatic and have a 5-year relative survival rate of 100%. Survival is offset by chronic and debilitating treatment side effects of sexual and urinary dysfunction, pain and fatigue. Side effects also lead to poor psychosocial functioning including mood disturbance, impaired intimacy and social functioning, and body image and masculinity concerns. As PC occurs primarily in men 55 or older, other age-related stressors such as retirement, isolation, loss of independence, sense of lack of productivity, caregiving burdens and comorbidities can exacerbate compromises in health related quality of life (HRQoL).[29, 30] Below we summarize studies examining the role of sociocultural, psychosocial and biobehavioral processes in HRQoL and health outcomes in PC[57,98,31,32,33,34,35,36,37,38,39] survivors based on 15 years of work in PC.

Disparities in Hispanic PC Survivorship. In 216 Hispanic and non-Hispanic White (NHW) PC survivors with localized disease, Hispanics showed poorer psychosocial functioning, greater treatment- related symptom burden and poorer HRQoL, controlling for relevant confounds (see Table C.1). Participants were evenly divided between surgery and radiation, and most completed treatment in the past 12 months. All were fluent in English and ethnicity did not vary by age, marital status or SES.

Psychosocial & Behavioral Adaptation, Symptom Burden and HRQoL. Hispanics reported less optimism, poorer emotional regulation, less tangible support, and greater perceived stress. Hispanics also reported worse sleep, less physical activity and lower adherence to nutritional guidelines. In regard to symptom burden and HRQoL, Hispanics showed significantly greater sexual and urinary dysfunction, less sexual desire and greater difficulty in achieving climax, greater bother associated with urine leakage and greater problems with daily incontinence. General HRQoL as measured by the Functional Assessment of Cancer Therapy (FACT-G)[40] and specific domains of HRQoL were also compromised.

Sociocultural Processes & HRQoL. In 108 Hispanics, closeness and familiarity with Hispanic culture (Hispanic Cultural Identity Index; unpublished) was associated with greater HRQoL (FACT total, r=.23 & functional well-being, r=.26), as well as with ABS positive affect (r=.26), and was inversely related to negative affect (ABS anxiety, r= -27; ABS negative affect composite, r= -.24). Cultural Estrangement (alienation from majority) was negatively associated with poorer HRQoL (FACT physical, r=-.24; emotional, r = -.28; and functional, r = -.37 well-being) and FACT Total (r=-.33; all p's <.05). Using the Multigroup Ethnic Identity Measure (MEIM)[41] "ethnic affirmation, belonging and commitment" was positively correlated with FACT-G (r=.19), tangible social support (r=.17), ABS positive affect (r=.20) and use of active coping strategies (r= .15, all p's <.05), and inversely associated with ABS depression (r=-.26), anger (r=-.15) and guilt (r=-.25). Similarly, "ethnic identity search" was positively correlated with emotional and tangible social support (r=.21 & r=.23), positive affect(r=.21), general FACT HRQoL (r=.20) and social/family well-being (r=.30), but inversely related to measures of negative affect, including ABS depression (r=-.21) and anger (r=-.16; all p's <.05). We also found that perceived discrimination and medical mistrust were associated with poorer FACT general, functional and emotional well-being (FACT scales; all r's >-.32),[42] CES-D depression (r=.45), and IES cancer distress (r=.25; all p's <.01). Fatalism was associated with poorer FACT emotional and physical wellbeing (all p's <.05).

Efficacy of CBSM in Reducing Symptom Burden and Improving HRQoL. Our prior CBSM work was conducted in 200 men treated for localized PC (51% surgery, 49% radiation), 18-months post- treatment with an average age of 65.4. About 41% were NHW, 27% Black/African-American (AA), and 32% bilingual Hispanics (H). CBSM relative to a one-day stress management control seminar improved general HRQoL (FACT-G). Perceived stress management skills (PSMS) mediated the relationship between group assignment and HRQoL (β = .27, $p < .001$).[57] Using structural equation modeling (SEM) we also showed that CBSM significantly improved both HRQoL and benefit finding, with effects mediated by CBSM-associated changes in PSMS.[57] In a model with baseline sexual functioning, age, comorbidities, and sexual aids, assignment to CBSM predicted post-intervention sexual functioning (β=.14, *P*<.05; see Figure 3). CBSM also improved FACT emotional well-being across the 12-mos. follow-up. CBSM also improved perceived sexual dysfunction pre- to post-CBSM (*p*<.05), and thru the 12-month follow-up (*p*>.05) (see Figure 4).[43] and improved urinary functioning pre-post CBSM (R^2 Δ=.03, p<.05) (see Figure 5).[43]

Pilot of a Linguistically Adapted CBSM Intervention with Limited Attention to Culture. We conducted a linguistic translation of CBSM for PC survivors treated for localized disease who were Spanish monolingual men. Based on this preliminary work and literature describing shared cultural processes that may interact with chronic disease management,[75,34] we translated the intervention using a professional company and internal verification and conducted some minor adaptations of the C- CBSM intervention to address how factors such as allocentrism and fatalism impact distress, interpersonal relations, self-management and health behaviors. We then conducted 12 focus group sessions following an iterative approach where we first presented the adapted C-CBSM to interventionists (n=4) and health care providers (n=8; Sessions 1-4) and incorporated revisions, then presented the revised CBSM to ten Hispanic PC survivors (Sessions 5-8) and added further revisions based on their feedback. Finally, we presented the further revised CBSM to interventionists, providers and patients combined (Sessions 9-12) and subsequently derived the final version. The vast majority (85-90%) of interventionists, providers and patients rated the final revision of C-CBSM "highly acceptable" and "highly relevant" to the needs of Hispanic PC survivors. Based on this qualitative work, we conducted a pilot study (N=71; surgery n=32; radiation n=39; all localized PC),[98]of this version of CBSM developed following standard adaptation procedures (e.g., information gathering, focus groups, expert & patient review).[75,44] Acceptance rate for fully eligible participants was 42% and attendance was 80%. Assignment to C-CBSM, relative to controls (one-day seminar), showed significant improvements in FACT total, physical and emotional well-being, and EPIC sexual functioning, provided

preliminary data on the feasibility and acceptability (80% attendance), as well as some preliminary efficacy on improving symptom burden and HRQoL for Hispanic PC survivors.

CBSM & Physiological Adaptation. We documented CBSM's effects on diurnal cortisol, circulating inflammatory markers and pro-inflammatory gene expression in circulating leukocytes.[124] In 84 PC survivors about 10.3 months post surgical or radiation treatment undergoing hormonal therapy, pro- inflammatory cytokines were associated greater symptom burden. Better urinary function pre- to post- CBSM was associated with decreases in both IL-1□ (r=-.55) and IL-6 (r=-.40). Similarly, decreases in fatigue across the intervention period were associated with decreases in IL-1□ (r=.41) and IL-6 (r=.35). We also found that decreases in IL-6 were associated with increases in both physical (r=-.38) and social (r=-.37) functioning, and decreases in anxiety (r=.40), while decreases in IL-1□ were associated with decreases in both CES-D depression (r=.40) and an ABS negative mood composite (r=.41; all p's <.05). In stage 0-III breast cancer (BC) survivors, CBSM reduced cortisol, changed circulating numbers of specific leukocyte subsets and cytokine production by T lymphocytes.[121,123,124,125] CBSM-treated BC survivors also showed reductions in expression of leukocyte pro-inflammatory gene pathways and enhanced expression of innate antiviral gene pathways . Genome-wide transcriptional profiling and bioinformatics analyses were conducted at baseline and 6- and 12-months post-CBSM in 79 BC survivors randomized to CBSM or health promotion. At baseline, negative affect was associated with a >50% differential expression of 201 leukocyte transcripts. This included upregulated expression of pro-inflammatory and metastasis-related genes. CBSM altered leukocyte expression of 91 genes by >50% at follow-up. Effects included downregulation of pro-inflammatory (e.g., *IL-1A, IL6, TNFA*) and metastasis-related *(MMP9*) genes and upregulation of Type I interferon (IFN) response genes. Promoter-based bioinformatic analyses showed a decreased activity of NF-kappaB/Rel and GATA family transcription factors and increased activity of IFN response factors and the glucocorticoid receptor, suggesting these as mediators of CBSM-induced reversal of upregulated inflammatory gene expression.[124] Although highly efficacious, active treatment (e.g., surgery & radiation; ~70% of cases) for localized prostate cancer (PC) can lead to significant symptom burden (i.e., sexual & urinary dysfunction) and compromises in multiple facets of health related quality of life (HRQoL). Hispanic PC survivors are at a physical and psychosocial disadvantage, yet evidence based treatments (EBTs) such as cognitive behavioral stress management (CBSM) that have proven effective in reducing symptom burden and improving HRQoL in cancer survivors have rarely targeted Hispanics or delivered culturally adapted CBSM in Spanish to diverse Hispanics in the context of a randomized behavioral clinical trial with an adequate sample size and long-term follow-up. This study will fill several critical gaps in our knowledge on the incremental efficacy of culturally adapted EBTs, relative to standard linguistic translations, on improving symptom burden and HRQoL in Hispanic men with localized PC, and map sociocultural, psychosocial and molecular mechanisms involved in the efficacy of CBSM, and therefore help guide targeted treatments for this critically understudied population and other Spanish speaking cancer survivors.

Active treatments are common and a significant source of symptom burden and poor HRQoL. Despite the utility of active surveillance (AS) in low risk PC, AS remains underused (i.e., ~12% of eligible patients).[45, 46] Independent of PC risk, use of active treatment increased about 10% from 2004- 2012 (~70% of localized cases receive active treatment).[47 ,48] Treatment related symptom burden (i.e., sexual & urinary dysfunction), pain, fatigue and compromised HRQoL (e.g., physical, social/family, emotional & functional well being) are a persistent source of concern and bother. [3, 4, 49] Years after treatment, 82% of surgery patients and 50% of radiation patients remain impotent (ED), and 68% report poor urinary control.[50, 51]The impact of ED on HRQoL is significant, affecting sexual interest and desire, relationship quality, body image, and masculinity and self-esteem, with up to 85% of men with ED reporting significant levels of psychological distress.[52,53,54,55,56]

Psychosocial interventions reduce symptom burden and improve HRQoL in cancer survivors. Psychosocial interventions facilitate adaptation and favorably impact mechanisms known to reduce symptom burden and improve HRQoL in cancer survivors.[57-58] In BC and PC, we have shown that a cognitive behavioral therapy (CBT) group-based stress and self-management psychosocial intervention (CBSM)[59,60] reduced symptom burden, and improved HRQoL, with stress management skills mediating these effects.[57] However, most of this work has focused on non-Hispanic whites (NHWs), with some attention to Hispanics but with extremely limited consideration of Spanish speakers or Hispanic cultural processes.

PC Survivorship Disparities. African Americans (AAs) and Hispanic/Latinos (Hispanics hereafter) treated for

localized PC report significantly lower HRQoL relative to non-Hispanic whites even after controlling for SES and disease related factors.[61,62] AAs are also more likely to be diagnosed with PC at a younger age, and are 2.4 more times likely to die of PC relative to NHWs.[63] Hispanics, in contrast, generally have lower incidence and mortality for most cancers including PC[64]; however, they experience poorer quality of care, [65,66] which may account for greater recurrence, poorer HRQoL, shorter survival and higher mortality for some cancer sites.[64] Relative to NHWs, Hispanic cancer survivors also report greater supportive needs with respect to connecting with other patients, stress management, coping with sadness, sharing thoughts/feelings, worries about their families and overcoming fears.[67] This is not surprising as they also report greater distress and worse HRQoL compared to NHWs.[68] In PC, Hispanics are more likely to present with advanced disease[69,70] and report poorer physical functioning and emotional well-being, less treatment satisfaction, greater sexual and urinary dysfunction, and poorer recovery post-treatment relative to NHWs.[67,68,69,70]They are also more likely to be poorer, have less education, and have no health insurance or source of primary care.[71,72,73,74] Despite this disadvantage, few evidence-based treatments (EBTs) target Hispanics or address Hispanic cultural processes.

Shared Hispanic sociocultural factors can impact health. Hispanics share sociocultural patterns with implications for disease management and health outcomes.[75] However, very few have addressed these processes in cancer survivors and their implications for the effectiveness of EBTs such as CBSM.[59,60] Family interdependence (allocentrism, familism) is associated with seeking medical care[76] and better health behaviors but can also compromise HRQoL for men who place family needs before their own.[77] Family support (familism) promotes emotional well-being in cohesive families, whereas family conflict is related to psychological distress.[78] Masculinity (gender roles) can heighten health maintenance but also contribute to negative health behaviors.[79] Lack of control about health (fatalism)[80] can inhibit positive behavior change.[81] Further, health care providers perceived as authority figures (power distance) and the need for harmonious interactions (simpatía) inhibit assertive and proactive communication/behaviors. In Hispanic breast cancer (BC) survivors, emotional and informational support is generally sought from the family[82] and both BC and PC survivors are more likely to use religion or spirituality to cope with cancer.[83,84,85] Such strategies are associated with less distress.[83] Also, treatment symptoms such as fatigue and hair loss not only compromises HRQoL but are also stigmatized and associated with low self-esteem[86,87] further compromising HRQoL.[88] In our own work we found that multiple sociocultural factors impact symptom burden and HRQoL in PC.

The need for a culturally adapted psychosocial intervention for Hispanic PC survivors. Available evidence suggests that culturally adapted psychological interventions and treatments are valuable and needed.[89] Integrating sociocultural components into EBTs can help achieve desired outcomes in specific populations.[90,91] In conditions such as asthma, diabetes, and HIV/AIDS,[92,93,94] culturally adapted EBTs have proven to be effective, and in depression, culturally adapted CBT programs show superior effects relative to standard treatment.[95,96,97] However, there are very few culturally adapted EBTs for cancer survivors.[98,99,100,101] In Hispanic BC survivors, linguistically translated and community-engaged stress management and peer-support interventions have shown feasibility and some preliminary efficacy.[102,103] In Hispanic BC survivors, physical activity interventions delivered in a culturally sensitive manner reduce distress, while adapted psychoeducational interventions decrease depressive symptoms.[104,105] Although promising, available studies have multiple conceptual and methodological limitations, and the vast majority only have involved a linguistic translation. A linguistic translation is limited in that language does not fully address cultural patterns, behaviors, frames of reference/world view, belief systems and other factors, does not imply cultural competence and therefore limits the potential of therapeutic gains. [89,106] In fact, in culturally competent care, by definition, a cultural adaptation involves "adaptation of interventions to meet culturally unique needs".[107] Consequently, there are significant gaps in understanding the efficacy of culturally adapted treatments: (a) cultural adaptation has generally involved a linguistic translation, or racial/ethnic pairing of interventionist, with no or very limited attention to cultural and social norms; (b) rarely have studies addressed how culture impacts provision and acquisition of EBT skills; (c) the vast majority of culturally adapted treatments have been paired against usual care, wait-list or other inert conditions thus limiting our knowledge on whether the cultural adaptation or the standard EBT mechanisms impacted observed outcomes; and (d) the utility

and incremental efficacy of adapted interventions, relative to standard EBTs, remains unknown.[89]

Why a focus on physiologic adaptation in Localized PC? Among cancer survivors, psychosocial processes (e.g., stress, anxiety, isolation) coupled with ongoing monitoring and symptom burden can promote dysregulation of neuroendocrine (e.g., cortisol) and immune (e.g., pro-inflammatory response) mechanisms, psychological and physical symptoms (e.g., pain, fatigue) and disease activity.[108] For example, low social support, repressive coping and anxiety are associated with disruptions in diurnal cortisol output and reduced glucocorticoid receptor sensitivity.[109,110] Cancer-related stress is also associated with cortisol dysregulation, and stress-modulated alterations in cortisol are related to disruption in immune function and cancer progression.[111,112,113,114,115,116,117,118] BC patients with altered cortisol patterns show greater inflammatory cytokine responses.[108,82,112] Stress-related disruptions in glucocorticoid sensitivity promote a shift from a Th1 to a Th2 pro-inflammatory response[108,113] that can promote or exacerbate symptom burden and negatively impact HRQoL.[114,115] Although limited to BC survivors, stress management interventions that improve psychosocial adjustment impact physiological mechanisms (e.g., cortisol, inflammatory markers) with salutary effects on physical symptoms (e.g., fatigue, pain), HRQoL and disease activity.[119,120,121,122,123,124,125,126,127] Very limited work has assessed these patterns in PC survivors.

What is the link between inflammation, symptom burden, HRQoL and overall health in PC survivors? Psychosocial stress can impact symptom burden and HRQoL via neuroendocrine and pro- inflammatory mechanisms.[128] In PC, higher C-reactive protein (CRP), IL-6, IL-8 and TNF-α are associated with ED[129,130,131] independent of risk factors. Inflammatory states can influence recovery from PC treatment by interfering with the recovery of pathways and tissue necessary for adequate sexual and urinary functioning.[132,133] For example, TNF-α reduces endothelial nitric oxide (NO) synthase thus interfering with erectile function. Inflammatory cytokines are also implicated in fatigue and in turn, fatigue is associated with distress and depression, and poor HRQoL.[134,135] In PC, avoidant coping is associated with disrupted diurnal cortisol,[132] while inflammation is related to greater fatigue.[136] Further, inflammation has also been implicated in bladder dysfunction.[137] In our preliminary work, we found that (a) CBSM improved diurnal cortisol regulation, and (b) improvements in cortisol regulation were associated with reductions in pain and better physical functioning. We have documented strong associations between inflammatory cytokines (IL-1, IL-6 & TNF) and sexual and urinary dysfunction, depression, pain and fatigue in PC.[138] Thus, regulation of glucocorticoid receptor sensitivity and inflammatory pathways via psychosocial mechanisms (e.g., stress reduction, mood) may provide one of several biological mechanisms of how stress, anxiety and other emotional/cognitive processes affect symptom burden and HRQoL. Furthermore, cardiovascular disease (CVD; e.g., heart attacks, congestive heart failure, vascular disease, stroke) is among the leading causes of death in localized PC. [139] Inflammation is a significant contributor to heart disease, and it is well established that inflammatory responses can exacerbate atherosclerotic processes.[140,141,142,143] As we expect that stress management will reduce inflammation, we will have the unique opportunity to evaluate how such changes in inflammatory responses are favorably associated with markers of cardiometabolic health including blood pressure and fasting glucose. [144,145,146]

Design and Procedures:

Participants:

This project will involve voluntary participation of approximately 200 men treated for a primary diagnosis of localized prostate cancer (PC; Stages1-3, NO, MO) within minimum of 1 month and maximum of -96 months with no evidence of disease recurrence. All participants will be self-identified Hispanics/Latinos (hereafter referred to as Hispanic) of any racial category who speak Spanish or are bilingual but express interest in a Spanish intervention program. We anticipate that about 50% of the population in our target communities is Spanish monolingual or is not proficient in English as these communities have large concentrations of foreign-born Hispanics. Nonetheless, we will also involve participants who are bilingual and agree to participate in a Spanish psychosocial intervention.

Inclusion Criteria:

- ≥ 18 years of age;
- Hispanic/Latino self-identification;

- Spanish speakers (including bilinguals who express interest in a Spanish-based psychosocial intervention);
- Primary diagnosis of localized Prostate Cancer (Stages 1-3, N0, M0);
- Surgical or radiation treatment (e.g., external beam, brachytherapy, proton) within minimum of 1 month and maximum of 96-months;
- Some patients with prior inpatient psychiatric treatment for severe mental illness or overt signs of severe psychopathology (e.g., psychosis) may be enrolled, per P.I. discretion, based on a case-by-case review;
- Willingness to be randomized and followed for approximately 12 months.

Exclusion Criteria:

- History of non-skin cancer within the last 2 years
- Prior inpatient psychiatric treatment for severe mental illness or overt signs of severe psychopathology (e.g., psychosis) within the past six months, as these conditions can interfere with adequate participation in our experimental conditions may be exclusionary, per P.I. discretion, based on a case-by-case review;
- Active alcohol dependence within the past six months may be exclusionary, per P.I. discretion, based on a case-by-case review;
- Active substance dependence within the past six months may be exclusionary, per P.I. discretion, based on a case-by-case review; and
- Acute or chronic immune system medical conditions, medications or conditions that impact immune and endocrine function (e.g., CFS, Lupus, rheumatoid arthritis, Hepatitis C, or immunosuppressive treatment requiring conditions), per P.I discretion, based on a case-by-case review.
- Individuals scoring >3 on the SPMSQ will be excluded, or per P.I. discretion, based on a case- by-case review.

This study will not include any of the following special populations: a) adults unable to consent; b) individuals who are not yet adults (minors): i.e. infants, children, or teenagers; c) pregnant women; or d) prisoners or other detained individuals.

Data Collection and Assessment Measures:

A Pre-Screening and Screening protocol will be followed to determine eligibility to the study. This study requested a partial HIPAA waver to conduct chart reviews using the Electronic Medical Integrated (EMR) system within the Cancer Center for pre-screening purposes to determine possible eligibility to the study. A partial waiver is requested to access the medical record prior to subjects' informed consent to enroll in the research. Any identifiers obtained in this process will be destroyed once the patient is deemed ineligible or consents or refuses to be involved in the research. Any documents containing identifying information generated in the process of recruitment will be concealed from non-research and healthcare individuals and will be stored in a secure location. We requested a partial waiver because it is not possible to identify the patients who are eligible without first accessing their medical record and specifically looking for eligibility and exclusion criteria. It is not practical for the potential subjects care provider to do this because assessing these criteria is not part of routine follow-up for these patients. Furthermore, not all of the care providers for potential subjects are investigators on this study. All personnel are trained in human subjects' research and the importance of patient confidentiality. These trained personnel will only use medical records to identify subjects who are eligible for research. These procedures are further described in the recruitment section of this protocol.

Pre-Screening: Preliminary eligibility to the study will be determined by conducting a chart review using the study inclusion and exclusion criteria (see exclusion and inclusion criterial section). For example if the potential participant is a male, is ≥18 years old, Hispanic, has a diagnosis of PC, and has undergone treatment in the past 96 months. If the potential participant meets the basic criteria to the study a formal screening protocol will be conducted. Individuals contacting us from the community will be asked to give us permission to contact their treating physician to determine basic eligibility by completing an Authorization for 3rd Party Disclosure form. Upon confirming basic eligibility the community participant will be contacted to proceed with the telephone screening. Individuals who are identified through Uchart review as meeting basic eligibility and have signed the consent to contact form will be contacted using the UHealth Consent to Contact script to confirm patient's identity and interest in the study. Individuals who express an interest will proceed to complete a phone screening to determine final eligibility. Individuals who are identified through UChart review but have not signed the consent to contact form will be approached through their treating physician and/or oncologist. We will advise their treating oncologist or physician, and direct medical staff of the possible eligibility to our study, and further request for them to introduce

our study to the patient and if the patient is interested to please call us.

Screening: Individuals who contact us or agree to be contacted to hear about the study will be provided with information on the study. Individuals who are identified as potentially eligible through UChart review and have signed a consent to contact will be contacted using the UHealth Consent to Contact Phone Script to confirm the patient's identity and interest in the study. After confirming the patient's identity and if they have expressed an interest, they will be asked for verbal permission to do a formal telephone screening interview. Full eligibility will be determined after completion of the study formal telephone screening interview is completed and reviewed by PIs or designated Co- Investigator through RedCap.

Baseline and Follow-up Assessment: After meeting full criteria and consenting to participate in the study participants will be asked to complete 4 psychosocial interviews, T1 (baseline), T2-T4 (follow- ups). The interviews may vary in length and may take up to 2.5 hours to complete, depending on the ability of the participants to answer each question. The following information will be collected:

Primary Outcomes: PC Symptom Burden and HRQoL.
Symptom burden is assessed using the EPIC-Short Form Sexual Summary (EPIC-S) score and the EPIC-Short Form urinary domain score (EPIC-UIN).[168,170,147] HRQoL will be measured with the Functional Assessment of Cancer Therapy-Prostate (FACT-P including 4 domains of the FACT-G)[40] and PROMIS short forms for pain and fatigue.[148] The FACT-P and PROMIS measures have been used to assess functioning (e.g., nausea, pain, fatigue, life engagement, work and/or daily activities) in cancer survivors and are available in Spanish.[148,149]

Possible Moderators of C-CBSM's Effects on our Primary Outcomes.
Socioeconomic Status (SES): We will collect SES by gathering information on household income.
Treatment Type: We will assess treatment type as surgery (e.g., radical retropubic, radical perineal, laparoscopic, robotic assisted), radiation (e.g., external beam radiation therapy; 3- dimensional conformal radiation; intensity modulated; proton beam; brachytherapy), and/ or hormone therapy (e.g., LHRH analogs & antagonists; anti-androgens). We will assess whether SES, and/or type of treatment modify the effects of C-CBSM. We will also explore whether major Hispanic origin categories (e.g., Mexican, Cuban, Puerto Rican, Central & South American) and acculturation moderate the effects of CBSM.
COVID-*19* Impact: We will use the COVID-19: Impact of the Pandemic and HRQOL in Cancer Patients and Survivors moderate the effects of the interventions.
Intervention Targets: Stress Management Skills, Psychosocial Distress & Interpersonal Function. C-CBSM intervention targets including stress awareness, cognitive appraisals, relaxation skills, coping and communication skills, and interpersonal skills will be assessed using the Measure of Current States (MOCS).[150] This instrument was designed to specifically evaluate efficacy of CBSM. For distress, we will administer the Memorial Anxiety Scale for Prostate Cancer patients (MAX-PC). The MAX-PC is an 18-item scale that detects symptoms of anxiety in PC patients. It evaluates three aspects of PC specific anxiety on 3 subscales: anxiety related to PC in general (PC anxiety subscale), anxiety specifically centered around prostate specific antigen (PSA) testing (PSA anxiety subscale) and fears of cancer recurrence (fear of recurrence subscale). The MAX-PC demonstrated high internal reliability and is well validated in PC patient samples.[151] The PROMIS- Depression and Anxiety, and the Sickness Impact Profile (SIP) will be used to assess psychosocial distress and interpersonal function.

Participant Feedback:
We will also obtain information on each participant's impression of our study and technology comfort level via the Feedback Form questionnaire and Technology Survey. The Feedback Form questionnaire is 5-item self-administered questionnaire that will help us capture the participant's impression of how much they liked the intervention and information provided during the group sessions. The Technology Survey is an 18-item questionnaire that will be administered by a study assessor at one of the study time-points. This questionnaire will help us assess usage of technology and comfort level to be considered as possible intervention delivery strategies.

Supplementary Questionnaires:
The study battery will consist of two supplementary questionnaires, the Acceptance & Action Questionnaire, and the Meaningful & Purpose Questionnaire. The Acceptance & Action Questionnaire is a 10-item questionnaire that measures the degree of experiential avoidance in our participants. The Meaningful & Purpose Questionnaire is a 7-item measure that assesses the meaning in life for our participants.

Medical & Disease Characteristics.
Study staff will collect medical treatment and disease characteristics (e.g. type of treatment, disease status markers such as Gleason score, PSA, TNM staging, time of diagnosis, etc.) via EMR review after written consent has been obtained by the participant. Free testosterone will be measured via ELISA. Study staff will enter a participant's medical chart after the T1-baseline assessment and screen for the aforementioned characteristics. Study staff will collect this information from participant's medical charts after each in-person assessment. Study staff will also collect these variables relevant to the time when participants were diagnosed with prostate cancer. All medical chart data collected will be used for study data analysis as outlined in the Informed Consent Form (ICF). Any medical conditions other than PC will be evaluated individually to form a comorbidity index using the Charlson comorbidity scale.[152]

Sociodemographic Characteristics.
We will also collect age, education, employment, relationship status, nativity or years in the US, race, and years of education in the US. Participants will also complete the Abbreviated Multidimensional Acculturation Scale (AMS).[153] Items are rated on a Likert-type scale ranging from 1 to 4 and assess multiple cultural domains. The AMSA has been widely used in research with diverse Hispanics.

Health Information and Biospecimens Collected:
After a participant consents to participate in the study additional health and treatment information will be obtained from their electronic chart. These include: Gleason Score, Prostate Specific Antigen (PSA) results, staging (TNM), time since diagnosis, type of treatments, HIV/AIDS status, Sexually Transmitted Diseases (STD's), Mental Health treatment, Substance Abuse and treatment, Sexual Assault information, Hospitalizations, Cardiovascular conditions, Gastrointestinal conditions, Hepatitis C, Behavioral & Cerebrovascular conditions, Hematology & Oncology, Nephrology and Genitourinary conditions, Respiratory conditions, Rheumatology conditions, other conditions (i.e. Bacteremia, Lupus, Sjorgren's Syndrome). Participants that are enrolled from the community will be asked to sign a medical release form to request this information from their treating physicians. In addition, each participant will be asked to provide a blood sample either in-person via intravenous blood draw (approximately 2 table spoons) or remotely via blood spot collection during each timepoint (T1-T4). Blood samples that are not able to be collected at the scheduled time-point through either of these two methods we will attempt to collect lab data at the next scheduled time-point or not collect them at all. The following are the health information and biospecimens that will be collected and analyzed for exploratory purposes:

Cardiometabolic Health.
For blood samples that are collected in-person via a blood draw procedure we will measure a panel of cardiometabolic risk markers including triglycerides, HDL-cholesterol, blood pressure (SBP/DBP), high sensitivity C-reactive protein (CRP) and fasting glucose following standard procedures used in prior work by the study PI.[154,155] For samples that are collected using a remote Blood Spot procedure we will measure CRP only.
Anthropometric Measurements. For lab samples that are collected in-person at one of our lab locations we will measure height, weight, and waist circumference. These measurements, along with blood pressure, may be used for further data analysis. For samples that are collected remotely we will obtain the height and weight from the participant.

Inflammation.
C-CBSM will ameliorate the pro-inflammatory phenotype that underlies symptom burden in PC. These effects will be evident at systemic, cellular and functional genomic levels of analysis. For participants who visit our lab location and provide us with an in-person blood sample we will measure IL-1b, TNF- a, IL-6 and IL-10 as markers of systemic inflammation. Among participants who provide us with a blood spot sample we will measure IL-6 and IL-10.

Systemic Level.
For in-person blood collection 8.5-ml of blood are drawn into BD Serum-Separator Tubes and serum harvested via manufacturer's instructions. Aliquots are frozen at -80° C until the study ends. Serum is assayed in a single batch for C-reactive protein (CRP) and interleukin-6 (IL-6)-widely utilized markers of inflammation. Assays are conducted with commercially available Quantikine immunoassays (R&D Systems), with detection thresholds of 0.02 ng/ml (IL-6) and 0.04 pg/ml (CRP). In our work, these kits show intra- and inter- assay CVs< 8%.

Cellular Level.
We activate cells ex vivo with ligands that engage toll-like receptors (TLRs), and monitor production of inflammatory cytokines. This assay stimulates cells with 9 ligands, each optimized to interrogate a specific TLR.[156] For in-person blood collection 10-ml of blood will be drawn into BD Cell-Separator Tubes. PBMCs are isolated through centrifugation and resuspended in R10 (Sigma). 6 x 10^5 PBMCs per well are plated with one of the TLR ligands (Invivogen). Plates are incubated for 24 hours under standard conditions, after which supernatants are harvested and frozen at -80°C. Thawed samples are assayed in single batch by electrochemiluminescence in Dr. Miller's lab on a SECTOR Imager 2400A, using multiplex kits from Meso Scale Discovery. These kits have a 5-log dynamic range, and results are highly accurate and reproducible. In past work, our CVs < 7%. We will measure four cytokines implicated in symptom burden and HRQoL: IL-1b, IL-6, IL-10 and TNF-a and standardized values will be averaged into an unweighted linear composite reflecting the magnitude of inflammatory response, as Miller's team has successfully implemented in multiple studies. [157,158,159] For remote blood spot collection we will not have the capacity to assess cellular production of inflammatory cytokines.

Genomic Level:
We conduct genome-wide transcriptional profiling of monocytes, the cells that initiate and maintain most inflammatory responses.[160,161] For in-person blood collection10-ml of blood are drawn into BD Cell-Separator Tubes. After PBMCs have been isolated through centrifugation, they are labeled with immunomagnetic beads against CD14,[162] a surface marker specific to monocytes. By passing the labeled cell suspensions through Mitenyi's autoMACS instrument, we can acquire a relatively pure (~90%) population of monocytes through positive selection. The acquired cells will then be lysed and stabilized (RNeasy Mini-Kits),[163] and frozen at -80°C until shipment to UCLA for transcriptome profiling assay. Again, both Miller and Blomberg's lab have successfully implemented this protocol in previous collaborations with Cole.157 Dr. Steve Cole's lab at UCLA will extract total RNA using PCR-clean and RNAse-free techniques, and check sample quantity and quality with NanoDrop 1000 and Agilent Bioanalyzer 2100 instruments. 150ng of the RNA will be transformed to fluorescent cRNA, hybridized to Illumina Human HT-12 bead arrays, and scanned on a Illumina iScan reader. Raw expression values will be quantile-normalized and log-2 transformed for statistical analysis, and the pool of differentially expressed genes will be identified by Linear Mixed Models that compare CBSM and C-CBSM groups, net of demographic and biobehavioral confounders (e.g. age, BMI, co-morbidities and disease-relevant confounders such as time of treatment, time since treatment). Differentially expressed genes are defined as those showing ≥1.5-fold difference between groups and a transcript-level false discovery rate of ≤ 5% (using standard Benjamini & Hochberg step-down analysis.[164] Up to 10 differentially expressed genes will be re-verified using quantitative RT-PCR with TaqMan gene expression assays (Applied Biosystems Inc.), a one-step enzyme system,[165] and manufacturer's specified thermal cycling protocol on a iCycler real-time PCR instrument (BioRad Inc.). To identify transcription control pathways underlying differential gene expression, we use a 2-sample variant of the Transcription Element Listening System (TELiS).[166] TELiS quantifies the prevalence of transcription factor-binding motifs within promoters of differentially expressed genes. Analyses focus on 3 transcription factors (TFs) by which C-CBSM could affect monocyte inflammatory activity: NF□B, the major pro- inflammatory TF; CREB, a TF that conveys adrenergic signals to monocytes, and whose activity reflects the amount of SNS signal reaching these cells' genome; and glucocorticoid receptor, a TF that propagates cortisol's anti-inflammatory signals within monocytes and, like CREB, indexes how much hormone signal these cells are registering. For the remote blood collection that is collected via dried blood samples (DBS) we will use standard DBS collection procedures that have been well validated and used by our research team (i.e., Miller). [200, 201] Briefly, the samples are collected by pricking the tip of the middle digit with a sterile disposable lancet, and then allowing drops of blood to wick onto filter paper cards Total RNA will be extracted from DBS samples by cutting 2– 4 blood spots from the 5-spot filter paper for each sample (using a separate razor blade for each sample to prevent contamination), depositing all filter paper spots from each sample into 370 µL of RLT in an RNAse-free sterile 1.5 ml microcentrifuge tube, incubating the tube for 30 min at 37° C with agitation (1000 rpm), transferring tube contents (including filter paper) into a QIAshredder column for 60 sec microcentrifugation at maximum speed, after which the 360 µL of remaining RLT was processed through the QIAcube nucleic acid extraction system using RNeasy Micro Kit reagents, the manufacturer's standard operating protocol (including DNAse treatment), and a 20 µL elution volume. DBS samples are highly stable, can sit overnight at room temperature and can be mailed for subsequent storage in a -80 freezer. Samples will be stored/batched at Dr. Bloomberg's lab and mailed to Co-I Miller's lab at Northwestern

University for analyses.

Procedures Involved:

Locations of Research and Recruitment:

The study will take place in two diverse communities in the US: Chicago and Miami. Miami will be the main site for this study. Miami-Dade County, Florida and Cook County, Illinois, represent the 3rd and 4th largest concentrations of Hispanics in the US. Therefore, our participants are from communities diverse in regard to Hispanic ancestry, SES and acculturation addressing limitations of prior survivorship studies that have focused on homogeneous Hispanic communities not representative of Hispanics in the US. Miami-Dade County is the largest county in the South Florida region and is home to about 1.75 million Hispanics that comprise 65% of the total population in this county. About 53% of Hispanics in this region are of Cuban origin (~856,000), while the rest are of other descent representing 15 distinct Hispanic countries of origin and a population of about 768,000. The majority of the "other" Hispanic ancestry is represented by individuals from Colombia, Venezuela and Argentina in South America, Honduras, Nicaragua and El Salvador in Central America and the Dominican Republic and Puerto Rico in the Caribbean. About 60% of Hispanics in Miami-Dade county are foreign born, over 50% are primarily Spanish speakers and 73% of households speak primarily Spanish at home.[167] Therefore, Miami-Dade County represents a very diverse community in regard to Hispanic ancestry. From 2004-2010, there were 13,500 new cases of PC in Miami-Dade and 40% of these cases (~5,400) were Hispanic.

Recruitment:

Our primary sources of referral will be our affiliated hospitals and clinics. In Miami, recruitment will take place at the University of Miami (UM) Sylvester Comprehensive Cancer Center (SCCC) and their satellite clinics and surgical oncology practices in Miami-Dade, Broward, Palm Beach and Collier counties in South Florida. Recruitment procedures follow similar approaches that we have used in our prior and current work with Hispanics and encompass highly integrated recruitment relationship between the research staff and the medical professionals at each location. Patients will be informed of the study via their physician, clinic staff or other personnel in their treatment settings or by obtaining recruitment flyers at various community-based clinics/organizations not directly affiliated with UM/SCCC (e.g. La Ligua Contra el Cancer). We also plan to participate in different local Spanish speaking radio and TV shows in order to inform the Hispanic community of our study. Information about the study will also be presented at different health fair venues and activities in order to raise community awareness about the study. Further, research staff will have IRB/HIPAA compliant approval to access electronic medical records (EMR) systems to pre-screen prospective participants. The University of Miami (UM) Sylvester Comprehensive Cancer Center (SCCC) has an electronic medical records (EMR) management systems that will be accessed by our staff consistent with IRB/HIPAA guidelines as we have in our prior studies. The study now available on Clinicaltrials.gov (study number NCT03344757) for potential participants to access. Additionally, we will work with the Florida Cancer Data System (FCDS) to obtain a list of potential participants meeting our study criteria. Identified participants from the FCDS will be mailed a packet including a patient contact letter and a patient response form and a letter from the Department of Health. If after 3 weeks from sending the initial packet there is no patient response, a second mailing will be sent with the addition of the telephone opt-out card. The telephone opt-out card explains to the patient if no response is received, the study investigator and/or a member of the study team will attempt to contact them via a telephone call, text, or email to introduce the study. If there is not response to the second mailing and the telephone opt-out card after 3 weeks, a telephone call will be attempted by the study staff. We will continue to use the established pre-screening and consent protocol for those participants who express an interest in our study (see below). For FCDS subjects we will use a Question and Answer Script (provided by the FCDS) that explains "how our study received their name". Information obtained from the FCDS registry will be treated with the utmost security, all data will be stored in our UM secure servers and only study personnel will have access to this information. Please refer to Privacy and Data Storage & Confidentiality section below for more information on data storage protocol.

Pre-Screening Protocol:

We will implement a pre-screening protocol by which chart reviews will be conducted to identify potential participants that meet the study's basic inclusion and exclusion criteria (example: male, ≥ 18, Hispanic/Latino, diagnosed with localized PC Stages 1-3,N0,M0, and had received surgical or radiation treatment within the last 96 months). We will attempt to contact individuals that meet the study's basic criteria by contacting those who have expressed an interest in our study or have signed a Consent to Contact form (UM SCCC patients are asked at each medical appointment if they would like to be contacted for research studies. Individuals who meet the study basic inclusion criteria as per Uchart review and have signed a Consent to Contact form will be contacted using the

Consent to Contact Script and will be asked verbal consent to proceed with the telephone screening questionnaire to determine full eligibility. Individuals who are identified through UChart review but have not signed the Consent to Contact form will be approached through their treating physician and/or oncologist. We will advise their treating oncologist or physician, and direct medical staff of the possible eligibility to our study, and further request for them to introduce our study to the patient and if the patient is interested to please call us. Individuals who express an interest in our study will be provided with information and will be asked their verbal consent to complete a telephone screening questionnaire . Any participants from non-affiliated sites/clinics and FCDS will also be asked to sign an Authorization for 3rd Party Disclosure form to obtain their medical records and determine basic eligibility. Once basic eligibility is confirmed the community potential participant will be called and asked their verbal permission to proceed with the telephone screening questionnaire and determine final eligibility.

Formal Screening Protocol.
Because the inclusion criteria for this study requires that the participants be Spanish speakers, all participants will be screened in Spanish by Spanish speaking research staff. Upon meeting initial eligibility via EMRs (see protocol section Recruitment), research staff will conduct phone screening to assess symptom burden using the EPIC-S[168,169] and -UIN[170,169] for sexual and urinary function and Short Portable Mental Status Questionnaire (SPMSQ) to assess cognitive function and detect impairment. We anticipate that ~70% of participants score in this range based on our prior work in PC. The Short Portable Mental Status Questionnaire (SPMSQ) will measure orientation, memory, attention, naming, comprehension capabilities and is sensitive to Hispanic populations; accounting for higher illiteracy rates in this community. The Short Portable Mental Status Questionnaire (SPMSQ) will be used as a screening instrument for dementia.[171] The SPMSQ is a 10- item test that assesses orientation, concentration, immediate and delayed verbal memory, language, 3- step praxis and constructional apraxia. Literate individuals scoring >3 on the SPMSQ will be excluded, or as per PI discretion based on a case by case review. SPMSQ is also calibrated to take into illiteracy into account, for illiterate individuals scoring >4 they will be excluded or as per PI discretion based on a case by case review. The screening process will take approximately 15-20 minutes (please refer to the screening form).

Per PI discretion – participants with a history of, or current, psychosis, current dependence disorders, organic mental disorder, or active suicidal ideation or panic disorders may be excluded because these are likely interfere with adequate participation in the group sessions. We will also assess other exclusion criteria (e.g., suicidality). Participants who meet full eligibility (see protocol section Inclusion and Exclusion Criteria and section Recruitment) are asked to come in-person to sign the study's Informed Consent (IC). Individuals that are not able to come in-person to sign the IC form will be consented remotely via Electronic-Consent (E-Consent via RedCap link sent to their email) or for those individuals that do not have a computer we will mailed two copies of the IC form to sign one copy and mail back to us. All individuals who will be consented remotely will be called to review the consent form and answer any questions they may have. We will use an IC check-list during the phone call to make sure the participant understands the informed consent document and all components of the study. As part of the consent process, participants will also be asked to opt-in into being audio or video recorded to aid with clinical supervision purposes. This will allow the P.I. and Co-I to evaluate the quality of the group sessions andhow they are facilitated by the group therapist. As this is an optional element, participants may still enroll in the study if they decline to be audio or video recorded (see protocol section Consent Process).If there is a participant who does not wish to be audio or video recorded, none of the participants will be audio or video recorded. All participants who do not meet eligibility criteria per the completed the formal screen will be thanked and provided with printed Spanish materials relevant to PC from the NCI, and ACS, as well as be referred to appropriate and relevant services. Over the past several years, both the Chicago and Miami sites have identified an extensive list of community referrals that include physicians, psychologists, social workers, community-based clinics and centers, etc. that are known to provide services to Hispanic men.

Consent Process:
The informed consent process will occur after eligibility has been fully established by the PI and/or Co-PI. The potential participant may be consented at the beginning of the first in-person assessment meeting or if he is not able to come in person to a scheduled assessment consent will be obtained remotely via E-Consent (RedCap link sent to the individual's email) or through Zoom. If the individual does not have a computer to provide consent via E-consent or Zoom, he will be mailed 2 copies of the consent form. All remote consents through Zoom or US mail will involve a 3-party telephone call with the potential participant, the person obtaining the consent, and a witness to review the consent documents and answer any questions the potential participant may have. We will use an IC Review

Checklist to ensure that all sections of the consent form are thoroughly reviewed and that individuals will be given ample time to ask any questions about the study. The IC Review Checklist will also have a statement describing the consent process, including the return method after signing the consent form or if the participant has difficulties in sending us their signed consent form. Participants in this study will be consented using IRB approved informed consent form (ICF) documents in Spanish or if they prefer in English as long as the participant agrees to participate in groups in Spanish. Research staff will review the ICF with the participant and assure that participants have a full understanding of the informed consent by asking them several questions to ascertain comprehension before having them sign. Participants will also be asked to consent to videotaping of sessions for clinical supervision purposes and informed that all videos are held in the highest regard of confidentiality and destroyed upon completion of the study. If participant decline to sign the consent to video, they will not be excluded from the study and no videos will be done where the individual declining to be videotaped is present. A copy of the consent form will be provided to the participant for their record.

Assessment and Data collection:
After meeting full criteria and consenting to participate in the study participants will be asked to complete 4 psychosocial interviews. Because the inclusion criteria for this study requires that the participants be Spanish speakers, all participants will be assessed in Spanish by Spanish speaking research staff. Participants complete in-person assessments at baseline (T1) and at approximately (plus or minus 2 months) 3-months (T2), 6- (T3) & 12-months (T4) post baseline. The interviews may vary in length and may take up to 2.5 hours to complete, depending on the ability of the participants to answer each question. Participants will have the choice of visiting our study office or conduct the interview at their home or via Zoom or phone if they are not able to meet us in-person. Participants will also be asked at baseline to complete a technology-based questionnaire; this questionnaire will allow research staff to determine the best method to deliver study-related material related to the group sessions. The study-related material will consist of audio files covering relaxation techniques reviewed throughout their 10-week participation. All assessments are completed and scored via RedCap, an online research management tool that enables researchers to create study websites for securely capturing data. RedCap is a web-based system led by the Department of Medical Social Sciences. Dr. Penedo the PI has extensive experience working with this system. All screening and assessment instruments are guided by our conceptual model for managing PC, have excellent psychometric properties (e.g., Cronbach's $\alpha \geq .70$) and have been translated and validated in Spanish speaking populations.

Blood collection: Participants will also be asked to provide a sample of blood via an intravenous blood draw (approximately 2 table spoons) or a remote home-based blood spot collection. All in- person blood samples will be drawn at one of the Sylvester laboratory locations (Miami, Lennar, Plantation and Kendall) by a licensed phlebotomist. The blood draw will be scheduled by a member of our study team and who will then meet the participant at the preferred lab. A member of our team will take with them appropriate study labels (participant corresponding ID, date, time and timepoint of blood draw). Blood samples will be transported after collection by a member of our study team to Dr. Blomberg's laboratory (1600 NW 10^{th} Ave. #3146A, Miami, Fl 33136) and the Department of Pathology, UMHC & Sylvester Cancer Center Lab (1475 N.W 12^{th} Ave, Miami FL, 33136) the same day of the blood draw. At the time of the blood draw we will also collect Cardiometabolic and Anthropometric measures (please see Data Collection and Assessment Measure). Remote dried blood spot (DBS) sample collection will be done by using a protein saver card to collect a total of 5 drops of blood. Participants will be mailed a blood spot packet consisting of a set of 2 protein saver cards, lancets, a desiccant, plastic bags, alcohol swabs, and gloves. Participants will also receive hard copy instructions on how to collect and ship samples. Participants will be instructed to collect the blood samples in the afternoon or evening and to send samples to Dr. Blomberg's laboratory via FedEx or equivalent for storing. Samples will be stored in a -80 freezer and stored until the end of the study or batched as per PI's discretion and sent to Dr. Miller's lab for analysis.

Randomization Protocol:
Participants will be randomized by cluster randomization (C-CBSM or CBSM) to balance treatment type across conditions. We project to retain 140 participants at our 12-months post-intervention assessment visit (T4). All participants will be asked to participate in 10-weekly 90-minute in person sessions targeting CBT based skills for managing stress and self-management in one of two experimental conditions—a linguistically translated (Spanish) and culturally adapted cognitive behavioral stress and self-management (CBSM) condition (i.e., C-CBSM) or in a standard version of CBSM that is only linguistically translated (CBSM). Following the baseline visit (T1, pre C-CBSM or CBSM), participants are randomly assigned into one of our experimental or control condition groups.

Randomization will be group type (C-CBSM vs. CBSM) to assure balanced representation at the end of the study. The dose of both our conditions is based on our prior work documenting the efficacy of 10-week group-based programs in improving multiple psychosocial, physiological and health outcomes across multiple chronic diseases including breast cancer, HIV, CFS, CVD and localized PC (including bilingual and Spanish monolingual Hispanics) and advanced PC. Thus we feel that a 10-week involvement in our CBSM intervention balanced against the possible benefits of engaging in a supportive group environment and acquiring stress and self-management skills is reasonable for our participants. We considered a health promotion or inert usual care condition but felt that for ethical considerations, offering an inert usual care condition was not ethical. Furthermore, the conceptual approach that we are following addresses whether culturally adapted evidence-based treatments provide an added benefit with respect to improving HRQoL and reducing symptom burden, relative to standard and non-adapted programs. Therefore, because our interest is to determine whether cultural adaptation matters, we chose a comparison condition that delivers the "ingredients" of our CBT-based CBSM, but does not consider the cultural context. This approach provides a methodologically sound test of our randomized trial and the extent to which the adaptation of CBSM (C-CBSM) exerts a greater impact on our study outcomes relative to standard CBSM treatment. In our preliminary work in CBSM interventions in localized PC, our attendance at weekly sessions have been over 80%. These rates suggest that our experimental conditions delivered once a week over a 10-week period for 90 minutes per session are well accepted and tolerated in our target population.

Intervention:

Experimental Design. Our primary aim is to examine the effectiveness and incremental efficacy of a 10-week group-based, linguistically and culturally adapted cognitive behavioral stress and self- management intervention (C-CBSM) vs. a linguistically translated standard CBSM (no cultural adaptation) on symptom burden and HRQOL in Hispanic men treated for localized PC. This is randomized control trial (RCT) with a 2x4 design with group assignment (C-CBSM vs. CBSM) as the between-group factor and time (baseline [T1], post-intervention [T2], 6-mos. [T3] & 12-mos [T4]. Post intervention [T4]) as the within-group factor. Primary outcomes are symptom burden (i.e., urinary & sexual function) and HRQoL (e.g., physical, social, emotional & functional). We will make every effort to engage and promote participation in all 10 sessions however we anticipate that some cases will not be able to attend all sessions due to multiple circumstances, such as change in employment or work schedule, health issues, relocation, unforeseen transportation difficulties, family crisis, social/environmental/health crisis (COVID-19), etc. This study uses an intent to treat intervention design model thus participation in all sessions may differ for some individuals. We estimate attrition at ~22% over the study although our prior rate is closer to 10%. Cluster randomization will occur by group type (C-CBSM vs. CBSM).

Experimental Conditions:

CBSM. The standard English language[59,60] intervention was developed for stress management, risk reduction, health maintenance and self-management by providing relaxation training and CBT-based strategies to improve symptom management, interpersonal adjustment and HRQoL, and reduce arousal and negative mood in men treated for PC. This standard, not culturally-adapted CBSM underwent forward and backward translation by Action Translation Services[172] with internal verification.

Stress management targets reducing arousal and anxiety, and symptom management (e.g., progressive muscle relaxation, imagery), changing negative stressor appraisals (e.g., cognitive restructuring), coping skills training (e.g., enhancing adaptive skills, accurate matching of coping & stressor, acceptance of uncontrollable stressors, spirituality), interpersonal skills training (e.g., anger management, communication) and building, enhancing and/or expanding social networks. The stress associated with having received treatment for PC and symptoms are used as catalysts for discussing strategies and as material used for in-session discussions.

Risk reduction & health maintenance strategies include: (a) increasing self-efficacy/self–management to promote positive health behaviors; (b) use of coping strategies to promote health maintenance; (c) increasing assertiveness and communication skills to improve physician-patient transactions (e.g., clarifying treatment & follow-up care instructions) and enhancing use of efficacious social networks to maintain positive health changes, (d) learning self-management (e.g., problem solving for obstacles to compliance, awareness of physical symptoms/limitations); and (e) preventing negative health behaviors such as alcohol, tobacco/ illicit substance use. All content in CBSM is linked to salient PC concerns and CBT-based skills provision to specifically target issues faced by PC survivors.

CBSM and CCBSM Format and Goals. CBSM and CCBSM interventions are delivered face-to- face or via a conference feature platform (phone or a tablet with video conferencing capabilities). Groups that will be conducted face to face will be held at one of our designated office locations (CRB). Groups that are run using a telephone

conference platform will use a private phone line where participants are called to join the group meeting. Groups that are conducted via a video conferencing format will be provided with a study tablet that connects to a secure conference network (Vidyo). The tablets connect to an AES encrypted channel which allows participants to access a secured video conferencing room (secured with pin) with the ability for the therapist to lock the room further after all the participants have entered before start of any group session. Each tablet will have a personalized pin number for participants to access its features. The pin numbers are reset upon completion of the intervention period and return of the tablet to our technical team. The delivery modality (face-to face, phone or through video conferencing) will be at the discretion of the PI and Co-PIs.

CBSM and CCBSM intervention groups are composed of 4-8 participants lasting 90 minutes/session. In the first 30 minutes, participants are taught/discuss a new anxiety/arousal reduction technique whereas the latter 60 minutes focus on stress- and self-management. Disease course, symptom burden, communication with intimate partner and/or family members and health care provider, impact of stress on physical and mental health and symptoms, and management of symptom burden and decrements in HRQoL are used for educational purposes and as catalysts for CBSM techniques. Participants describe stressors with an emphasis on symptoms and disruption, HRQoL and their coping responses for in- session role-plays. Participants receive a participant workbook with all the relaxation and stress management didactics, homework, self-monitoring tools and exercises to implement skills learned in the CBSM sessions in their own "real world" settings. Homework assignments are considered a practice activity to be reviewed in group discussions, these are voluntary and not mandatory.

C-CBSM Intervention Cultural Adaptation. We followed a systematic approach to culturally adapt CBSM that considered language, culture and context (e.g., symptom burden) to develop a linguistically and culturally adapted CBSM (C-CBSM) intervention compatible with our participants' cultural patterns and belief systems, meanings, values and social context.[89,173,174] Our goals were not to promote change in culturally held beliefs, but rather ensure that Hispanic values and context were grounded in each of our CBSM components designed to improve our outcomes. We were guided by theory to make cultural adaptations of evidence-based treatments (EBTs).[89,175,176] These models involve a "top-down"/"bottom-up" approach where theoretical frameworks and intervention procedures from EBTs are used as starting point components of an EBT. These components are subjected to scrutiny by members of the target culture who provide recommendations to shape the adapted version of the intervention to be developed and evaluated.[177] This occurs in four stages: (a) information gathering (e.g., differences in modifiable risk, outcomes & cultural influences on core intervention components); (b) preliminary adaptation design (e.g., integrate input of key stakeholders); (c) preliminary adaptation tests (e.g., train facilitators, pilot adapted intervention); and (d) adaptation refinement (e.g., feedback from pilot to revise the EBT). The final step involves testing the adapted treatment in a full scale RCT. Our C- CBSM intervention underwent all preliminary stages and is now ready for a full-scale RCT.

Our cultural adaptation process involved: (a) forward/back translation of CBSM; (b) review of literature on Hispanic cultural values and evidence of disparities in Hispanic PC survivors; (c) review of metaphors (e.g., concepts shared in PC), content (e.g., cultural values & traditions), illness perceptions (e.g., controllability, fatalistic themes) and context (e.g., acculturative stress, social support & ties to country of origin); (d) review of equivalence criteria of core components of the adapted EBT; (e) expert and patient review of the protocol (e.g., session by session changes); (f) focus groups; and (g) a pilot trial.[173,175,178] Based on this process and feedback from our pilot, and additional data relating sociocultural processes to symptom burden and HRQoL, we have made further modifications to our C- CBSM intervention. The full scope of adaptations to CBSM based on Hispanic cultural factors, their implications for uptake and implementation of CBSM mechanisms, and how cultural factors based on literature and expert/participant feedback are integrated in C-CBSM sessions.

Training, Intervention Fidelity & Evaluation. The MPIs and co-PIs oversee all training for recruitment and assessment staff. We have a vast pool of CBT trained facilitators, several of whom have been trained in CBSM. C-CBSM training is based on Hispanic sociocultural processes and how they interact with CBT-based programs. All group leaders will have completed a 20-hr. training seminar based on our Therapist Training Manual for C-CBSM or CBSM comprised of the following: intensive in-class training in relaxation techniques, cognitive restructuring, and assertiveness training; role-playing exercises with other staff and trained therapists with attention to adherence to protocol; and readings on group therapy/process in cancer populations. Using a standardized checklist, data is collected to document protocol adherence, identify problems at each session, and record attendance to ensure conditions are administered in the manner prescribed.[179] State of the art video-conferencing platform (WebEx)[180]

is available to the PIs and also used for clinical supervision.

Cultural Awareness & Sensitivity Training. We will provide a 2-day training seminar on cultural sensitivity and awareness for all personnel involved in recruitment and assessment, and interventionists leading the C-CBSM condition only. To reduce contamination, interventionists in the CBSM condition do not undergo this training. To maximize participant accrual, retention and comfort with all procedures, emphasis will be on Hispanic PC survivors and involve thorough training on multicultural awareness that incorporate cultural attentiveness and sensitivity including cultural awareness (commonly held beliefs & practices by a culture), appreciation (respecting cultural differences specific to the delivery to therapeutic targets; e.g., collectivistic & familial frames of reference), and respect.[181,182,183] Dr. Penedo has successfully implemented these training models in CBT-based interventions, and he is fully Spanish bilingual and has extensive experience working with Hispanics and particularly Hispanic cancer survivors.

Preventing Attrition and Reducing Burden. We will use strategies for enhancing retention[184] such as meeting with participants to discuss the study and answer any questions (e.g., implications of randomization, roles of C-CBSM & CBSM, nature of intervention, psychosocial & biological assessments, homework assignments, study benefits & risk, etc.). To prevent participant drop-out and reduce burden, we will use recommendations for enhancing clinical trial retention[184] such as meeting with the participants in individual sessions at our recruitment sites during scheduled visits or speaking with them via telephone as requested to discuss study participation and answer any questions (e.g., implications of random assignment, roles of C-CBSM & CBSM, duration & nature of intervention, rationale for the psychosocial & biological assessments, homework assignments, study benefits & risk, etc.). We have found that regular contact with participants improves retention rates. We also have multiple strategies to prevent attrition and reduce participant burden. Understanding that this is an older, co-morbid population facing multiple contextual barriers, we have taken steps to address the multiple challenges and barriers that may lead to participant burden, prevent participation or promote attrition. These strategies include providing transportation for assessment or intervention visits for up to 30% of the sample. This will provide us with the flexibility to offer participants the option of receiving transportation services to attend our clinic or intervention visits. In our past work we have found that about 30% of all PC survivors make such requests; however, we will actively promote such accommodations to ease participation burden and reduce attrition. In addition to these accommodations, we follow procedures as we have in all our prior cancer survivorship studies where we provide snacks, refreshments and breaks during our assessments and intervention sessions, and provide flexible appointment schedules (e.g., weekends) to maximize participation, reduce burden and prevent attrition. We will also offer participants the option of completing a shorter version of the study assessment in person or by telephone. Telephone assessments will be determined on a case by case basis by the PI or Co -PIs who will assess the level of difficulty the participant has in completing the entire assessment face to face, for example unforeseen changes in employment and/ work schedule, health issues, relocation, unforeseen transportation difficulties, family crisis, social/environmental/health crisis (COVID-19), etc. Group facilitators will also reach out to participants via “booster” telephone calls in between participants’ T-2 through T-3 in person interview and T-3 through T-4 in person interview. The “booster” calls will serve as a mini-review session with participants to discuss content covered in the group sessions. Phone scripts for the booster calls are in the development by study staff and will be sent to PMRC and UM IRB in the next modification for approval. Study staff will also conduct **two** check-in calls to discuss general comments and/or concerns a participant may have; these check-in calls will also serve to remind participants of their next in-person assessment. The first check-in call will take place four weeks after the completion of the 10-week group sessions, while the second check-in call will take place four weeks after the second phone booster call. We will make every effort for participants to complete their follow-up assessments within their expected timeline (see Assessment and Data Collection section), however we anticipate that some participants will require additional 2 months to accommodate for life changes. If a participant’s follow-up assessment passes the extra 2 months period we will attempt to collect the next timepoint assessment. We will also encourage participants to complete all follow-up assessments however we anticipate that some participants may encounter difficulties in completing an assessment at the scheduled timepoint due to multiple circumstances, such as unforeseen changes in employment and/ work schedule, health issues, relocation, unforeseen transportation difficulties, family crisis, social/environmental/health crisis (COVID-19). . We will make sure that these participants are still willing to continue participating in the study and review their assessment timeline regularly. We will continue to assess the participant’s interest in continuing in our study via check-in calls and booster calls . Collectively, these strategies are designed to address the multiple medical and contextual challenges that our targeted sample is likely to be facing and thus promote study participation with minimal burden to the participant.

Additional Retention Strategies: Participants who may be experiencing multiple challenges (e.g., financial, access to care, comorbid illness, etc.) present special problems for which alternative procedures are required in order to maximize retention. As mentioned above we will be compensating participants for their assessment visits, and mailing them follow-up reminder cards two to three weeks before their subsequent appointments. If a participant does not call to make an appointment for re- assessment, the contact staff will call on the individual indicated as primary contact by the participant. This contact may take place through telephone or face-to-face. The staff person making the call will attempt to collect information that will lead to location of the participant. Secondary and tertiary contacts named in the participant's locator files will also be part of the contact staff's repertoire for finding a seemingly lost participant. In the event that cancer or other medical condition hinders a participant's ability to attend an assessment visit, we will offer them the option of home visits for data collection. In all such cases, we will respect the participants' right to refuse this option and will be acutely sensitive to their desire to maintain their privacy during these difficult times. If the participant does consent to home visits, we will furnish the personnel to visit them. If the full battery of tests is too burdensome, we will use an abbreviated battery consisting of our primary outcome measures. For participants who refuse to return for assessments or who have dropped out of the study, we will offer them the opportunity to schedule their assessment at any time of day at the most convenient location and will offer them the opportunity to complete only the abbreviated form of the battery should they so request. We will also respect a participant's refusal to undergo blood draws. Repeated failure to locate a participant for follow-up will lead to our contacting the Florida Departments of Health to learn of death certificates issued in the period since the missed assessment.

Data Analysis Plan including Statistical Procedures

Study Hypotheses:

Hypothesis 1 (Aim 1): C-CBSM will show significantly greater reduced symptom burden and improved HRQoL from baseline (T1) to 3-, 6- and 12-month follow-ups (T2-T4) relative to CBSM.

Hypothesis 2 (Aim 2): C-CBSM will show significantly greater improvements in intervention targets (i.e., improved stress management, and reduced psychological distress and interpersonal disruption) from baseline (T1) to 3-, 6- and 12-month follow-ups (T2-T4) relative to CBSM.

Test of Study Hypotheses. All analyses will be intent-to-treat analyses[198] and linear mixed models will be used to test Hypotheses 1-2. These models classify time of measurement as a categorical variable in order to give full flexibility to different mean time courses in the two randomized groups. Latent growth modeling (LGM)[185] with relevant covariates is used to test the three sub-hypotheses of Aim 4. Advances in LGM and structural equations modeling (SEM)[186] allow us to blend these methods to test complex models of change[187] as latent growth models. LGM allows for missing data, as well as irregularly spaced measurements across time, time-varying and invariant covariates, accommodation of individual-specific deviations from the mean time trend and estimation of population variance associated with individual effects. Analyses of the first 3 hypotheses inform the functional form of the LGM time course. Software to implement these analyses is available (e.g. Mplus).[188,189] The software permits the blending of continuous and categorical data, the specification of linear and nonlinear models of change, and the specification of longitudinal structural models. Adequate model fit will be established by several fit indicators (Comparative Fit Index [CFI] > .95, Root-Mean-Square Error of Approximation [RMSEA] ≤ .05, Standardized Root-Mean-Square Residual [SRMR] < .08).[190]

Exploratory Hypotheses:

Hypothesis 3 (Aim 3): C-CBSM will show significantly greater activation of leukocyte glucocorticoid receptor (i.e., greater sensitivity) and lower inflammatory gene expression (i.e., less activation) pathways from baseline (T1) to 3-, 6- and 12-month follow-ups (T2-T4) relative to CBSM**.**

Hypotheses 4a-4c (Aim 4): 4a: Relationship between group assignment (C-CBSM vs. CBSM) and reduced symptom burden, and improved HRQOL from baseline (T1) to 3-, 6- and 12-month follow-ups (T2- T4) is mediated by improvements in intervention targets; **4b:** Relationship between group assignment and greater activation of glucocorticoid leukocyte receptor and lower inflammatory gene expression pathways from baseline (T1) to 3-, 6- and 12-month follow-ups (T2-T4) is mediated by improvements in intervention targets; **4c:** Relationship between group assignment and reduced symptom burden, and improved HRQOL from baseline (T1) to 3-, 6- and 12-month follow-ups (T2-T4) is mediated by greater activation of glucocorticoid receptor and lower activation of inflammatory gene pathways.

Hypothesis 5 (Aim 5): 5a: SES, acculturation, Hispanic ancestry and treatment type moderate C-CBSM's effect; **5b:** C-CBSM improves cardiometabolic markers (e.g., lipids, fasting glucose) via reduced inflammation.

To Test Exploratory Hypotheses. Aim 3: For Hypotheses 3, the linear mixed model will include fixed effects for the experimental group (C-CBSM vs. CBSM) and observation time (T1–T4), and random effect for person with a compound symmetry covariance structure for the repeated residuals within person. A group by time interaction and post-hoc tests on this model effect will indicate whether and how the time course of the dependent variable differs between the groups. Hypotheses 1-3 will all be analyzed in a similar manner using the outcome measures described in sections C.6.c (Primary Outcomes), C.6.d (Intervention Targets) and C.6.e (Inflammation) respectively. These measures include markers of symptom burden, systemic inflammation, and cytokine production following cellular activation with TLR ligands. Data from gene expression profiling are analyzed using advanced bioinformatics techniques, and described in C.6.e, and as reported previously by Antoni et al.[124] As each outcome across the different study hypotheses have been carefully selected to address a priori hypotheses, no adjustment for testing of multiple outcomes will be made. However, within the analysis of a specific outcome, Tukey or Bonferroni adjustment will be made for the multiple tests across different time points. The power calculation below adjusts for this multiplicity. **Aims 4a-4c:** These hypotheses involve tests of proposed mediators of C-CBSM's effect on our primary outcomes. To test mediation with LGM, individual change trajectory (in each outcome of interest) is characterized by an intercept and a slope factor. The overall pattern of change (e.g., linear, quadratic, etc., as informed by analyses for Aims 1-3) for the whole group can be specified by a particular set of coefficients associated with the slope factor. First, we will specify a growth curve model for all participants with an intercept factor representing our outcome of interest at baseline, and the slope factor reflecting the change trajectory in our outcome measure from T1 to T4. For example, to test that increased stress management skills (e.g., MOCS) in the C-CBSM group accounts for reductions in symptom burden (e.g., EPIC-S), we will first test a LGM model without the stress management skills (the mediator) and then test the model with change in stress management skills from T1 to T4. In the model without the stress management skills, we expect that group assignment is not related to baseline symptom burden, but that group assignment will be related to a greater negative change (reduction) in symptom burden scores. In the next step, we will add stress management skills and expect that after adding this mediator in the model, the path between group assignment and symptom burden slope will become non- significant, while the path between the mediator and symptom burden slope is significant thus suggesting mediation. This approach will be applied to test all mediation models in hypotheses 4a-4c.[191,192] **Aim 5a-5b:** To evaluate moderators and mechanistic pathways of C-CBSM's effects, we will use LMM and latent variable mediation models. For Hypothesis 5a, we will test moderation by including interaction terms between group assignment (C-CBSM vs. CBSM) and each moderator of interest (e.g., SES, acculturation, Hispanic ancestry, treatment type) within the LMM framework. These models will include fixed effects for group, time (T1–T4), the moderator, and the group × moderator and group × time × moderator interactions. A significant three-way interaction (group × time × moderator) will indicate that change in the outcome (e.g., inflammation, symptom burden, HRQoL) over time differs by both treatment group and the level of the moderator. Post-hoc comparisons will clarify the nature of the moderation effects across timepoints. For Hypothesis 5b, we will test whether improvements in cardiometabolic markers (e.g., lipids, fasting glucose, blood pressure) in the C-CBSM group are mediated by reductions in inflammation using SEM. Parallel process LGMs will estimate trajectories for inflammatory markers and cardiometabolic outcomes across time. The indirect effect from group assignment to cardiometabolic outcome slope via inflammation slope will be tested. This approach allows for simultaneous modeling of changes over time, capturing both within- and between-subject effects. Model fit will be evaluated using standard criteria (CFI > .95, RMSEA ≤ .05, SRMR < .08), and significance of indirect effects will be tested using bias-corrected bootstrapped confidence intervals.

Preliminary Analyses and other Statistical Considerations. Descriptive statistics will be computed to ensure values are within expected ranges and to eliminate any errors. We will use PRELIS2[193,194] to examine multivariate normality. Non-normally distributed variables will be transformed using log transformations. We will compute estimates of internal consistency (Chronbach's α) for all scales and composite scores. If reliability is <.70, we will evaluate the internal consistency of the measure and delete items or subscales as needed.[195]

Power Analyses. The primary aim compares pre-post change in symptom burden scores between the randomized arms. A sample of 100 per arm is assumed, although T1-T3 time points will have larger samples. Power is based on the effect size defined as the group difference in the mean change divided by the standard deviation of the change. Power calculations are based on effects of the C-CBSM pilot study.[98] With 100 per arm, there is 80% power to detect an effect size of 0.40 assuming a two-tailed test and a Type I error rate of 5%. Since multiple tests look at change in various post-intervention time points, using a Type I error rate of 1% results in a detectable effect size of 0.49. If effect sizes are calculated from Figure 6 from our preliminary work, then the observed effect sizes as defined above are 0.52 for FACT-G and 0.40 for EPIC-S. Effect sizes for subscales FACT-PWB and FACT-EWB are

0.81 and 0.42 respectively. With greater effect sizes anticipated in the proposed study, the sample size of at least 100 per arm has sufficient power to detect differences even after adjusting for the analysis of change from baseline to post-intervention time points. Power for C-CBSM's effect on down regulation of inflammatory genes are based on Antoni et al.[124] study which indicated that the observed effect size was one standard deviation in a sample size of 45 in the experimental condition. Glucocorticoid receptor sensitivity demonstrated similar effects. With a T4 sample size of 100 in the C-CBSM group, effect sizes of 0.48 standard deviations are detectable with 80% power at a 2-tailed Type I error rate of 1%, so that expected effects will be detectable with sufficient power. While pilot data are not available for all outcome measures, the constant in the power calculation regardless of the outcome is the effect size expressed in terms of standard deviations, which is 0.40 or 0.49 depending on whether the Type I error rate is 5% or 1%.

Covariates, Cohort Effects, Intent to Treat & Missing Data. A number of variables (e.g., SES, disease factors) will be considered as possible covariates. These putative confounds will be entered as covariates if correlated with our outcomes (at $p<.10$). Random assignment should render groups equivalent on covariates and this will be verified post-hoc. We will test differences among cohorts who have completed our conditions by doing an ANOVA within each condition with k levels of cohort. If we find a cohort with differential outcomes (significant Condition x Cohort x Time interaction), we will conduct a Group x Time interaction tested within each cohort, and a Cohort x Time interaction tested within assignment. We have never observed a significant cohort effect in prior CBSM work. We will also use an intent-to-treat approach in that all participants will be retained in the analysis, including those with missing data at time points by using full information maximum likelihood (FIML) estimation. FIML, a recommended state-of-the-art method,[197,198] uses all available data for each participant and provides unbiased estimates of parameters when the data are missing at random.

Cost to the Participants:
There will be no cost to the participants for taking part in this study. All expenses related to the study activities, including laboratory tests done and lab materials.

Risk and Benefits:
Risks: Though we regard the risks of participating in this study as relatively low, we will take every measure to ensure that every recruiter, interviewer or project personnel, is trained to handle situations sensitively and with empathy. All research staff are required to complete site mandated training on the Protection of Human Research Participants, and this training experience must be renewed on a yearly basis. Certificates for all research staff will be kept on file in the Project Manager or PI's office at each respective site. As risks are relatively low and easily managed, and because benefits for participants are potentially substantial, the balance of risks-to-benefits are reasonable.
In both experimental conditions, participants will be given specific Spanish PC-related information, as well as be asked to participate in the assessment of sensitive topics that may lead some to experience transient and mild anxiety. In addition, some participants are likely to manifest signs of severe symptoms, and in rare cases, disease progression, throughout the longitudinal component of the study, and they are likely to experience affective distress. There is also a slight possibility that participants may experience discomfort at the site of venipuncture as we are obtaining venous blood or during the remote blood spot collection in which the participant is instructed to use a lancet to obtain 5 drops of blood. In these cases, every attempt will be made to provide relief and to ameliorate the source of the discomfort. Participants will be mailed a set of instructions that include safety procedures in collecting blood drops. Should participants experience extreme acute or persisting affective reactions at any point during the study period, they will be referred to a psychiatrist or clinical psychologist associated with the site for care.

In the event that a participant reports symptoms or concerns of extreme distress (e.g., severe symptoms of depression and/or anxiety suggesting clinical concerns, suicidality, etc.), our interventionists will directly target such symptoms and assess the severity of such distress within the group context while maintaining the group process and eliciting support from other participants. Subsequent to the intervention session, the participant will be contacted individually by one of the interventionists for a more comprehensive assessment of distress. If it is determined at that point that the participant needs individual care, our interventionists and research staff will be prepared to refer the patient to a source of clinical intervention other than our C-CBSM or CBSM intervention (a list of referrals is available for each community). Similarly, should participants experience extreme, acute or persisting affective reactions at any other point during the study period (e.g., assessment, individual contact), they will be referred to the appropriate channels within the UM Departments of Psychiatry or Psychology, the UM/JMH and/or the Courtelis Center for Psychosocial Oncology at the UM/SCCC. Alliance and other community participants will be referred to a vast

network of community resources (e.g. Liga Contra el Cancer) known to treat Hispanic cancer survivors. They will also be provided a list of community resources/catchment sites in the South Florida area prepared to deliver resources to deal with extreme distress. As we will collect information on several cardiometabolic markers including blood pressure, fasting glucose, triglycerides, and HDL-cholesterol, participants with clinically elevated values will be alerted and results will be mailed, with participant consent, to primary care providers. For participants who report lack of a primary care provider, we will facilitate referral and access within our medical networks and community hospitals and clinics at each study site.

If, for some unforeseen reason, a situation arises in which a participant experiences more harm than good during the study, the Principal Investigator may choose to withdraw this participant. Though highly unlikely, such situations could include excessive physical, psychological, or emotional suffering. When participants withdraw from the research, study staff will update their data set (i.e. tracking spreadsheets) to reflect this change. Study staff will no longer contact participants to schedule groups or assessments, depending on the time point at which the participants withdraw. Unless a participant expressly requests the destruction of whatever data (biological or otherwise) that has already been collected, and unless a participant requests no further data be collected about him whatsoever, study staff may continue to gather certain information (i.e. medical chart data) at the other time points at which the participant would have been seen had he remained active in the study.

Benefits: Participants will benefit from a culturally adapted cognitive-behavioral stress and self- management intervention (C-CBSM) or a standard CBSM intervention. Participants will be experiencing a psychosocial intervention specifically adapted to address and consider Hispanic sociocultural values and beliefs that is designed to ameliorate the distress, symptom burden and health- related quality of life (HRQoL) challenges experienced in localized PC. In both conditions, participants will be receiving relevant PC information, and strategies to manage stress, reduce symptom burden and improve HRQoL. In the C-CBSM condition, these strategies are delivered in a culturally informed and targeted manner and are thus hypothesized to have greater efficacy on our study outcomes, relative to standard CBSM. Nonetheless, both conditions will provide benefits. Thus, participants should all be in a position in which they experience less distress, better symptom management and HRQoL. The findings of this study will inform future interventions for Hispanic Spanish speaking men living with localized PC who have undergone surgery or radiation treatment. Further, should the C-CBSM intervention prove to be more effective, this research will benefit other Hispanic and Spanish speaking cancer survivors via its documentation of the incremental efficacy of a culturally targeted program.

Participant Compensation:
Given the time demands of this study, we will offer compensation of $75 at each assessment visit, for a total of $300 for study participation. Participants who are able to complete the entire interview (blood work and questionnaire) will receive $75. Participants who complete 75% of the interview (blood work and the socio-demographic, health related, stress/distress questionnaires) will receive $50. Participants who complete the other 25% of the interview (Interpersonal, Mechanics, Culture, and Other sections) will receive $25 upon completion. We will also provide parking or transportation for assessment or intervention visits for up to 30% of the sample. This will provide us with the flexibility to offer participants the option of receiving transportation services to attend our clinic or intervention visits. Participants will not be paid for those research activities that they do not complete. However, they will not incur any additional costs for being in our study.

Vulnerable Populations:
N/A

Withdrawal of Subjects:
Participation in study is completely voluntary where participants can elect not to answer any specific question on the questionnaire. It is also voluntary to complete the questionnaire/test/specimen banking and can elect to not participate at all in the study.

Data & Safety Monitoring:
The informed consent, all assessment measures, and intervention modules have been reviewed and approved by the UM Institutional Review Boards (IRB). In addition, the study will be closely monitored by the Sylvester Comprehensive Cancer Center (SCCC) Data and Safety Monitoring Committee (DSMC) in accordance to the Cancer Center's Data and Safety Monitoring Plan (DSMP) and a Community Advisory Board (CAB). In its oversight capacity, the DSMC bears responsibility for suspending or terminating this study. DSMC oversight of the

conduct of this trial includes ongoing review of adverse event data, and periodic review of the study's aims (refer to Data Analysis section). The guidelines appearing in this section are offered for DSMC consideration in assessing adverse events and treatment response or other study endpoint. In addition, the DSMC will review reports from all audits, site visits, or study reviews pertaining to this clinical trial and take appropriate action. The SCCC DSMC to which this study is subject can be found at www.sccc.org.

Community Advisory Board (CAB):
We will take a CBPR approach to engage key stakeholders.[199] PC survivors and health care professionals review all study procedures to optimize sensitivity, appropriateness and cultural relevance. Our prior work developing C-CBSM involved an iterative approach where health providers who treat our target population were involved in all steps of the development. We will establish a community advisory board (CAB) of community partners, health care and administrative professionals, and Hispanics treated for localized PC to optimize dissemination and sustainability. Two CAB meetings take place in Years 1 and 5, and one each year during Year 2-4. Meetings elicit input from patients, health care providers and administrators in our Hispanic communities (5 individuals from each city), which are stakeholders in the proposed aims of the project. These meetings will maximize implementation and plan for sustainability.

Trial Monitoring, Auditing, and Inspecting
The investigator will permit trial-related monitoring, quality audits, and inspections by, government regulatory authorities, of all trial-related documents (e.g., source documents, regulatory documents, data collection instruments, case report forms). The investigator will ensure the capability for inspections of applicable trial- related facilities. The investigator will ensure that the trial monitor or any other compliance or QA reviewer is given access to all trial-related documents and trial-related facilities. Participation as an investigator in this trial implies the acceptance of potential inspection by government regulatory authorities.

Quality Assurance and Quality Control
In addition to the Clinical Monitoring component of this protocol, Quality Assurance will be implemented (QA) to assess compliance with GCP and applicable regulatory requirements. Data or documentation audited shall be assessed for compliance to the protocol, accuracy in relation to source documents and compliance to applicable regulations.

Publication policy/Results Reporting/Progress and Final Reports:
This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH- Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial is registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 7 years after the completion of the primary endpoint by contacting Dr. Frank Penedo or the University of Miami.

Privacy, Data Storage, & Confidentiality:
Privacy: All material will be obtained exclusively for research purposes and in full IRB and HIPAA compliance. All sources of information will be coded using a special participant number, which precludes it being matched with identifying information. Because all our participants will be men treated for PC, the issues surrounding confidentiality are of supreme importance. In all cases, highly personal and clinical information will be obtained. By signing the informed consent form, participants attest to their understanding that the information they provide will be held as personal and confidential to the extent permitted by law. Access to the computer data files will be by password codes. The list matching participant number to identifying information will be maintained in a locked drawer, in the PI's office. Additionally, in order to be able to track participants across the longitudinal period of the project, we will keep a separate record of each participant's address, telephone number and contact person information. This record will indicate whether or not a participant has completed an assessment but will not include information concerning their assessment or intervention performance. Participants will be made explicitly aware at the time of the informed consent of the nature of the two separate records that will be kept.

Confidentiality and Data Management: The sources of research material obtained from participants will be the participants themselves in the form of medical history and blood specimens. In addition, participants will furnish demographic, psychiatric and psychosocial information and self-reports of changes in symptoms. As previously noted, we will also collect medical treatment and disease characteristics (e.g., type of treatment, disease status

markers such as Gleason score, PSA, time since diagnosis, etc.). Medical treatment and disease characteristic information will be collected via chart review by our research team under procedures established in prior work with our Urologist Dr. Kava**.** The majority of self-report data obtained from participants will be stored via the secure website Redcap. Per IRB policy, study data collected will be stored for 7 years after the completion of the study.
Biological specimens (participant blood samples) will be labeled with a code that does not contain personal or identifying information. All lab results are kept confidential and under no circumstances will the information gained from blood samples be shared with anyone outside of the research team. All data is kept in encrypted and password protected files on a locked Northwestern University and the University of Miami network. Participant names and all other identifying information are kept in a separate, locked and protected location to ensure participant identity cannot be linked to the blood sample provided. Biological specimens, including participant blood samples, will either be processed by the Department of Pathology at the UMHC & Sylvester Cancer Center lab (PSA & A1c) or stored in a predestinated research laboratory space in Dr. Blomberg's lab located in Rosenstiel Medical Science Building,1600 NW 10th Ave. #3146A, Miami, Fl 33136. Only the laboratory technician on staff and supervising immunologist will have access to blood samples. Biological specimens (i.e. blood) obtained from participants will be stored for the duration of the study (4 years) and then will be destroyed. Blood samples processed by the Department of Pathology at UMCH SCCC Lab will be destroyed by the lab upon completion of the lab PSA and A1c analysis. Blood samples will not be used for future research and will not be shared with other researchers.
The project's benchwork will involve collaboration amongst four laboratories. Immediately following collection, the specimens will be transported by courier to Dr. Blomberg's lab (Miami patients). Experience staff at these labs (Dr. Diaz) will harvest serum for measurements of systemic inflammation, culture leukocytes with TLR ligands to assess cytokine production, and isolate monocytes for genome-wide transcriptional profiling. At the conclusion of the study, culture supernatants will be transported to Dr. Miller's laboratory for multiplex cytokine analysis on the MSD platform, and monocyte lysates will be shipped to Dr. Cole's laboratory for genome-wide expression profiling. While this is admittedly a complex workflow, the participating laboratories have many years of experience working together, and as the publications cited above show, can successfully execute the specified protocols. Unless required by law, only the study investigator, members of the investigator's staff, representatives of The National Cancer Institute (NCI), the respective site's Institutional Review Boards (IRB), and representatives from the Office for Human Research Protections (OHRP) will have access to review study records. Research staff will complete HIPAA (CITI) training courses on the protection of human subjects in research in order to better understand the precautions they must take with sensitive participant data. Again, all participant data will be de-identified and stored in secure locations (i.e. locked offices or labs) for the duration of the study and electronic information will be password protected and stored on secure university machines or secure websites. Approximately every 6 months, research staff, will conduct a quality check of their medical chart review data. This quality check will help ensure that all research staff are using the same methodology when extracting information from charts. Research staff will also cross-check hand-entered data to ensure that information being collected on paper forms is transmitted accurately into study spreadsheets. In regard to the data analysis plan, descriptive statistics will be computed for all variables to ensure that values are within expected ranges and to eliminate any errors.

Data and if applicable, Specimen Banking:
All psychosocial data, participant tracking and flow, and intervention data will be collected via University of Miami Redcap (https://recap.miami.edu), including previously collected transferred data at Northwester University at Chicago Redcap (https://redcap.nubic.northwestern.edu/redcap/). EMR and physiologic data will also be entered in the Redcap platform. Redcap is securely stored at the Northwestern University (NU) and University of Miami Research Data Centers and available via the web. The data management environment meets the security requirements identified in the Agency Automated Information Systems Security Program (AISSP) Handbook. Redcap requires use of current passwords and log-on codes to protect sensitive AIS (Automated Information System) data from unauthorized access: All system access requires a user name and password. All users who require anything more than "internet user" security to the NU and University of Miami campus network must have a unique ID assigned. The NU and University of Miami ID is used to control access to data files and applications that reside on the network. Every NU and Miami ID is required to have a complex password assigned. Access to Redcap is restricted to participants by means of a username and password incorporated within the participant registration process. Because SQL Server 2008 R2 is integrated with Windows, SQL Server and Windows (MySQL at the University of Miami) authentication is used to prevent unauthorized access. Restriction to Redcap involves maintaining an encrypted list of current users and authorizations based on permissions and roles assigned to each user. NU and the University of Miami provides Redcap administrators with secure Virtual Private Network (VPN) access. Operating system and database based permissions are set by the Redcap administrators. User accounts have limited system resource access. The availability and flow of data is limited to the security access identified and

signed off by management, and is controlled by the database administrator who pre-defines security access levels. This ensures that only data necessary for that individual's work function are viewable. All requests are validated before attempting to submit data to the database. Any internal or stored reference to a participant is accomplished through a unique identifier key. Data is stored and accessed in full compliance with institutional IRB and governmental regulations regarding privacy and security. NU and the University of Miami have a secure data center that houses all servers. This center is limited to authorized employees via the use of a card swiping system and biometric reader on the entrance doors. NU's Department of Medical Social Sciences and the University of Miami IT Department have established standard operating procedures relevant to data retention and removal based on NIH data retention requirements. Sensitive participant identifiers of on-going studies are encrypted and kept confidential. This procedure was initially designed to comply with HIPAA requirements. Terminated studies have all participant identifiers removed from electronic media storage after the retention period. Hard copy documents with participant identifiers will be shredded in a timely manner. NU and the University of Miami provide comprehensive data backup. At NU all data is stored in a dedicated storage server on top of redundant disk array. A snapshot of the virtual machines is taken every night and stored on backup storage that is alternated every two weeks. A full backup of the database is taken every night with incremental backups taken every two hours. Communications lines terminate in locked PBX rooms and in the data center.

Contingency plan for disaster recovery is in place. The NU Research Data Center has two Uninterruptible Power Supplies and a Diesel generator in the event of a power shutdown. These units are tested on a routine basis. At the University of Miami data is encrypted at rest using AES 256 encryption, server is backed up daily. Systems updates are performed monthly and RedCap application upgrades are performed bi-annually. The University of Miami also has an Uninterruptible Power Supplies in the event of a power shutdown.

Miami Site Setting:
The study will housed at the Coral Gables campus, the office of Dr. Michael Antoni, Co-PI Department of Psychology (Flipse Building, 5665 Ponce De Leon Drive, Coral Gables, Fl 33146) and the medical campus, the office of Dr. Dolores Perdomo, Project Manager, at the Center on Aging, Department of Psychiatry (1695 NW 9th Avenue, Suite 3204L, Miami, Fl 33136).

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