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"*¡Alegrate!*"—A culturally adapted positive psychological intervention for Hispanics/Latinos with hypertension: Rationale, design, and methods

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ABSTRACT

Growing evidence links psychological well-being (e.g., optimism) with superior cardiac health, but there remains a critical scientific gap as we do not know whether (or how) interventions to cultivate emotional well-being may reduce cardiac risk. Hispanics/Latinos in the U.S. have high cardiovascular disease risk and poorly controlled blood pressure (**BP**) compared to peers of European ancestry, and represent a population in need of new and innovative therapeutic approaches. This paper details the "*¡Alégrate!*" study, a cluster-randomized Phase II trial testing efficacy in improving BP of a culturally tailored positive psychological intervention designed to boost emotional well-being in Hispanics/Latinos with hypertension. A total of 126 Hispanics/Latinos aged ≥18 years, fluent in English or Spanish, and with elevated sitting BP (≥140/90 mmHg) will participate in one of two trial arms: (1) a positive psychological intervention, or (2) a wait-list control condition. The "*¡Alégrate!*" group-based intervention consists of 8 weekly 90–120-min sessions delivered in-person by a psychologist/social worker. Targeted skills include noting daily positive events, positive reappraisal of stressful events, effective expression of gratitude, performing acts of kindness, and regular practice of mindfulness and meditation, among others. The primary outcome is improvement in BP, both sitting values and 24-h ambulatory readings, as measured at baseline and 8- and 12-weeks post-baseline. Secondary outcomes include emotional well-being, engagement in healthful behaviors, and circulating levels of inflammatory markers. We hypothesize that BP control, psychological well-being, healthful behaviors, and chronic inflammation will be significantly better in the "*¡Alégrate!*" arm at follow up compared to the wait-list control group.

1. Introduction and background

A recent paradigm shift in public health and medicine shifts focus from psychological distress and deficits and instead expands its view to include positive psychological assets that focus on human flourishing and resilience [1]. Observational evidence links multiple domains of psychological well-being (e.g., happiness, optimism) with better overall coping, greater quality of life, reduced mortality, and healthful longevity [2]. Independent of traditional cardiovascular disease (**CVD**) risk factors, psychological assets are independently associated with favorable lipid profiles, reduced circulating inflammatory markers, and reduced odds for incident heart disease and cardiac-related mortality [3,4]. Although evidence links psychological well-being with superior cardiac health, there remains a critical gap as we do not yet know whether (or how) interventions to cultivate emotional well-being may reduce cardiac risk.

One group with high CVD risk that may greatly benefit from a novel therapeutic target in the form of cultivating and improving positive psychological assets is the Hispanic/Latino population in the United States [5]. The burden of CVD is disproportionally high in Hispanics/Latinos. Approximately three-quarters of Hispanics/Latinos have at least one major CVD risk factor [5,6] and 30% of mortality in this underserved and understudied group is attributable to cardiovascular illness [7]. Unfortunately, the American Heart Association reports that

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currently-available CVD prevention efforts are sparse and ineffectual in minority populations, highlighting the need for new and more effective disease prevention strategies [8].

Interventions designed to boost psychological assets may be particularly useful for reaching Hispanics/Latinos as a means of improving risk profiles and overall heart health. Given that hypertension holds the highest attributable risk for CVD morbidity and mortality [9], an important risk factor to target is elevated and/or poorly controlled blood pressure (**BP**). About 22.2% of Hispanics/Latinos have elevated BP with evidence of inferior control when compared to non-Hispanic White and Black counterparts [10]. Evidence suggests that psychological well-being is related to healthier BP profiles [3]. Among 1,000 healthy adults, individuals with higher levels of hope, curiosity, and positive emotional vitality had lower odds of incident hypertension at the 1-year follow-up, compared to individuals with low levels across well-being domains [11]. Novel psychological strategies to boost emotional well-being and thus promote healthy BP profiles are not likely to be pursued in at-risk minority populations in the absence of clinical trials that can provide causal evidence.

Current interventions focus on populations of European decent, include patient populations with prevalent heart disease, and omit tailoring based on cultural preferences. The "¡*Alegrate!*" ["*Get Happy!*"] trial addresses these limitations by testing the efficacy of a culturally-tailored 8-week intervention intended to boost emotional well-being in Hispanics/Latinos with hypertension by examining changes (relative to a wait-list control) in BP control, emotional well-being, health behavior adherence, and circulating serum inflammation. We hypothesize that, compared to controls, "¡*Alegrate!*" participants will show greater improvements in blood pressure control, higher scores for psychological well-being, greater engagement in healthful behaviors, and lower levels of circulating inflammatory markers at follow up. We also seek to test plausible mechanisms through which "*¡Alegrate!*" might influence blood pressure control.

2. Methods

2.1. Overview and study design

We will conduct a cluster randomized Phase II trial to test the efficacy of an 8-week positive psychological intervention in Hispanic/Latino adults with hypertension. A total of 6 churches will be allocated in a 1:1 ratio to receive the "¡*Alegrate!*" intervention or be assigned to a wait-list control group (see Fig. 1). Cluster randomization was selected given the potential for contamination had we randomized at the individual-level across church sites as parishioners within a church are likely to socialize, thus increasing the likelihood of information flow between intervention and control participants. The targeted sample size is 126 Hispanics/Latinos recruited over a 3-year period. Sites for recruitment include catholic churches located in Urban neighborhoods in Chicago heavily populated by residents of Hispanic/Latino background. The "¡*Alegrate!*" trial was approved by the Institutional Review Boards at the University of Illinois at Urbana-Champaign and the University of Illinois at Chicago. This trial is registered at Clinicaltrials.gov (#NCT03221114). Similar methods will be employed to that used when initially piloting our "*¡Alegrate!*" trial for feasibility using a pre-experimental design, as previously published [12].

2.2. Participants

Parishioners will be eligible to enroll in the trial if they meet the following criteria: (1) self-reported Hispanic/Latino heritage, (2) age ≥18 years, (3) fluent in English or Spanish, (4) elevated sitting blood pressure (i.e., ≥140/90 mmHg), and (5) intention to remain in the country for the duration of the trial. Parishioners will not be eligible to participate based on the following exclusion criteria: (1) cognitive impairment denoting dementia (assessed using the Short Portable Status Questionnaire) [13] and (2) severely reduced life expectancy (e.g., self-reported diagnosis of metastatic cancer, congestive heart failure, or end-stage kidney disease).

2.3. Recruitment procedures

Participant recruitment will occur across 6 church sites in Chicago and surrounding suburbs where Dr. Hernandez (PI) has established relationships and rapport. These sites are in areas with residents predominantly of Hispanic/Latino heritage. First, research staff will recruit parishioners by verbally communicating details of the study during Sunday masses with the invitation to receive a no-cost blood pressure screening. A pre-drafted recruitment script will be read aloud to parishioners at the end of each mass prior to dismissal from the parish priest. The parish priest will encourage participants to attend the free screening and to inquire of their eligibility. Those interested in participating in the study will be asked to approach research staff to determine full eligibility. The second recruitment approach will use written materials in the form of flyers and advertisements printed in the church bulletin. Recruitment will start in Year 2 (2017–2018) and will end when all 6 sites have been engaged. We expect the total recruitment period to span no more than 36 months.

2.4. Intervention arm: "¡Alegrate!"

Our "¡*Alegrate!*" ["*Get Happy!*"] positive psychological intervention was adapted from previously published and empirically validated curricula [14,15], with additional content informed by formative qualitative work [16] identifying the cultural importance of incorporating religiosity and familialism. Targeting of our intervention specifically for Hispanic/Latino adults included, but was not limited, to the following: (1) lively music at the start of each session (e.g., Salsa music by Celia Cruz), (2) encouragement by facilitator for heartfelt greetings and embraces when entering the classroom, (3) intermittent participation of the parish priest to deliver a prayer, particularly when discussing meditation/mindfulness, (4) deemphasis on the "classroom" setting and minimizing of written exercises to allow full comfort, particularly in those with limited formal schooling, and (5) integration of audiovisuals such as videos and music to reinforce class content. Indeed, it is well-known that the cultural profile of a population is an important influential factor in fulfilling targeted objectives of any intervention.

The full intervention consists of eight weekly sessions delivered in-person by a bilingual licensed psychologist or social worker that teaches participants behavioral and cognitive skills known to boost positive affect and overall psychological well-being. Each weekly session is 90–120 min in length. The "¡*Alegrate*!" intervention content focuses on the following skillsets: (a) identifying and using personal strengths, (b) noticing positive events in daily life, (c) prolonged appreciation and relishing of positive events, (d) positive reappraisal of stressful events or situations, (e) gratitude, (f) regular practice of mindfulness and meditation, (g) setting and working toward pragmatic and achievable goals; and (h) planning and performing acts of kindness. During the last session, participants are asked to invite a family member or friend to the graduation ceremony during which time they identify the unique strengths or talents of the family unit or of their invited social support network.

Table 1 charts content of the 8-week course, the skillsets taught at each weekly session, and the at-home practice exercises assigned. In addition to attending in-person sessions, all participants owning a cell phone will receive a weekly text message from research staff highlighting the skillset taught that week with the reminder to put those skills into daily practice. Research staff will keep track of text messages delivered and subsequent confirmation by participant that content was both received and read.

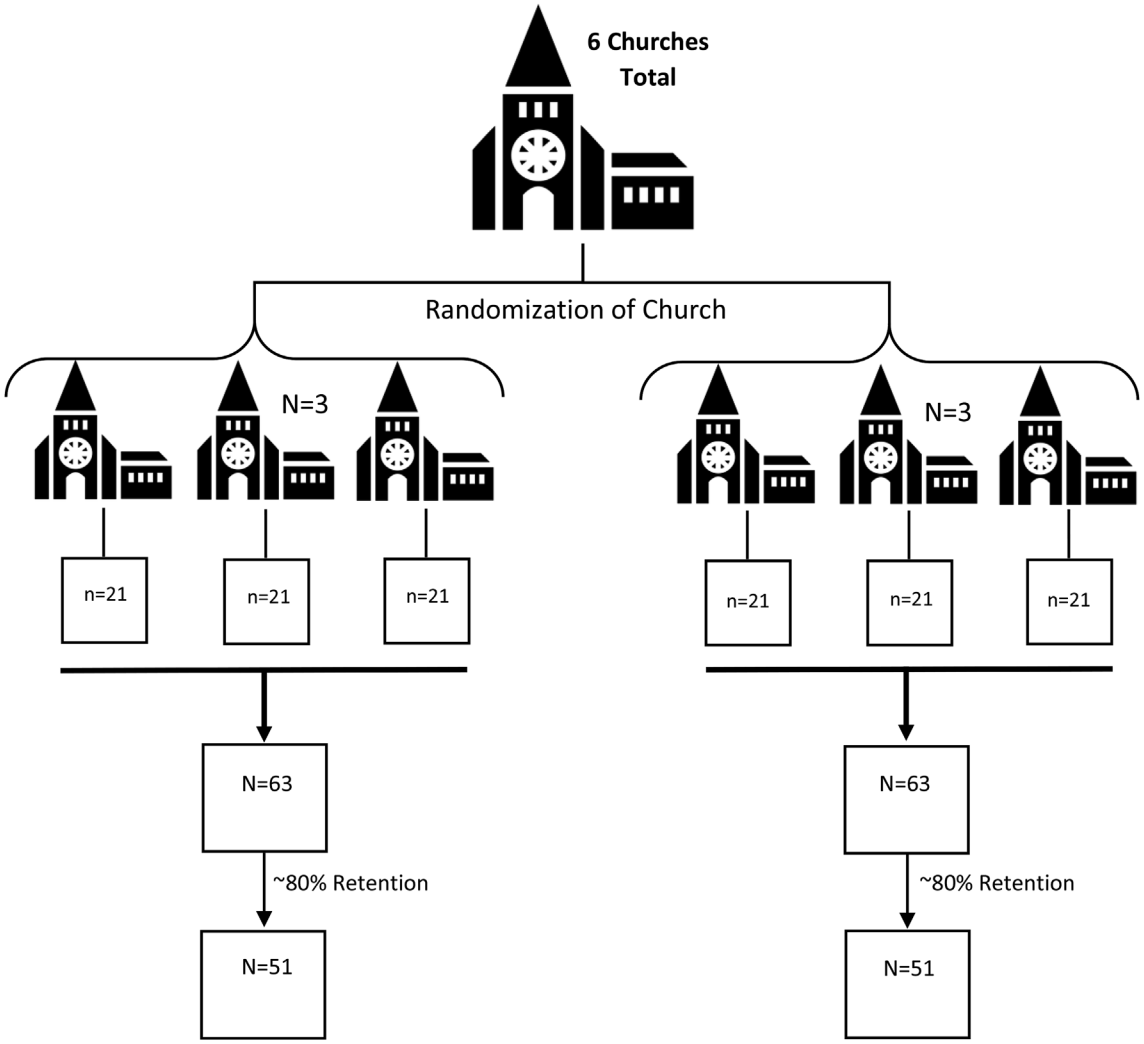

Fig. 1. Proposed flowchart of participation.

2.5. Control group

Participants attending parishes randomly assigned to the wait-list control group will only be asked to complete survey and clinical assessments at baseline and at 8 and 12 weeks during the study period. Monthly checkups will be completed for the wait-list control group to ensure blood pressure values don't exceed values requiring immediate attention. A physician visit will be recommended when resting blood pressure increases by more than 10% relative to original baseline values. Concerted efforts will be undertaken to promote retention among participants in the control arm, including postcard notices and phone calls to remind participants of scheduled clinical assessments. Finally, after the final assessment visit, those in the control group will be offered the opportunity to enroll in our 8-week "¡*Alegrate*!" intervention with no further data collection scheduled.

2.6. Measures

Spanish-language in-person interviews will be conducted by trained bilingual research assistants for the collection of baseline and follow-up data. A majority of survey instruments to be used in the current trial have undergone previous psychometric testing showing adequate

Table 1
Positive psychology skills imparted in the 8-week face-to-face intervention.

Week 1	Focusing on Personal Strengths (**Skill 1**)	Identifying and focusing on one's strengths as a form of self-affirmation to evaluate the resources possessed to cope with a stressful event.
Week 2	Positive Events (**Skills 2**)	Training of individuals to note positive life events in their day-to-day encounters.
Week 3	Capitalizing of Positive Events (**Skills 3**)	Capitalizing is an expressive response to positive events and includes telling others about it, marking the occurrence in some way, or even thinking about the even again later on.
Week 4	Gratitude (**Skill 4**)	Gratitude is defined as a feeling of thankfulness and appreciation expressed toward others, which may include other people, nature, or God.
Week 5	Altruistic Behaviors/Acts of Kindness (**Skill 5**)	Engagement in volunteerism and other altruistic behaviors.
Week 6	Mindfulness (**Skill 6**)	Mindfulness is defined as the ability to intentionally pay attention to and maintain non-judgmental awareness of one's thoughts, feelings, and physical sensations in the present moment
Week 7	Positive Reappraisal (**Skill 7**)	Positive reappraisal is a form of coping in which the significance of the event is reinterpreted in a more positive way.
Week 8	Attainable Goals (**Skill 8**)	Setting of realistic goals and imparting techniques to increase their progression and attainment.

validity and reliability in the Spanish language. For those not previously translated, our team will conduct thorough forward and backward translation procedures to craft a Spanish-language adaptation with linguistic equivalency. Similar data collection methods and survey tools were used when piloting our "*iAlegrate!*" intervention for feasibility using a pre-experimental design [12].

2.6.1. Antecedent variables

Demographic Factors: We will gather basic demographic information from all participants including: age, sex, income, educational attainment, marital status, health insurance status, employment type, nativity status and number of years in the U.S., and country of origin.

Anthropometric Measurements: Research staff will ascertain measures of height (to the nearest centimeter) and weight (to the nearest 0.1 kg) and will calculate body mass index (BMI) using these values. The waist-to-hip ratio will be derived from abdominal and hip girth obtained using a Gulick II 150 and 250 cm anthropometric tape measure with participants wearing light clothing.

Acculturation/Cultural Factors: The Short Acculturation Scale for Hispanics will be used to capture the construct of acculturation in Hispanic/Latino adults [17]. The 10-item scale inquires on language use (Spanish vs. English) across settings (home vs. social life), language in which entertainment is consumed, and race/ethnicity of individuals across varied social circles. This scale has been previously validated in the Spanish language. Derived from the Duke University Religion Index [18], religiosity will be assessed using a 5-items scale that includes questions such as, "My religious beliefs are what really lie behind my whole approach to life." It also assesses frequency of attendance at religious institutions and engagement in religious practices.

Current Health Status and Medical Comorbidities: Self-reported physical and mental health will be measured using the 12-item Short Form Health Survey (SF-12) [19]. Participants will also self-report previous or current existence of any of the following medical conditions: heart attack; congestive heart failure; stroke; diabetes; arthritis; moderate or severe renal disease; fracture of the hip, wrist, arm, or shin; asthma; cirrhosis of the liver or liver disease; cancer; bypass of arteries in the leg; Parkinson's disease; Alzheimer's disease or dementia; HIV or AIDS; depression; or anxiety disorder.

2.6.2. Primary outcome

Sitting and Ambulatory Blood Pressure: An ambulatory BP monitoring (ABPM) method will be used to capture 24-h daytime and nighttime BP readings in the natural environment (CONTEC™ Automatic Blood Pressure Monitor [ABPM50]); this device has shown adequate reliability and accuracy [20]. We will consider 24-h mean systolic and diastolic readings. Weighing 1.87 lbs the ABPM monitors will be fitted and pretested prior to 24-h use [21]. We will additionally use an automatic sphygmomanometer to evaluate sitting BP. This measurement device has been validated across multiple cohort studies including MESA, NHANES, and HCHS/SOL [22,23]. Three systolic and diastolic blood pressure readings will be taken with participants in the seated position; mean values will be obtained by averaging the last two readings.

2.6.3. Secondary outcomes

2.6.3.1. Psychological well-being. ***Depressive Symptoms***: The 20-item Center for Epidemiologic Studies Depression Scale (CES-D) will be used to measure depressive symptomatology [24]. The CES-D uses a 4-point Likert scale to probe the extent to which an individual has been troubled by depressive symptoms within the last seven days; scores range from 0 to 60.

Perceived Stress Scale (PSS): The PSS includes 10-items to assess self-perceived levels of stress over the previous month using a Likert scale ranging from never to always [25]. Previously validated in the HCHS/SOL cohort [26], overall scores range from 0 to 40 for the full scale and includes items such as, "How often have you felt confident about your ability to handle your personal problems?" and "How often have you felt difficulties were piling up so high that you could not overcome them?" Higher scores are indicative of greater perceived stress.

Positive and Negative Affect: Participants will be asked to recall emotions experienced in the past week using a modified version of the Differential Emotions Scale [27]. A list of 26 different emotions will be provided (e.g., grateful, happy, guilty, relieved, ashamed, or humiliated) and participants will be asked to identify how often they have experienced each on a scale ranging from 1—*Not at all* to 9—*All the time*.

Dispositional Optimism: The revised Life Orientation Test (LOT-R) will be used to assess dispositional optimism. The LOT-R is a validated 6-item self-administered questionnaire with possible scores ranging from 0 (least optimistic) to 24 (most optimistic) [28,29]. The scale includes 3 positively worded items and 3 negatively worded items that are rated on a 5-point Likert scale.

Emotional Vitality: Emotional vitality is characterized as a sense of overall well-being through active engagement in day-to-day activities and effectual regulation of emotions. Borrowing items from the General Well-being Schedule this construct will be captured using a 6-item measure previously used in published studies with available evidence of adequate psychometric properties [30,31]. Respondents are asked to think about the previous 30 days, and using an ordinal scale are instructed to rate statements such as, 'Has your daily life been full of things that were interesting to you?' and 'Have you been feeling emotionally stable and sure of yourself?"

Life Engagement and Meaning (LET): The LET is a 6-item instrument that probes the extent to which an individual engages in activities which they personally value and find meaningful [32], e.g., "To me, the things that I do are all worthwhile." Scores range from 6 to 30 with respondents rating items on a 5-point scale from 'strongly disagree' to 'strongly agree'. Higher scores characterize an individual that experiences greater life engagement and purpose.

Happiness Inducing Behavior (HIB): This 38-item survey inquires of the extent to which participant engage in behavior or prescribed strategies known to induce happiness, e.g., relaying gratitude, engaging in mediation and religious practices, focusing on positive life events, among others [33].

Social Support: The Medical Outcomes Study (MOS) Social Support Survey will be used to quantify social support as provided by family, friends, and acquaintances [34]. This 20-item instrument first directs participants to quantify the total number of close friends and relatives they possess, i.e., defined as the people they feel at ease with and can talk about what is on their mind. Remaining items ask participants to rate statements using a 5-point Likert scale that inquire of the perceived availability of support from family, friends, or others, if or when needed. Sample statements include, "someone you can count on to listen to you when you need to talk," "someone to help with daily chores if you were sick."

2.6.4. Engagement in healthy behaviors

Objective Measure of Physical Activity: Physical activity will be captured with a wireless activity tracker (Fitbit™ One) to be worn on 7 consecutive days. The device used during waking hours, is worn at the hip, and captures the frequency, intensity, and duration of physical activity. The device will be initialized using participant's study ID with programmed activation at the clinic visit scheduled for baseline (Visit 1) and post-baseline (8 week, Visit 2). Raw data will be downloaded and processed for analysis using standard statistical software. Data will be included in analysis if the wireless tracker displayed at least 10 h of data in a 24-h period on at least 3 days.

Sodium Intake: The Scored Sodium Questionnaire will be used to measure dietary intake specifically targeting quantification of sodium consumption [35]. Participants will be asked to report dietary patterns over the last 7 days across multiple food groups (e.g., breads, processed

meats, tinned or packet soups) with response options indicating daily consumption to rare or never eaten items. Dietary intake will also include items of the Summary of Diabetes Self-Care Activities questionnaire [36].

Smoking Status: Participants will be asked to identify whether they are current smokers, former smokers, or if they have never smoked before. Those identifying as current smokers will additionally report the average number of cigarettes they smoke per day.

Self-reported Sleep Quality and Duration: Two self-report items were used to capture subjective rating of sleep. The first inquired about the number of hours per night of sleep (i.e., during the main sleep period) that participants were getting on weekdays or workdays. The second asked participants to rate their typical night's sleep during the past 4 weeks, with a Likert response option ranging from 'very sound or restful' to 'very restless.'

Medication Use and Adherence: Participants will be asked if they were prescribed oral medication for their high blood pressure. Those indicating use of antihypertensive medication will be asked to identify the start date when they first initiated said use. We will also document whether participants had taken their blood pressure medication on the date of their clinical visit, and if so, the approximate time of day. Finally, medication adherence specific to antihypertensive drugs will be assessed using the Morisky Medication Adherence Scale [37]. At each scheduled assessment, participants will be instructed to bring all medications currently taken. Research staff will document details across medication (e.g., dosage) and they will save a digital picture of associated pill bottles.

2.6.5. Marker(s) of CVD

Serum Blood Spots: Serum blood spots will be collected from each participant at baseline and immediately post-intervention (8 weeks). A trained research staff will prick the participant's middle or ring finger using sterile procedures. After wiping away the first spot of blood, 5 subsequent drops will be collected using Whatman #903 filter paper. The blood spots will be stored for future analysis in a -20° freezer at the Institute for Minority Health Research at the University of Illinois at Chicago.

2.7. Procedures

2.7.1. Randomization

Cluster randomization will be implemented with allocation using a 1:1 ratio at the church-level to avoid cross-contamination between treatment and control arms. Randomization across the 6 churches will yield 3 sites assigned to treatment and 3 remitted to a wait-list control arm. The website https://www.randomizer.org/ will be used to randomly derive group assignments.

2.7.2. Enrollment

Screening to determine full eligibility will be offered using varied arrangements. First, parishioners with elevated sitting blood pressure ($\geq$140/90) as determined via our no-cost screening will be given the option to immediately meet with research staff to learn about the "*¡Alegrate!*" trial and to undergo a 5-min assessment to gather inclusion and exclusion metrics for eligibility. Parishioners not wishing to be screened on-site will have the option to call research staff at a later date to schedule an in-person screening. Those deemed eligible to participate will be invited to schedule their initial 2–3 h baseline clinical exam at which point they will review and sign an informed consent form prior to collection of any research data.

2.7.3. Testing

Survey and clinical exams will primarily take place at the study site (i.e., private room within church site) with the option of undergoing testing at the Institute of Minority Health Research at the University of Illinois at Chicago or at the participants home, if preferred by enrollees. During the scheduled baseline exam, prior to any data collection participants will again learn details of the study and associated requirements with review of the Informed Consent Document (ICD). After thoroughly reading the ICD, and upon agreeing to join the study, participants will provide their signature indicating said willingness. Testing will begin only after consent has been secured.

Trained bilingual research staff will collect survey data using REDCap™, a secure internet-based platform. Surveys will be administered in either English or Spanish based on the participant's preferences. Staff will use flashcards presenting associated Likert scales to facilitate item response. At this time, research staff will also collect anthropometric measures, blood pressure readings, and blood spots. It is estimated that clinical exams will take 2–3 h to complete at which point participants will receive $30 cash as compensation for their time. Follow-up testing will occur again immediately post-intervention (8 weeks) and again at the 12-week mark. Individuals in both the treatment and control arms will have identical assessment timepoints, i.e., baseline and 8- and 12-weeks post-enrollment. Snacks will be provided at each clinical visit and participants will be offered reimbursement for transportation.

Toward the end of each clinic visit, participants will be fitted with the CONTEC™ Automatic Blood Pressure Monitor [ABPM50]. Participants will be instructed to wear the ABPM50 at all times (day and night) over a 24-h period, with the exception of periods when the participant showers and/or engages in water-based activities. The ABPM50 meets standards of XANSI/AAMI SP10-1992 with a documented sensor accuracy of $\pm$ 3 mmHg [20]. Participants will be instructed to return the ambulatory monitor in person at their designed church site, where research staff will then retrieve and download data to a secure server. Research staff will also instruct participants on use of the Fitbit™ monitor over a 7-day period, which will be worn at the waist and removed when showering and during sleep.

2.7.4. Study fidelity

2.7.4.1. Staff and training. The principal investigator and research staff are all bilingual and bicultural personnel who will undergo extensive training prior to recruitment and data collection. Research staff will learn details of the research design and associated protocol. An item-by-item review will occur across all survey instruments with the opportunity to deliver mock interviews in both English and Spanish prior to delivery among enrollees. Shadowing of clinical staff of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) [22] will occur on multiple occasions to train in gathering clinical data including anthropometric measures, serum blood samples, and blood pressure and BP, all of which will follow HCHS/SOL's validated protocols. Practice sessions for clinical measures will also occur with multi-staff triangulation to ensure accuracy. Finally, staff will train on initializing Fitbit™ trackers to collect physical activity patterns and fitting 24-h blood pressure monitors for continuous at-home monitoring.

Trained clinicians (i.e., psychologist and/or social worker) will deliver the 8-week positive psychological curriculum face-to-face in a group-based setting. Clinicians will undergo additional training to learn of the field of positive psychology and its theoretical underpinnings, the evidenced-based skillsets known to promote positive emotion and overall well-being, and a detailed description of all curricular content. In-class training led by the principal investigator and a licensed clinical psychologist will be required to master the curricular content and to practice its hands-on delivery. Clinicians will also receive an instructor's manual that includes all curricular content and detailed instructions of the in-class and at-home practice exercises to be delivered each week. A research assistant will be in charge of taking attendance and ensuring that all class materials and handouts are made available.

2.7.4.2. Delivery of the intervention. Clinicians will use a pre-drafted set of Power Point presentations to aid in delivery of the curricular content

of "*¡Alegrate!*". All in-class sessions will be video recorded. The principal investigator will review 37.8% of these recordings to ensure fidelity in delivering the positive psychology content as intended and as documented in the instructor manual. Fidelity will be assessed qualitatively with detailed comments across components of each session. Video recordings will also capture nuanced adaptations deemed necessary by the clinician to enhance comprehension, group participation, and overall engagement. Technical assistance and feedback will be provided to clinicians to maximize fidelity of the intervention's delivery.

2.7.4.3. Receipt of the intervention. Attendance will be documented at every class session; dosage received will be a derivative of class attendance. Strategies to promote and improve retention will include reminder calls before each session and a phone inquiry when a participant misses a session. Midway through the intervention period, we will mail participants a letter thanking them for their continued cooperation and time invested. Research staff will also send weekly text messages to reinforce class content and will document participants who acknowledge having received and read the text. After each weekly session prior to dismissal, participants will complete a survey with quantitative and open-ended items to share their overall satisfaction with the in-class session. They will rate the clarity of the material presented, enjoyment of in-class exercises, and ability to implement skills at-home as well as identify their most- and least-favorite aspects of the session. At the conclusion of the 8-week positive psychological intervention participants will also participate in an informal discussion to share their subjective thoughts regarding program content with recommendations for improvement.

2.8. Data analytic plan

2.8.1. Data management

Data will be collected using a laptop computer with direct input using the Research Electronic Data Capture (REDCap™) system. REDCap™ is a secure web-based application used to deliver survey instruments for research purposes, with multiple tools built-in to facilitate data collection and improve overall accuracy of amassed information, e.g., value input restrictions, direct export into statistical software. Data collected via REDCap™ will be downloaded and stored in a password-protected server at the University of Illinois at Urbana-Champaign. After data is exported for use into SAS (9.4) software, we will run analytic checks to identify any outliers, duplicates, or other errors in data capture that can appear when working with complex databases that collect information across multiple points in time. We will develop a protocol to secure missing data directly from enrollees as well as procedures for multiple imputation should missing data pose a risk for analytical bias.

2.8.2. Power analysis and sample size

We estimated the number of church sites (cluster level-1) needed assuming an intra-cluster correlation of 0.025 with random assignment to two groups, e.g., treatment vs. wait-list control and an anticipated between-group mean systolic blood pressure difference of 6 mmHg [21,38]. Church pairs matched by location and membership size will be randomized to the positive psychological intervention (n = 3 churches) or to a wait-list control arm (n = 3 churches), using random allocation procedures. Randomization procedures duplicate validated methods to ensure similar resource availability across parishes, congruent church cultures, and similarities in baseline characteristics [39]. Assuming a between-subjects standard deviation for systolic blood pressure of 12 mmHg [21], a two-tailed type I error of 0.10 [40], and an attrition rate of 20%, we will need to enroll 21 participants per church at baseline to have 80% power to detect a difference of this magnitude or larger, using a two-independent sample *t*-test. This is congruent with the requirement of at least 144 individual BP measurements per treatment arm. Note, a liberal alpha is proposed given deployment of a Phase II clinical trial, which derives a reasonable error rate when applying statistical considerations and when initially exploring benefits of the intervention (See Schoenfeld [40]).

2.8.3. Hypothesis testing

2.8.3.1. Aim 1 hypothesis. Blood pressure control (sitting BP and 24-h ambulatory blood pressure readings) will be greater among Hispanic/Latino adults in the intervention arm (vs. the wait-list control group) immediately post-intervention (8-weeks) and at 12-weeks.

Bivariate analyses will be used to compare participants of the treatment vs. control arms on baseline characteristics to ensure statistical balance at the outset; evident differences will inform covariates when performing subsequent inferential statistics. The primary outcomes are sitting BP and 24-h ambulatory BP, with mean values for systolic BP and diastolic BP computed for the intervention and attention control conditions. We will implement an intention-to-treat approach. Multiple imputation procedures will be used across missing values to ensure inclusion of all observations, particularly those resulting from participants who withdraw or are lost to follow up, or do not complete all assessments, such as Independent samples t-tests will be performed using 8-week systolic BP and diastolic BP as the dependent variables with treatment condition serving as the grouping variable. Other model-based approaches to handle missing data, such as weighted estimating equations, will be implemented [41]. We will also use mixed effects models to compare changes in BP between the control and intervention arms as measured at baseline, 8 weeks, and 12 weeks. The independent variables include a time variable t (t = 0, 8, 12), a dummy variable N (N = 1 if PP intervention group; N = 0 if attention control), and cross-product term t X N. Models will account for clustering at the church level. For ambulatory data collected across a 24-h period, sensitivity analyses will compare mean overall daytime versus nighttime values of BP. All data analysis will be conducted using SAS 9.4 software (SAS Institute, Cary, NC). Note, a liberal p-value of 0.10 will be implemented when testing the null hypothesis given implementation of a Phase II trial and as per Schoenfeld (1980) [40].

2.8.3.2. Aim 2a Hypotheses. Significantly higher scores for psychological well-being and greater engagement in healthful behaviors will be evident at 8-weeks for the "*¡Alegrate!*" group compared to those in the wait-list control arm. Furthermore, psychological well-being and health behaviors will serve as intermediates through which "*¡Alegrate!*" impacts blood pressure control.

Similar analytic techniques will be implemented for Aim 2 Hypotheses as used for Aim 1. The interaction of Group x Time will test if greater improvements are evident for psychological well-being and engagement in healthful behavior (e.g., diet and Fitbit data) at 8-weeks post-baseline for the treatment arm as compared to the wait-list control group. RM-ANOVA will also be used to examine whether the "*¡Alegrate!*" intervention is associated with greater improvements in psychological well-being and engagement in healthful behavior. In addition to reporting nominal p-values, we will document the number of tests conducted and associated Bonferroni correction. When analyzing actigraphy data derived from Fitbit monitoring, we will use average 24-h activity counts for the week of baseline monitoring and average 24-h activity counts for the week following treatment. Finally, we will conduct mediation analysis to test whether psychological well-being and health behaviors serve as intermediates (or mediators) through which "*¡Alegrate!*" impacts blood pressure control.

2.8.3.3. Aim 2b Hypotheses. Participants in "*¡Alegrate!*" will have lower levels of chronic inflammation (i.e., high-sensitivity C-reactive protein) at 8-weeks post-baseline compared to those in the wait-list control arm. Moreover, the mechanism through which "¡Alegrate!" influences blood pressure will involve reductions in chronic inflammation.

Similar analytic techniques as previously described will be used when testing intervention effects on chronic inflammation. Specifically, the term capturing Group × Time interaction will test whether lower levels of inflammation are evident at 8-weeks post-baseline for the intervention group vs. the wait-list control arm. Assuming positive and significant intervention effects, mediation analysis will also be conducted to test whether chronic inflammation is involved in the pathway through which "¡*Alegrate*!" positively impacts blood pressure control.

3. Limitations and challenges

The current study will address an important and clinically significant gap in the literature though its investigation of whether an intervention to boost emotional well-being in Hispanic/Latino adults results in therapeutic benefits for blood pressure control. Notwithstanding the scientific contributions to be made, a few limitations need to be acknowledged. First, the setting of the current study is limited to the Chicagoland area which is an urban setting that will likely include a large proportion of adults identifying Mexico as their country of origin. This can limit generalizability and may merit future studies that are multisite and that include a more heterogeneous distribution of Hispanics/Latinos, e.g., rural areas, Latin American heritage. Second, our design includes a wait-list control arm that may not adequately adjust for effects derived from social support and in-person contact as imparted in the treatment group. Third, it is possible that cluster-randomization will lead to significant differences at baseline on demographic variables between those in the treatment versus control arms. Although we have attempted to match church sites based on location and membership size, it will be important to control for any marked differences across intervention arms when examining intervention effects. Fourth, recruitment and retention may prove challenging, particularly as we are targeting an underserved community with hypertension and who may be disproportionately composed of older adults. Elevated rates of attrition in older adults is reportedly a consequence of weather conditions, neighborhood walkability, and medical comorbidities [42]. We will, however, implement multiple evidence-based strategies to enhance recruitment and retention, e.g., offering no-cost blood pressure screenings, mailing post-card reminders, and holding raffles. We are also targeting church sites largely attended by Hispanic/Latino parishioners and who often hold 3–4 Spanish-language masses every Sunday. Finally, generalizability (and potentially power) may be affected by selective enrollment if those attracted to our positive psychological intervention have high levels of well-being from the outset, thus, making them more accessible and enthusiastic participants. On the opposite spectrum, those experiencing psychological distress may be more open to joining an intervention aimed at boosting their emotional well-being as led by a trained clinician.

4. Discussion

The "¡*Alegrate*!" clinical trial is a critical step in developing and deploying an evidence-based therapeutic intervention that is feasible, enjoyable, and cost-effective. It also has potential to positively impact cardiovascular health profiles of Hispanic/Latino adults, particularly when it comes to blood pressure control. Hispanic/Latino adults continue to be a rapidly growing segment of the U.S. population and they experience widening health disparities and overall poor cardiovascular health [5]. For instance, it is projected that by 2050 approximately 1 in 3 U.S. Hispanics/Latinos will have diabetes [43]. One potential avenue to mitigate incident CVD-events and to preserve cardiovascular health is by targeting profiles of emotional well-being. Indeed, the recent literature identifies a plethora of observational studies, both cross-sectional and longitudinal, that document the cardioprotective influence of well-being attributes including optimism, happiness, positive emotion, and life meaning and purpose among others [2,3]. There is suggestive evidence, however, that ethnic minorities experience lower subjective well-being when compared to dominant cultural groups and that they are less likely to maintain favorable CVH profiles over time as compared to peers of European ancestry [44]. We have yet to test, however, whether specifically targeting improvement in emotional well-being translates to physiological benefits in the form of favorable blood pressure control and overall maintenance of CVH.

Thus, the current cluster-randomized trial seeks to test efficacy of a culturally adapted psychosocial intervention that directly seeks to cultivate positive psychological assets among Hispanic/Latino adults. Hispanic/Latinos are a vital population for such work due to an overwhelming need for interventions to improve cardiovascular health and evidence that emotional well-being may be a particularly relevant target [3,45]. This is especially true within the context of a cultural group that values building positive emotional bonds and encourages collectivism [46], and yet continues to experience widening cardiac-related health disparities [5]. Development of psychosocial interventions has overwhelmingly been informed by theories that draw heavily from Western-centric perspectives [47] especially those directly targeting improvements of psychological assets [48,49]. This neglects culturally bound frameworks. Culture may impact the efficacy of positive psychological interventions in a variety of ways including altering people's interpretation, performance, or benefits from specific intervention strategies [50]. Cultural adaptations in interventions can include efforts to make interventions more accessible, selecting particular modalities on the basis of a group's culture, or using cultural elements to modify traditional treatment elements [51]. Targeted approaches that incorporate social and cultural adaptations are needed as these may result in greater adherence, enjoyment, and superior gains across targeted behaviors.

Our primary aim is to determine intervention effects on blood pressure control, but we are careful to include assessment of numerous elements hypothesized to form part of the causal pathway between emotion and health [3]. First, we measure emotional well-being because the skillsets imparted during weekly sessions are known to enhance life satisfaction, positive emotion, and overall well-being. We speculate that proliferation of these well-being attributes imparts direct physiological benefits that are therapeutic in nature and that positively impact neurotransmitter and hormone activity and affects overall metabolic function. As such, our staff collects serum blood samples during clinic visits to assess levels of C-reactive protein which is a circulating inflammatory marker highly predictive of CVD risk [52]. Second, we posit that indirect effects on blood pressure control are a consequence of positive influences across health behaviors. Available evidence in both healthy populations and those with existing chronic illness, links favorable psychological well-being with enhanced exercise regularity, smoking abstinence [53], a healthier diet [54–56], and increased medication regimen adherence. In our current trial we assess diet, smoking patterns, and sleep via self-report and additionally have participants wear a Fitbit™ monitor over a 7-day period to objectively capture physical activity. Finally, we measure culturally relevant constructs that plausibly modify effects of our psychosocial intervention. This includes social support from family and friends, nativity status, and acculturation among others.

To date, we have developed the first Spanish-language positive psychological intervention directly targeted at Hispanic/Latino adults residing in the US. Our intervention content derives from previously validated curricula with tailoring informed by qualitative work in which our research group conducted focus groups to learn how Hispanics/Latinos conceptualize happiness and well-being [16]. We then tested our newly designed curriculum using a non-experimental design. Specifically, pilot testing of our "¡*Alegrate*!" intervention using a single group pre-post design evidenced robust feasibility and facilitated derivation of strategies to enhance tailoring and increase overall retention [12]. Specifically, 11 of 19 Hispanic/Latino adults completed the 8-week pilot for a 57.89% retention rate, with a majority of factors

that led to drop out unrelated to program content or mode of delivery. Most participants felt satisfied overall with each session (97.1%). Largest increases relative to baseline after receiving the intervention were found in engagement in happiness-inducing behaviors (e.g., meditation), emotionality vitality, and subjective happiness. These promising results were the impetus to further test our positive psychological intervention using more robust methodology.

If the following efficacy trial proves successful, a larger effectiveness study may follow that extends and adapts "¡*Alegrate*!" to other racial/ethnic groups, divergent settings, and more real-world settings such as healthcare clinics. It may also offer the impetus to transfer our intervention content into more easily disseminatable formats using web-based tools. A future effectiveness trial can further inform replicability, cost-effectiveness, and potential modifications needed when implemented under less rigorous procedures.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100348.

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