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C.E.R.E.B.R.O.: A home-based physical activity study for older Latino adults

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ABSTRACT

Background: The growing Latino population is 1.5 times more likely to develop Alzheimer's Disease (AD) and Related Dementias (ADRD) than non-Latino Whites. Interventions that can reduce the risk of ADRD are needed. Older Latinos face many barriers to the incorporation of physical activity (PA) into their daily lives given a lack social support, caregiving responsibilities, and lacking resources to maintain PA. Walking and dancing are the two most frequently reported forms of PA among older Latinos, and indoor PA programs conducted in a community location or at home can overcome barriers to participation.

Methods: C.E.R.E.B.R.O. (Cognitive Enhancement and Risk-reduction through Exercise for Brain-Related Outcomes; meaning "brain" in English) is testing two remote intervention programs, the BAILAMOS™ dance program and ¡En Forma y Fuerte! (Fit & Strong!), a PA/behavior change program. Participants are randomly assigned to either study condition. The BAILAMOS™ dance program is a 6-month long dance program, in which participants learn different Latin dances including Merengue, Cha Cha Cha, Bachata, Salsa, Cumbia, and Kizomba. Trained CEREBRO staff also lead monthly discussions. Persons randomized to the 3-month long ¡En Forma y Fuerte! program participate in flexibility and aerobic exercise, strength training, and health education. All classes are held live via Zoom. Trained study staff assist participants with technology-related issues. Data are collected through remote testing at baseline, 12 weeks, and 24 weeks after the start of the interventions. Outcomes include PA, cognition, quality of life, social connectedness, and cost-effectiveness.

Conclusion: CEREBRO has the potential to provide evidence regarding the advantages of providing remote intervention programs to reduce PA barriers in the older Latino community.

1. Introduction and background

By 2050, 20 % of older the population in the U.S will be comprised of Latinos. Unfortunately, the health of many older Latinos is poor [1] and Latinos have twice the incidence of Alzheimer's disease (AD) [2] compared to non-Latino Whites. Pharmacological treatments available for cognitive decline and Alzheimer's disease and related dementias (ADRD) have shown limited effectiveness reducing cognitive and functional decline. Participation in regular physical activity (PA) can mitigate risks for these outcomes [3] a broad range of studies including animal models [4–7], exercise interventions targeting cognitive performance [8,9], and fitness correlations observed with preserved brain

structure [10,11] support the hypothesis that PA protects against cognitive decline. However, Latinos have the lowest leisure time PA rates among ethnic/racial group [12]. Unfortunately, many Latinos face barriers (e.g., lack social support, have caregiving responsibilities, lack resources) that make it difficult for them to incorporate PA into their daily activity [13]. Thus, the establishment of scalable PA interventions are needed.

Walking and dancing have been mentioned as the only ageappropriate PA for older Latina women [14] and are the two most frequently reported forms of PA among older Latino [15]. We propose that indoor PA programs conducted in a community location or at home can overcome significant barriers to participation.

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Latin dance is a type of PA that is culturally acceptable to older Latino adults. Dance is a form of PA that can also be adapted to different populations, ages, and physical limitations. Dance is an important form of socialization and leisure in Latin cultures [16] that also challenges individuals physically and cognitively. The limited literature on the health effects of dance for older adults indicates that dance can significantly improve lower extremity function and balance [17]. Dance also requires individuals to plan, monitor and execute a sequence of goal-directed complex actions, potentially making it ideal for preventing cognitive decline in executive function.

However, PA interventions have not included dance programs specifically for Latinos, a historically excluded population at high risk of cognitive impairment. Given the need to address health inequities in Latinos, the BAILAMOSTM (Balance and Activity In Latinos, Addressing Mobility in Older Adults) dance program was created as a Spanishlanguage, Latin dance program. Program outcomes from pilot trials and randomized controlled trials have included improvement in PA, physical function and cognition [18–20].

Participation in traditional exercise is less common amongst older Latinos, but some programs have been adapted for Latinos. Fit & Strong! for older adults with arthritis is recognized as a top tier evidence-based PA/behavior change program for older adults by the National Council on Aging as a result of the efficacy and effectiveness trials in support of it. It has demonstrated significant benefits on PA, self-efficacy for exercise, pain, and joint stiffness as well as improved lower extremity strength and mobility among older non-Latino adults with osteoarthritis [21]. Based on the success of this program and the need for programs for the Latino community, ¡En Forma y Fuerte!, an adaptation of Fit & Strong! for Latinos with arthritis, was developed and evaluated for feasibility in a small study that enrolled older Latinos in Chicago and Phoenix [22].

The current research responded to the funder's request to implement promising, evidence-informed interventions and solutions to reduce risk for dementia and improve quality of life for persons with symptoms of cognitive decline. Cost-effectiveness of such interventions is also of value, as we can learn about the costs of a program relative to the health benefits achieved. If a program does not cost much to implement, yet has positive health benefits, then a decision could be made to implement it. Positive improvements in cognition can be impacted in short-term PA interventions as short as three months in duration [8]. As such, it tests the short-term impact of two evidence-based interventions for older Latinos that were developed by the authors. C.E.R.E.B.R.O. (Cognitive Enhancement and Risk-reduction through Exercise for Brain-Related Outcomes; meaning "brain" in English) is conducting a 6-month RCT comparing BAILAMOSTM @home/en casa and ¡En Forma y Fuerte! @home/en casa among older Latino adults with symptoms of cognitive decline at baseline (see Fig. 1).

Aim 1a is to demonstrate feasibility and intervention adherence and safety through benchmarks. It is hypothezied that feasibility will be achived by: (1) feasibility of recruitment and retention—100 participants

enrolled and >75 % retained at year 2 end; (2) intervention adherence - \geq 75 % participants with \geq 80 % of intervention sessions completed across waves; (3) safety - zero unexpected adverse events (AEs) that are serious and study related. Means, standard deviations, proportions, and frequencies will be used to measure feasibility. Aim 1b is to examine PA, cognition, quality of life, and social connectedness in those randomized to ¡En Forma y Fuerte! @home/en casa compared to those in BAILA-MOSTM @home/en casa program. We hypothesize that participants in ¡En Forma y Fuerte! @home/en casa will show comparable improvements in self-reported and accelerometer-assessed PA, cognition, quality of life, and social connectedness compared to the BAILAMOSTM @home/ en casa program. Aim 2 is to assess the cost-effectiveness of these remote PA interventions based on time logs and using wage rates to approximate costs from a provider perspective. It is hypothesized that both interventions, ¡En Forma y Fuerte! @home/en casa and BAILAMOS™ @home/en casa, will be cost-effective.

1.1. Study designs and methods

This study is a feasibility and comparative effectiveness RCT (not meant to be fully powered) with randomization at the level of the individual to the BAILAMOSTM dance program @home/en casa (6-month program) or <code>¡En Forma y Fuerte!</code> @home/en casa (3-month program). This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Institutional ethics approval was received for this study, and informed consent was obtained from participants. The trial has been registered with clinicaltrials.gov, ID NCT05588778.

1.2. Target population/sample

Inclusion criteria include: (1) age \geq 60 years old; (2) selfidentification as Latino/Hispanic; (3) ability to speak Spanish; (4) participation in ≤2 day/week of aerobic exercise; (5) mild cognitive impairment indicated by scores on the Montreal Cognitive Assessment (MoCA) [23] of ≥18 and < 25 or subjective memory complaints determined by a response of "Very often," "Often," or "Sometimes" (not "Rarely" or "Never") to the following question of the Rush Alzheimer's Disease Center: About how often do you have trouble remembering things?; (6) danced <2 times/month over the past 12 months; (7) willingness to be randomly assigned to either study group; (8) no plans to leave the country for more than two consecutive weeks over the next 6 months. Exclusion criteria include needing a caregiver for daily functioning, self-reported presence of uncontrolled cardiovascular disease or uncontrolled diabetes mellitus, pacemaker in situ, stroke, severe chronic obstructive pulmonary disease (COPD), and recent healing or unhealed fracture(s).

The Exercise Assessment and Screening for You (EASY) is used to screen participant risk for PA [24] engagement The EASY has clear recommendations for when evaluation by a physician is needed before

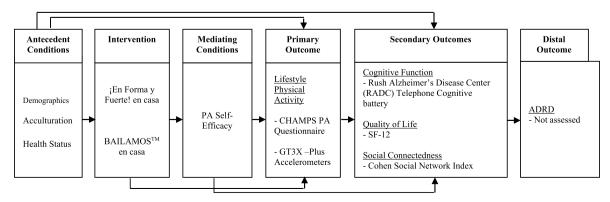


Fig. 1. Conceptual model.

beginning a PA program (e.g., when the individual reports new-onset shortness of breath, pain, or dizziness that has not been previously evaluated by a health care provider), and we follow these recommendations. The EASY also asks if they fall, feel unsteady, or use an assistive device while standing or walking. If they respond Yes because they fall or always use assistive device, then they are ineligible. If they respond Yes because they report unsteadiness while standing or walking, then they must get medical clearance before they can participate.

Power analysis and Sample size. This study is meant to assess the potential capacity of two evidence-based interventions to reduce risk for ADRD and improve quality of life for persons with symptoms of cognitive decline. The study is not intended to be a fully powered RCT. Sample size (N=100) was determined by the investigators' previous experience in running the two interventions, with feasible recruitment of 100 participants per 12-months of recruitment, which fit within the two-year total time frame available from the funding.

1.3. Recruitment

Participants are being recruited from the Chicago area using established relationships developed by the Principal Investigator who has been working with Chicago Latino communities since 2007. Two waves of the study interventions are expected. Recruitment is primarily led by a community liaison and qualified and trained research staff and is done through virtual and local presentations at group functions, coalition meetings, hospitals, churches, word of mouth, distribution of flyers to community partners, and presence at senior and health fairs. In short, for individual meetings, the PI, community liaison or qualified and trained research staff would set up a meeting and confirm acceptable recruitment activities with that community partner. Despite the study and all research-related procedures being fully remote, the majority of participant recruitment is being done in-person. When an individual expressed interest, they would sign an IRB-approved form allowing the study team to contact them to tell them more about the study and do screening, if interested.

1.4. Randomization

Older Latinos who qualify for the study are randomly assigned to the BAILAMOS $^{\text{\tiny TM}}$ dance program @home/en casa or the $_{i}$ En Forma y Fuerte! @home/en casa program in a comparative effectiveness trial design. Randomization is performed using the Research Electronic Data Capture (REDCap) randomization module. A 1:1 randomization ratio is used, with no blocking or stratification.

1.5. Protocol

All testing is done remotely. Data collection research staff are blinded to participants' research condition. After participants are deemed eligible, they are scheduled for a baseline assessment via telephone at which a staff member explains the study and reads the Informed Consent. After participants agree to participate, they sign the Informed Consent electronically using the e-consent function on REDCap. To econsent, participants are sent a personalized link of their Informed Consent document via text message or email. Participants are able to electronically sign by (1) signing their name with their finger on their smartphone or (2) signing their name with their computer mouse. After e-signing, participants receive a copy of the downloaded signed consent form in PDF format. Participants with low technology literacy were provided with verbal guidance and assistance over the phone. Study team members guided the participant through the e-consent steps, which included (1) opening their personalized link, (2) electronically signing and dating their Informed Consent document, and (3) hitting submit. When possible, participants were also asked to complete the informed consent with the assistance of a family member or friend at home. Questionnaires and measures (in Spanish or English) are then

administered. Participants must be able to speak/understand Spanish to be eligible for the study; however, some participants may prefer to use questionnaires in English. Based upon our team's experience the consent and administration of the questionnaires takes about 90–120 min. Participants are compensated with \$15 for their participation in each assessment. Testing is conducted with both study groups at baseline, 12-weeks (3-months), and 24 weeks (6-months) after the beginning of the intervention.

Posttest questionnaires and tests are administered in the same order as baseline testing. Completion of testing at the different data collection timepoints is expected to require less than 3 weeks at all timepoints.

1.6. BAILAMOSTM dance program

The BAILAMOSTM dance program originally encompassed four dance styles: Merengue, Cha Cha Cha, Bachata, and Salsa, generally considered amongst the most popular in terms of recognition and preference. We have added two styles for the current trial to appeal to the largely Mexican-origin Latinos in Chicago (i.e., Cumbia and Kizomba). BAILAMOSTM runs for 24 weeks, two times per week for 60 min per session Additional details of the program can be found elsewhere [25]. Specific modifications for remote delivery via Zoom include the following: 1) adapting dance programming to remove partner dancing, 2) developing a technical assistance plan for before and during delivery of the remote interventions, 3) developing a participant safety protocol, and 4) mailing of study materials.

Throughout the program the instructor emphasizes increasing household and transportation PA in addition to the dance program. Monthly discussion sessions, done the hour before the dancing session, are delivered by a research team member with expertise in PA. The discussion sessions utilize a Social Cognitive Framework, and focus on increasing knowledge, outcome expectations, social support, and self-efficacy in order to increase lifestyle PA. The sequencing of dance styles was determined by level of difficulty to enhance self-efficacy through mastery and accomplishment. Self-efficacy is also increased through participants having vicarious experiences via social modeling. Consistent verbal encouragement also contributes to increased self-efficacy. In addition to monthly discussion sessions, 5-min icebreaker questions were incorporated to the beginning of each class session to facilite socialization among study participants.

1.7. Fit & Strong!/¡En Forma y Fuerte!

Fit & Strong! was developed to break the chain between presence of joint impairment in lower extremity weight bearing joints and development of disability among older adults with OA [26]. Given the noted growing number of older Latinos in the US, and that Latinos consistently report higher rates of arthritis-related activity limitations compared to non-Latino White individuals [27], adaptations were made to the original Fit & Strong! program. ¡En Forma y Fuerte!, the Hispanic version of Fit & Strong!, was tested with groups of older Latino adults at sites in Chicago, IL and Phoenix, AZ. Fit & Strong! @Home is a synchronous, live-streamed version of the program that enables instructors to observe class participants in real time. The classes meet 2 times per week for 12 weeks for 90 min per session. Each class consists of 60 min of exercise and 30 min of health education. The exercise portion includes 10 min of warm-up and cool-down exercises, 20 min of low-intensity aerobic exercises, and 20 min of lower extremity strengthening. The exercises are progressive in nature and tailored to individual capabilities. The group health education component uses a structured curriculum. These health education lesson plans aim to build self efficacy for PA. PA is encouraged outside of the class sessions, but it is not prescribed. Additional details of the program can be found elsewhere [28].

The impact of the online version via Zoom has not been tested nor has the program been tested with participants with cognitive impairment. Thus the CEREBRO trial is expected to provide rich data on the comparative uptake and potential of both the BAILAMOS $^{\text{TM}}$ and Fit & Strong at home programs via Zoom to mitigate cognitive decline.

1.8. Technical Support

Sessions for both study groups are held live via Zoom. Participants who do not own a device, like a computer or tablet with a webcam, receive a study-provided tablet. Before either program begins, research team members schedule one-on-one sessions with study participants to introduce them to the Zoom platform (and their study-provided tablet for those that receive one) and important features that they are likely to use (e.g., turning their microphone on and off) during a live dance or exercise session. Research team members also developed hard copy instructions that are mailed to study participants before their programs begin. These paper guides provided step-by-step instructions for performing the tasks (e.g., logging into a Zoom room) that are covered in the one-on-one time with study team members. Once both programs begin, two research team members are present at each live Zoom session to provide technical assistance to program instructors and participants. Research team members are available to call participants directly via telephone if they require additional support.

1.9. Safety protocol

Study participants are asked to identify a space inside their homes where they can comfortably participate. Participants are asked to clear a space where they can take a couple of steps in each direction that is free of tripping hazards like carpets and rugs. Participants are also asked to participate in their chosen household spot throughout the length of the program and to keep their cameras on during class. Throughout the programs, participants are reminded to wear appropriate shoes for class and the importance of moving at their own pace. In the case of a fall or adverse event, a research team member evaluates the situation and contacts emergency services and the emergency contact that was provided by the study participant at enrollment.

Study procedures are completed remotely; therefore, study materials are mailed to participants' homes via the United States Postal Service (USPS). Self-addressed stamped return envelopes are included for any material that needed to be returned to the research team, like the class logs.

1.10. Sample retention

Strategies previously used successfully by Drs. Marquez (PI) and Hughes (Co-I) will be used to retain participants. Strategies incorporate the following: (1) clearly communicating the intervention schedule and data-collection times; (2) scheduling convenient day, evening, and weekend appointments for remote data collection; (3) providing reminder calls for data-collection appointments; (4) requesting designation of a family member or friend who can be called when participants cannot be reached; (5) providing compensation for participation in testing; (6) taking attendance at each class; and (7) research staff calls to participants who miss class sessions.

1.11. Study fidelity

The Behavior Change Consortium's model of treatment fidelity is used to monitor the reliability and validity of the intervention [29].

Staff and Training. Dr. Marquez (PI) trains the hired bilingual/bicultural Project Coordinator and research assistants prior to the start of data collection. Training is in research responsibilities including recruiting participants, screening participants, and administering questionnaires in Spanish and English. This training includes general orientation to the design and purpose of the study, instructions for conducting initial contacts, item-by-item reviews of the questionnaires, practice interviews, and use of accelerometers (initialization and downloading of

data). Trained staff from the Rush Alzheimer's Disease Center conduct cognitive measures training and determine when staff are prepared to deliver the measures.

Delivery of the intervention. Members of the study team will join remote classes monthly to observe instructors, or will watch recordings of the classes. The detailed class-by-class schedule of each program will ensure that classes cover the same material at the same timepoint of the intervention. Observation of classes will be conducted by individuals familiar with the respective programs who will use a modified Implementation Checklist developed and tested by Dr. Hughes (Co-I) for Fit and Strong!

Receipt of intervention. Participants will complete a program evaluation survey. This survey includes items on satisfaction with the instructor, the timing and location of the class, and overall satisfaction with the program. It is administered at the end of the program. The number of sessions attended and program completion will also be assessed as measures of receipt of intervention.

1.12. Measures

The measures to be administered at three timepoints in both study groups are described below. All have been previously used by our research team in Spanish and English. Assessments will be administered interview-style to reduce participant burden and literacy concerns.

1.12.1. Antecedent variables

- <u>Demographics</u> Information about age, sex, education, income, marital status, cultural heritage/country of origin, race, ethnicity, preferred language, and number of children is assessed.
- 2. <u>Acculturation</u> The Short Acculturation Scale for Hispanics (SASH) that assesses acculturation, familism, ethnic identity, religious behaviors, and perceived discrimination is used [30] as a descriptive variable about the sample so that researchers can compare the acculturation levels of our sample to their samples.
- 3. <u>Health history/status</u> A brief survey will elicit standard items about participants' health history. Current health is measured with the single-item global self-reported health question from the BRFSS [31].

1.12.2. Intervention variables

- Intervention attendance Attendance at each session will be recorded as the number of classes conducted (24 or 48, respectively) divided by number of days attended.
- Intervention engagement Individual participant logs will record number of minutes of dance or exercise, Ratings of Perceived Exertion [32], Feeling Scale [33], and enjoyment of the session.

1.12.3. Mediator variable

1. <u>Physical Activity Self-Efficacy Scale</u> [34] assesses participants' beliefs in their ability to be physically active over incremental week periods. We will calculate an efficacy score by summing all given response scores and dividing by the total number of items. The range of this score is 0–100. This measure is valid and reliable [35].

1.12.4. Intervention feasibility

<u>Feasibility of recruitment and retention</u>. Feasibility is defined as ability to enroll a total of 100 participants with \geq 75 % retention in the respective programs.

 $\underline{Intervention\ attendance} \ - \ Feasibility\ is\ defined\ as \ge 75\ \%\ participants$ who complete $\ge 80\ \%$ of intervention sessions across waves.

<u>Safety</u>. Feasibility is defined as zero unexpected adverse events (AEs) that are serious and study related.

1.12.5. Outcomes

1.12.5.1. Lifestyle PA.

- Self-Report PA The CHAMPS Physical Activity Questionnaire for Older Adults [36] is a change-sensitive PA scale that assesses weekly frequency and duration of lifestyle PA (leisure time, household, occupational, and transportation PA) typically undertaken by older adults. The CHAMPS has been translated into Spanish and employed with older Latino adults [37], and has adequate validity and reliability [38].
- 2. Device-assessed PA ActiGraph Model GT3X-Plus accelerometers (The Actigraph, Pensacola, FL) are small and lightweight triaxial waist-worn accelerometers. ActiGraph accelerometers provide valid assessments of lifestyle PA in men and women [39,40]. Time spent in light, moderate or vigorous intensity PA [41] will be assessed. We will include participants in the analysis whose accelerometer displays at least 10 h of data (>0 count values for each hour) in a 24-h period on at least 4 days.3. Cognition: Neuropsychological measures of executive function, attention, episodic memory, processing speed and working memory from the from the Rush Alzheimer's Disease Center (RADC) Telephone Cognitive battery [42] are used. Tests include: East Boston Memory Test (Immediate), Category Fluency, East Boston Memory Test (Delayed Recall), Digit Span Forward/Backward, BDAE Complex Ideational Material, and Digit Ordering. These measures can be administered remotely over the phone and have been used by key personnel on our team.
- 4. Quality of life: The SF-12 scale consists of 12 items and the composite physical (PCS) and mental health (MCS) scores are computed using the scores of the 12 items, ranging from 0 to 100, where zero reflects the lowest health level and 100 the highest level [43].
- 5. <u>Social connectedness</u>: Social connectedness is assessed with Cohen's Social Network Index [44] a 12-item questionnaire that assesses participation in 12 types of social relationships including spouse, parents, friends, family members, etc. A brief version is being used in the HCHS/SOL study with Latinos in English and Spanish.
- 6. Cost Effectiveness Measures and Analysis: We will directly measure and assess the costs of running the BAILAMOS™ @home/en casa and the ¡En Forma y Fuerte! @home/en casa interventions based on time logs and using wage rates to approximate costs from a provider

Table 1 Cost analysis.

Cost Analysis Components			
Personnel Time	Participant Time	Costs of Programs/ Differences in Cost	Additional Costs
Time spent interacting with participants (hours) • Recorded weekly Time spent in meetings (hours) Time spent solving participant-related concerns (hours)	Time spent by study participants in the BAILAMOS™ intervention group Time spent by study participants in the ¡En Forma y Fuerte! intervention group	Differences in per participant costs will be combined with differences in average per person effects to assess incremental cost effectiveness of BAILAMOS TM compared to ¡En Forma y Fuerte!	Training Costs Instructor Training Material Costs Mailing Participant Materials for Interventions

perspective (See Table 1). Specifically, hours spent interacting with participants will be recorded weekly in each of the study arms along with any other meetings needed to meet and solve any participant related concerns. Actual wages of the personnel involved in the interventions, as well as US average wages for similar occupational titles from the US bureau of labor statistics will be considered. Sensitivity analyses with other occupational titles that could potentially run the intervention will also be conducted. Further, we will include a societal perspective cost analysis that includes the time spent by the participants on the different interventions. Here, time will be captured via time logs of the programs along with the number of participants participating. To convert participant time to costs, average US wages will be used. We will conduct sensitivity analyses using the 25th and 75th quartile of wages according to https://www.bls.gov/oes/current/oes_nat.htm.

Aside from personnel and participant time, the costs of running the interventions are anticipated to be about the same. Differences found across the intervention arms in per participant costs will be combined with differences in average per person effects to assess the incremental cost effectiveness of BAILAMOSTM @home/en casa as compared to <code>¡En Forma y Fuerte!</code> @home/en casa using (separately) the average levels of the primary outcomes. Specifically, the ratio of (C_B - C_{EFF} -) and (E_B - E_{EFF}) where C_B represents costs of the BAILAMOSTM program and E_B the effects measured using (separately) the primary outcomes and analogously for C_{EFF} and E_{EFF} for <code>¡En Forma y Fuerte!</code> will be measured from both a health provider and societal perspective and variance in those estimates examined in sensitivity analyses. In addition, the costs of setting up each of the interventions in terms of training and materials will be measured.

1.13. Evaluation plan/performance measurement

Data management. As participants provide answers to questions, the data collector/research assistant will enter the data into UIC-secure REDcap forms. All missing data will be flagged and routines will be developed for imputations of missing data where the proportion of missing data is small. More complex imputation strategies will be developed if warranted.

1.14. Data analysis

Standard descriptive statistics will be calculated for all demographic, clinical, and acculturation variables. Descriptive statistics will also be used to assess completeness of study data, normality of outcome measures, and to identify potential covariate imbalances between study arms.

For each dependent variable, we will use linear mixed model to examine the difference between <code>¡En Forma y Fuerte!</code> @home/en casa and BAILAMOSTM @home/en casa groups adjusting for potential covariates (e.g., age). We will build the upper-bound of the two-sided confidence interval for the group indicator (1: BAILAMOSTM @home/en casa, 0: <code>¡En Forma y Fuerte!</code> @home/en casa) to examine if the effect of <code>¡En Forma y Fuerte!</code> @home/en casa is not inferior to the effect of BAILAMOSTM @home/en casa. For each dependent variable, we will test if the mediating condition for PA self-efficacy scale is different between two groups [45].

For the primary analysis, we will initially adopt an "intention to treat," modality with exclusion of cases with missing outcomes data at any session. In addition, we will use multiple imputation of missing values if data are missing at random. If data are not missing at random, we will conduct exit interviews to obtain the reason for study dropout and conduct sensitivity analyses based on the assumed missing mechanism.

1.15. Dissemination and implementation plan

Throughout the two years of funding for this project, we will share all results, findings, reports, products or processes developed under this cooperative agreement with CDC. We plan to partner with UsAgainstAlzheimer's CDC-funded Center for Brain Health Equity to translate SIP learnings into culturally tailored public health messages that will be disseminated through the Center's robust distribution channels, including its online and phone-based platform BrainGuide, available in Spanish and English, that empowers people with knowledge and resources to take the best next steps in managing their own or a loved one's brain health.

1.16. Translation plan

Our study team of co-investigators and consultants have extensive experience translating programs into scalable interventions. We will work with them and other key stakeholders whom we identify over the course of the project to develop strategies to facilitate the widescale dissemination of <code>¡En Forma y Fuerte! @home/en casa</code> and <code>BAILAMOSTM @home/en casa</code>. We will also develop recommendations for CDC and others to identify appropriate target audiences and strategies for reaching Latinos with cognitive complaints with evidence-based programs.

2. Discussion

It is well established that engaging in regular PA is beneficial for the mind and body, yet older Latinos engage in low levels of leisure time PA. Programs that draw upon one's culture such as the BAILAMOS™ dance program and programs that have been adapted for Latinos, such as ¡En Forma y Fuerte! have been shown to increase the PA of older Latinos. The current study examines the feasibility of offering the two evidence-based programs remotely; and also compares the effectiveness of each program in increasing PA, cognition, quality of life, and social connectedness.Results of the current study can be used to determine changes or revisions that need to be made to make remote delivery more feasible so that the programs can be disseminated more broadly. Additionally, aspects of the programs might need to be revised to provide a greater dose of physical activity to generate the desired response of PA, cognition, quality of life, and social connectedness.

3. Limitations and challenges

This study is only recruiting older Latinos from the Chicago area. It is possible that Latinos in other parts of the U.S. differ from Latinos in Chicago. A multi-site effectiveness trial in urban areas around the U.S. can be proposed in the future. We do not have an assessment-only control. We believe that given the goals of the funding mechanism, comparing two evidence-informed programs makes sense. Also with community-based research, especially with underserved populations, it is potentially unethical to recruit participants for whom there would be no perceived benefits. Our data collection takes place over the phone, and it is possible that fatigue will set in for some participants. Thus, data collection can be broken into more than one phone call if needed. We expect that recruiting and retaining older Latinos with subjective memory complaints will be challenging. To meet our goals we will use our extensive networking among Latino service providers, as well as multiple strategies that have worked in previous trials conducted by our research team. Also, indoor PA programs conducted in a community location or at home can overcome significant barriers to participation, but they can also create new barriers such as technical issues and feeling uncomfortable using video conferencing. Technical support is needed to overcome these challenges. Finally, the two programs selected were of different lengths, and thus different time attention was given to the two groups. However, given that the funding request was to implement promising, evidence-informed interventions and solutions to reduce risk for dementia and improve quality of life for persons with symptoms of cognitive decline, we used the interventions as is.

Together, we think that the strengths of this study substantially outweigh the weaknesses and that the rich data that we will obtain on feasibility and outcomes from testing these cutting edge programs with this high risk population will contribute substantially to our knowledge.

CRediT authorship contribution statement

David X. Marquez: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. Mariana Tellez: Writing – review & editing, Writing - original draft, Project administration, Investigation, Data curation. Jocelyn Ocampo-Mota: Writing – review & editing, Writing – original draft, Project administration, Data curation, Michelle A. Jaldin: Writing – review & editing, Writing – original draft, Investigation. Susan Hughes: Writing - review & editing, Writing - original draft, Methodology, Investigation, Conceptualization. Olusola Ajilore: Writing - review & editing, Writing - original draft, Methodology, Investigation. Jinsong Chen: Writing - review & editing, Writing original draft, Methodology, Investigation, Conceptualization. Surrey Walton: Writing - review & editing, Writing - original draft, Methodology, Investigation, Conceptualization. Naoko Muramatsu: Writing review & editing, Writing - original draft, Methodology, Investigation.

Declaration of competing interest

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

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Data availability

No data was used for the research described in the article.

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