Research Protocol
IRB Protocol # 2012-0851
BAILA: Being Active, Increasing Latinos Healthy Aging
NCT01988233

1. Title Page

Title:
BAILA: Being Active, Increasing Latinos healthy Aging

Sponsor:
NINR/NIH

Protocol Version Number: 38

Date:
June 6, 2016

2. Study Hypotheses and Specific Aims:

1) Test the impact of the revised BAILAMOS© program on lifestyle PA at 4 months and BAILAMOS© maintenance activities on lifestyle PA maintenance at 8 months.
o Hypothesis 1: Lifestyle PA (self-reported and accelerometer-assessed) will be significantly higher in the BAILAMOS© group at 4 and 8 months compared to the control group.

2) Test the impact of the revised BAILAMOS© program at 4 months, and BAILAMOS© maintenance activities at 8 months, on self-efficacy (mediators) and on health outcomes (physical function, cognitive function, and self-reported functional limitations and disability).
o Hypothesis 2a: Self-efficacy for PA, Balance, and Gait will be significantly higher in the BAILAMOS© group at 4 and 8 months compared to the control group.
1. Self-efficacy for PA, Balance, and Gait will mediate the effect of the BAILAMOS© program on lifestyle PA and health outcomes.
o Hypothesis 2b: Physical function, cognitive function, and self-reported functional limitations and disability scores will be significantly better in the BAILAMOS© group at 4 and 8 months compared to the control group.

3. Background and Significance

Older Latinos comprised 7% of the older adult population in 2002, but are expected to constitute 20% by 2050.(1) Physical activity (PA; any body movement that results in energy expenditure) can influence potential declines in the health outcomes of physical and cognitive function that lead to functional limitations (self-reported restrictions in performance) and disability (functional limitations placed in a social context(2)). Self-efficacy (confidence in one's capabilities to successfully carry out courses of action/confidence in capabilities to exercise) is both a determinant and an outcome of PA(3) and has been shown to predict functional limitations.(4)

Unfortunately, Latinos aged 65-74 are 46% less likely to engage in leisure time PA than older non-Latino whites(5) and little is known about PA maintenance among ethnic minorities compared to non-Latino whites.(6) In part as a result of low levels of PA, the physical and cognitive function of older Latinos is poor relative to older non-Latino whites. Older Latinos are almost twice as likely to report difficulty walking than non-Latino whites and their use of assistive devices is 33% higher.(7-9) Moreover, the number of Latinos in the U.S. with Alzheimer's Disease (AD) is projected to increase by 600% in the next 50 years(10) and AD symptoms may begin seven years earlier in Latinos than in non-Latino whites.(11) Participation in PA has substantial potential to help older Latinos maintain both physical and cognitive function as they age. Walking and dancing are the two most commonly reported forms of PA among older Latinos.(12-15) However, urban older Latinos cite unsafe neighborhoods and extreme weather conditions as significant barriers to walking. Dance is a widely popular form of PA among Latinos of all ages(16, 17) and holds considerable promise as a culturally appropriate form of PA that challenges individuals both physically and cognitively. To date, PA programs designed for older Latinos are lacking. BAILAMOS© is an innovative dance program that has been developed by Dr. Marquez (PI) based on focus group input from older community-dwelling Latinos and in collaboration with an accomplished Latin dance instructor. A single group, pre-post 3-month pilot of BAILAMOS© demonstrated substantial program feasibility (only 3 of 12 participants dropped out, and participants attended 85% of the 24 sessions). Effect sizes (Cohen's d) indicated greater self-reported lifestyle PA (*accumulation of leisure time, household, occupational, and transportation PA over the entire day*)(18) (d=1.38) and greater enjoyment of PA (d=.61) following the intervention. Improvements in physical function (mobility, d=-.56; usual gait speed, d=-.10) and cognitive function (ds=.11-.12) were also seen. Now, a larger efficacy trial conducted over a longer time period is necessary to examine the intervention effects.

The original 3-month BAILAMOS© dance program has been revised according to participant and dance instructor feedback. Eight sessions (1 month) have been added to increase overall dose of PA from 24 sessions over 3 months to 32 sessions over 4 months. Also, discussion sessions covering topics related to increasing lifestyle PA were added. We propose a randomized controlled trial (RCT) to test the efficacy of the revised 4-month BAILAMOS© program for improving lifestyle PA and health outcomes (physical and cognitive function, self-reported functional limitations, disability) in sedentary older Latinos at risk for disability relative to an attention control group. We will also test whether lifestyle PA and health outcomes can be maintained over an additional 4-months through BAILAMOS© maintenance activities, which include using indigenous dance leaders. This study will use an RCT (N=166 Treatment, 166 Control) with a health education control group that will allow us to examine the adoption of PA and its impact on health outcomes (first 4 months), and the short-term maintenance of PA and its impact on health outcomes (8 months) among older Latinos.

4. Methods

a. Research Design

A randomized controlled trial (RCT) followed by a debriefing session. Participants will: (a) testing at 0, 4, 8 months and (b) take part in the dance intervention or health education condition.

b. Eligibility Criteria

Inclusion criteria include: (1) age > 55 years old; (2) self-identification as Latino/Hispanic; (3) ability to understand Spanish; (4) participation in <3 days/week of aerobic exercise; (5) at risk for disability; (6) adequate cognitive status as assessed by the Mini Mental State Examination (>14/21); (7) danced < 2 times/month over the past 12 months; (8) willingness to be randomly assigned to treatment or control group; (9) no plans to leave the country for more than two consecutive weeks over the next year; stroke survivor 1 year or more post.
At risk for disability includes the following: (a) Presence of diabetes; (b) Underweight (BMI lower than 18.5); (c) Overweight (BMI greater than 25.0) or Obese (BMI greater than 30.0); or (d) Difficulty/change with any one of the following four tasks: (1) walking a long distance (4 blocks or ½ mile), (2) climbing 10 steps, (3) transferring from a bed or chair, (4) walking a short distance on a flat surface. Two questions will be asked for each task: ''Have you had difficulty (task)'' and ''Have you changed the way you (task) or how often you do this, due to a health or physical condition?'' Older adults with difficulty/change with any one of the four tasks will be eligible for the study, similar to methods used by Weiss et al. and those used in our BAILAMOS© pilot. **Inclusion Criteria for Directors: Coordinate or oversee the day to day operations of a Senior Center where our program took place.**

Exclusion criteria include presence of uncontrolled cardiovascular (CV) disease or uncontrolled diabetes mellitus, stroke 1 year or less post, healing or unhealed fracture(s), hip or knee replacement in the last 6 months, heart failure, and had recurrent falls in the past 12 months. Also, regular use of a walker or wheelchair.

Exclusion Criteria for Director's: any individual that does not have the role of Director or Coordinator at Senior Centers where our program took place.

Participants will be administered the Exercise Assessment and Screening for You (EASY) for risk assessment during screening (Resnick et al., 2008). The EASY has recommendations for when medical clearance is needed before beginning a PA program. We will follow those recommendations, with some revisions (below). If participants need medical clearance, we will ask for participant permission for us to fax information about the study and a letter that the physician can sign and fax back to us giving permission for the participant to participate in the research. This document will assist the researcher in obtaining the required consent from his/her physician without being reliant upon the subject to remember to obtain and/or return this document.

1. Do you have pain, tightness or pressure in your chest during physical activity (walking, climbing stairs, household chores, similar activities)?

EASY recommendation:

If you answered yes to this question and this is a NEW problem, see your health care provider first before starting any exercises. Ask your health care provider "Are there any exercises that I cannot do"? Work with your doctor to identify activities that are appropriate for you.

If it is not new, or has already been evaluated, begin or continue your exercise program.

<u>Our procedure:</u>

If they answered yes to this question and this is a new problem, or one that has not been evaluated by a doctor, then they must get medical clearance first.

2. Do you currently experience dizziness or lightheadedness?

EASY recommendation:

If you answered yes, it is recommended that you talk with your health care provider before initiating a new activity program.

Ask if there are any exercises you cannot do. Work with your provider to identify exercises good for you.

Our procedure:

If they answered yes to this question, then they must get medical clearance first.

3. Have you ever been told you have high blood pressure?

EASY recommendation:

If your blood pressure has not been checked in the last 6 months, get it checked by a healthcare provider.

If you answered yes, you may continue to exercise to improve your overall heart health and prevent disease.

Our procedure:

If they answered yes to this question, and they have not had blood pressure checked within 6 months, then they must get medical clearance first.

If they answered yes to this question, and they have had blood pressure checked within 6 months, then their blood pressure must be <180/100, as per Dr. Resnick.

4. Do you have pain, stiffness or swelling that limits or prevents you from doing what you want or need to do?

EASY recommendation:

If you answered yes, continue to enjoy your exercise to prevent worsening of your arthritis and help manage your pain. If you have osteoporosis always avoid stretches that flex your spine or cause you to bend at the waist, and avoid making jerky, rapid movements.

Our procedure:

If they answered yes to this question, then we will make a note that no bending exercises should be done by the participant, should they qualify and participate. Given it is a dance program, and not an exercise program, this should not be problematic.

5. Do you fall, feel unsteady, or use an assistive device while standing or walking?

EASY recommendation:

If you answered yes, it is recommended that you talk with your health care provider before initiating a new activity program.

Ask if there are any exercises you cannot do. Work with your provider to identify exercises good for you.

Our procedure:

If they answered yes to this question because they fall or use an assistive device, then they will be excluded as those are other exclusion criteria. If they answered yes to this question because they feel unsteady, then they must get medical clearance first.

6. Is there a health reason not mentioned why you would be concerned about starting an exercise program?

EASY recommendation:

If you answered yes, SHARE this information with your health care provider

Most reasons can be addressed and you can begin an exercise program that will improve your overall health and well-being.

Our procedure:

If they answered yes to this question, they are encouraged to share this information with their doctor. Apparently this question is meant as motivation to talk to their doctors, not as exclusion criteria (per Dr. Resnick)

Additional reasons to require medical clearance:

If participants report having the following: Stroke, 1year or more post; pacemaker in situ, severe chronic obstructive pulmonary disease, major head trauma within past 6 months, chronic kidney disease.

c. Justification for inclusion of any special or vulnerable populations

Not applicable

d. Plans for subject selection, recruitment, and documentation of informed consent.

Participants will be recruited using established relationships developed by Dr. Marquez (PI), who has been working with Chicago Latino communities since 2007. The Community Engagement Advisory Board (CEAB) of the Center for Clinical and Translational Science (CCTS) at UIC will also provide assistance. Recruitment will be done through presentations at group functions, coalition meetings, hospitals, word of mouth, flyers in mailboxes of senior housing facilities, presence at senior fairs, presence at health fairs, articles and ads in neighborhood and city-wide newspapers. More specifically, the following recruitment strategies will be employed, before any screening or testing takes place:

- Study flyers and permission to contact forms will be distributed to senior center and community center members

- Study flyers will be made available for volunteers to pick up at the senior center and community centers in the area of the study site

- Permission to contact forms will be available in the sites, and participants can put them in a sealed envelope for study staff to retrieve from the senior center

- Study flyers will be posted in the site buildings and other buildings in the area such as grocery stores

- The PI and Key Research Personnel will set up tables and make announcements at study site, health fairs, and local churches to promote the study

- Physicians at local health centers and hospitals will be contacted to see if they would hand out flyers to potential participants for our study. The physicians will give them a flyer, and ask the participant to call our research team if they are interested in the study

- Newspaper ads will be placed in neighborhood papers

- Radio ads will be made for local radio programs

- Word of mouth

After we have permission to contact participants, potential participants will be screened using the document titled, "Introduction and Screening Script" which includes the MMSE and EASY. After participants are deemed eligible they will be scheduled for a baseline assessment.

e. Description of Procedures

- There are several ways potential volunteers can consent to be screened: Learn about the study in person from a research staff member and be immediately screened; Learn about the study and sign a form agreeing to be called by a research member at a later time for screening; Learn about the study in another way and call our office to be screened.

- Persons who respond to recruitment materials or face-to-face meetings will be asked for consent to be screened for eligibility. After participants are deemed eligible they will be scheduled for a baseline assessment, and they will be randomly assigned to the dance treatment or to the health education control group using Study360 software .

- Individuals who are not eligible for the study will be thanked for their time.

- Testings will take place at Baseline, 4-months (posttesting), and 8-months (end of maintenance intervention) at the Clinical Research Center (CRC), participant's home, Senior Center, and our Lab Building at UIC; and the intervention will take place at various senior centers, community centers, parks, etc.. Data collection research staff will not be told to which experimental group (BAILAMOS or control) participants are in. Participants will be offered a ride from FlashCab taxi service (using an established contract of the PI with FlashCab), which will transport participants from their homes to the UIC CRC and vice versa.

- At the testing sessions a staff member will explain the study and read the Informed Consent form aloud to the participant. After participants agree to participate, they will sign the Informed Consent. All measures are available in Spanish or English.

- All participants will then have their heart rate, blood pressure, height and weight taken. Participants will then complete interviewer-administered questionnaires and tests of physical functioning (balance, mobility, and strength).

- Accelerometers. At testing they will be given an accelerometer to wear for one week and return to study staff. At the last class participants will be given an accelerometer to wear for one week. Participants will return for assessment and to return accelerometers.

- Intervention. The BAILAMOS© program. BAILAMOS© includes a 4-month, twice-weekly dance program. The PI and a professional dance instructor co-developed an extensive BAILAMOS© Dance Manual and class-by-class schedule. A 4-month maintenance intervention including the twice-weekly dance program will be completed.

- Sedentary older Latinos randomly assigned to the health education control group will participate in classes developed for older adults and offered by the University of Illinois Extension for the past 10 years. All classes are conducted in Spanish by extension staff using Spanish-language materials. The curriculum covers topics such as heart disease, diabetes, cancer, stress, asthma, osteoporosis, immunizations, home safety, and sexual health. Classes will meet one day per week for two hours, to provide equitable social contact as the treatment group.

- If participants are put into the health education program, they will be offered a short, 4-session dance program during the additional 4-month period, consisting of one class for each of the four styles of dance taught in the larger BAILAMOS© dance program.

- For the dance group and the health education group, separate lotteries will occur during the initial 4-month program and the follow-up 4-month maintenance program. All participants who meet criteria of having attended 75% of classes over each 4-week period are eligible for the lottery. One lottery will happen every four weeks (four lotteries total for the initial 4-month program and four lotteries for the follow-up 4-month maintenance program), and two participants from the dance group will win $50 and two participants from the health education group will win $50 for each lottery. All participants who are eligible will have an equal chance of winning, and the odds of winning are dependent upon the number of participants who meet lottery eligibility criteria (for example, if 10 participants are eligible, you have a 1/10 or 10% chance of winning). For each lottery, if you are eligible, your name will be put into a hat; the winner will be randomly drawn from the hat; your name will not be linked to research data; and the names will be destroyed immediately after the lottery occurs.

- At 4-months post-intervention, and at 8-months, testing will occur. Questionnaires and tests will be administered in the same order as baseline and 4-month testing.
- After the PRE-intervention testing (baseline/month 0) a $10 cash gift will be provided, and participants will be asked to wear an accelerometer for 7 days. When that accelerometer is returned, participants will receive another $10 cash gift.

- After the initial 4-month program, testing will occur. After this POST-intervention testing (month 4), a $10 cash gift will be provided, and participants will be asked to wear an accelerometer for 7 days. When that accelerometer is returned, participants will receive another $10 cash gift.
- After the maintenance 4-month program for dancers, testing will occur for both participants from the dance group and the health education group. At this month 8 testing, a $10 cash gift will be provided, and participants will be asked to wear an accelerometer for 7 days. When that accelerometer is returned, participants will receive another $10 cash gift. Thus, a total of $60 is possible.

- Through Amendment # 16, we would like to allow research participants in the maintenance component of the program to invite 1 or 2 family member(s) or friend(s) to come dance with them. Both of the sites which are in the maintenance phase of the program are struggling with attendance adherence.

  The person our participant invites will not be involved with any of the study procedures, such as:
  - No visits to the University of Illinois at Chicago for questionnaires (No data collected on them)
  - No need to wear accelerometer
  - Not eligible for lotteries
  - Not eligible for compensation

  In addition, in order to attend a dance session, the person will need to:
  - Be 55 years or older
  - Be able to speak English and/or Spanish
  - Not be in the Health Education group of the study
  - Be physically able to dance (no assistive devices permitted like canes, walkers, or wheelchairs)
  - Sign a one-time waiver
  - Sign-in at each class attended

  The investigator may stop a person from participating in the dance sessions of the maintenance program if the person is at risk of injury, or if he/she is disruptive or inappropriate during any session.

  <u>Emergency Procedures for Study Participant</u>
  In the event of an emergency, staff responds quickly and calmly.
  All emergencies are documented in the participant's file and if the project coordinator is not onsite, she is notified immediately by the Indigenous Leader (Participant Leader). The emergency is brought to the attention of the Principal Investigator by the Project Coordinator, so he is aware of the problem and can discuss how to prevent future emergencies. In addition, the Project Coordinator files an adverse report form with IRB

(Institutional Review Board Office), stating nature of incident, extent of injury and reports participant injured by name and ID number.

Medical Emergencies for Study Participant

In the event of a medical emergency, staff responds quickly and calmly. The Project Coordinator is notified of the emergency by the Indigenous Leader (Study Participant), Project Coordinator notifies Principal Investigator. If a serious medical emergency arises, the Indigenous Leader (Study Participant) calls 911 and notifies participant's emergency contact. In addition, the Project Coordinator files an adverse report form with IRB (Institutional Review Board Office), stating nature of incident, extent of injury and reports participant injured by name and ID number.

Emergency Procedures for "Invitees":

In the event of an emergency, "Invitees" will follow the site protocol. The Indigenous Leader (Study Participant) responds quickly and calmly, following the site protocol for emergencies. The emergency is brought to the attention of the Project Coordinator. Project Coordinator notifies the Principal Investigator, so he is aware of the problem and can discuss how to prevent future emergencies.

Medical Emergencies for "Invitees"

In the event of a medical emergency, Indigenous Leader (Study Participant) responds quickly and calmly, following site protocol, which is to call 911. Indigenous Leader (Study Participant) notifies Project Coordinator and Principal Investigator.

Below are the medical emergency procedures for our current sites:

- West Town Satellite Senior Center: Notify Senior Center Coordinator, who will then make Security aware of situation, and if necessary, Security will call 911 and make an incident report.

- Pilsen Satellite Senior Center: Call 911 and notify emergency contact/family member on record, center Coordinator will file incident report.

- Kelvyn Park Satellite Senior Center: Call 911 and notify emergency contact/family member on record, center Coordinator will file incident report

Under Amendment #18, we added a short survey for Senior Center directors to be collected at 1-month and 6-months after the Maintenance program ends to see if people are still dancing, and to get Directors' thoughts, feelings, and perceptions of the program's sustainability.

Under Amendment #21, we propose to audiotape the Senior Center Director's responses to our Questionnaire (previously approved under Amendment #18). This will allow us to

record their response more accurately. These recordings will be transcribed within 6 months of being collected; and will be destroyed once the data has been published.
To maintain confidentiality, Directors will be assigned an identification number (ID). Only the ID will appear on the questionnaire. There will be no identifying information on the questionnaire. The ID and participant's name will be kept on a password protected computer.
The hardcopy Informed Consent documents will be kept in a locked drawer in Dr. Marquez' Lab (room 611, Applied Health Sciences Building). The hardcopy questionnaire will be kept separately in the PI's lab. The Director's response files and transcripts will be kept on a password-locked computer in Dr. Marquez' lab and on the secured College server. Only the PI and Key Research Personnel will have access to data. Key Research Personnel will need access to the files in order to analyze data. All access to data will be granted by the PI, Dr. Marquez. Hard copies of the data will be kept in a locked storage room of Dr. Marquez' lab for 5 years after the completion of the study. At that time all data will be destroyed.
Inclusion criteria for Senior Center Directors: to oversee daily operations of senior center where our program takes place. Exclusion: not oversee or coordinate daily operations of Senior Center.

Under Amendment# 34

We would like to add a question regarding dance history to see how much experience participants had with dancing before enrolling into the study. The question is:

Before you started the BAILA Program, please rate how much dance experience you had?

1. A lot
2. Some
3. A little
4. None

We have submitted our Question & Script in English & Spanish.

Under Amendment # 35

Research has shown a protective effect of hormone replacement therapy on cognition. For this reason, we would like to add a question regarding the use of hormone replacement therapy of enrolled participants. Hormone replacement therapy information will only be linked to cognition data, to see if there was a protective effect of HRT on cognition.

We would like to know if any of the participants have used hormone replacement therapy while enrolled in our study. We will contact study participants via phone to ask them the questions below.

1. When the BAILA Program was going on, did you take any hormone replacement medicine?

○ Yes

○ No

a) If yes, what was the name of the medication?
_____

b) For how long did you take it? _____

Sites:

1. Our Lady of Mount Carmel
2. West Town Satellite Senior Center
3. Pilsen Satellite Senior Center (Alivio Medical Center)
4. Kelvyn Park Satellite Senior Center
5. Villa Guadalupe Senior Services INC
6. Southwest Center
7. St. Agnes of Bohemia
8. West Suburban Senior Services
9. Catholic Charities of Archdiocese of Chicago, St Mary of Celle
10. Northwest Copernicus Regional Senior Center
11. Holy Cross Immaculate Heart of May Church
12. Mile Square Health Center—Recruitment ONLY
13. Dance Academy of Salsa

f. Statistical Methods

Aim 1. Hypothesis: Lifestyle PA (self-reported and accelerometer-assessed) will be significantly higher in the BAILAMOS© group at 4 and 8 months compared to the control group.

The proposed study uses a between-groups design with two groups and individual covariates. Initially, descriptive statistics will be obtained (e.g., for continuous variables we will examine means and standard deviations) and we will screen for wild codes (e.g., extreme values as the result of typos in data entry).

Using t-tests and chi-square tests, we will examine all baseline outcomes and covariates to determine whether randomization has produced equivalent groups. Variables exhibiting differences will be added as covariates to analyses. Transformations to achieve normality will be applied as needed; and residuals from analysis will be examined to detect multivariate outliers. Data will be examined for differential dropout but dropout is expected to be missing at random (MAR) and will thus not be imputed unless necessary.

Analysis will be carried out using standard mixed model analysis of variance and covariance using the SAS program (i.e., PROC MIXED), controlling for antecedent factors measured at

baseline including demographics, body composition, acculturation, and health status. For Aim 1 the Group x Time interaction term will test whether there is greater improvement in self-reported and accelerometer-assessed lifestyle PA at 4 and 8 months in the treatment group compared to the control group.

Aim 2. Hypothesis 2a: Self-efficacy for PA, Balance, and Gait will be significantly higher in the BAILAMOS© group at 4 and 8 months compared to the control group.

The same analysis strategy in Aim 1 will be applied for Aim 2, Hypothesis 2a. The Group x Time interaction term will test whether there is greater improvement in self-efficacy at 4 and 8 months in the treatment group compared to the control group.

Aim 2. Hypothesis 2a1: Self-efficacy for PA, Balance, and Gait will mediate the effect of the BAILAMOS© program on lifestyle PA and health outcomes.

In connection with Aim 2, Hypothesis 2a, we will conduct mediation analysis following testing procedures recommended by MacKinnon. We will examine whether self-efficacy is a necessary intervening variable to produce the PA and health outcome differences. We will use methods provided in the M-Plus statistical package, which offers special facilities for estimating standard errors of mediation terms.

Aim 2. Hypothesis 2b: Physical function, cognitive function, and self-reported functional limitations and disability scores will be significantly better in the BAILAMOS© group at 4 and 8 months compared to the control group.

Analysis will be the same as Aims 1 and 2. The Group x Time interaction term will test whether there is greater improvement in physical function, cognitive function, and self-reported functional limitations and disability scores at 4 and 8 months in the treatment group compared to the control group.

g. Safety Monitoring and Assessment

Risks:

The risk level of the intervention is minimal. For the proposed study there is the potential that undocumented Latinos will want to participate and will be concerned about anonymity and confidentiality in participating.

There is a small possibility that the older adults could injure themselves during the testing or the dance program.

Possible risks associated with physical injury that could occur during the dance intervention include those that one would experience with any physical activity, including (1) strains, sprains, muscle soreness, aggravation of arthritic conditions, etc. (2) slipping/tripping/falling; (3) bumping into another participant; (4) a very slim chance that cardiac irregularities can occur. This is very rare and the benefits of exercise are known to outweigh the risks. Serious physical injury or severe pain is considered unlikely. In our pilot test of the BAILAMOS© dance program, we had 12 participants, 9 of whom completed the 12 week program that took place two times per week. We experienced no serious injuries or falls.

The following provides steps that we will take to (1) address the potential for risks, and (2) handle injuries should they occur.

1) Addressing the potential for risks

a. All participants will be free of medical conditions (e.g., uncontrolled diabetes) requiring higher levels of supervision, and will not have had hip or knee replacement in the last 6 months.

b. Prior to participation, each participant will complete the Exercise Assessment and Screening for You (EASY), developed and successfully used by Barbara Resnick, PhD, FAAN, for risk assessment during the screening. Participants with new risks based on EASY items will be required to discuss these risks with their healthcare provider and obtain medical approval before participating in the trial.

c. During warm-up and cool-down participants will be advised to NOT attempt an activity/stretch/maneuver that they do not feel comfortable performing.

d. The warm-up and cool-down sessions will decrease the risk of straining a muscle.

e. During discussion sessions and throughout the intervention participants will be educated on risks of physical activity and methods to minimize risks (e.g., start low and go slow) and will receive safety tips and information on warning signs and symptoms.

f. To reduce and/or prevent any physical harm or injury, BAILAMOS© has been designed to present the easiest, least complicated dance styles first, followed by more difficult dance styles.

g. Participants will be advised on what clothing and shoes should/should not be worn.

h. Participants will be encouraged to sit and/or take a break whenever they feel it is necessary.

i. There will be adequate spacing between participants when dancing, decreasing the risk of slipping/tripping/falling or bumping into another participant.

j. Emergency contact information for each participant will be available, and emergency protocol will be posted on the walls of the study sites.

k. We will employ dance leaders who have experience working with older adults.

l. The surface area used for the dance classes will be a large, well-lit, unobstructed space that is not carpeted to reduce the risk of slipping/tripping/falling or bumping into other participants.

2) Handling injuries, should they occur

a. All personnel who assist with instruction and/or testing will be CPR and First Aid certified, will have a comprehensive first-aid kit on-site, and all will be familiar with emergency protocol procedures of the study sites.

b. Emergency contact information will be collected at baseline. Should an injury or any other adverse event occur, we will contact the emergency contact person immediately, followed by the UIC IRB, and the program officer assigned to this grant.

c. We will tell participants that should they become injured due to dancing, they should notify the dance leader and/or research assistants in attendance and to consult their physician if necessary.

d. If a participant injures him/herself and/or falls, we will assess and treat with first aid.

e. If there are medical facilities and/or medical personnel available at the research site, we will inform them and request assistance, and also follow the stated protocols and procedures of the site. For those sites without medical facilities, we will follow the stated protocols and procedures of the site.

f. If needed, we will arrange for transport to the emergency room.

Adverse events will be tracked and categorized as "serious" (for example illness requiring hospitalization, or events deemed life-threatening) or “minor” adverse events. Serious events will be reported to the IRB immediately, whereas minor adverse events will be documented in the annual summary sent to the IRB.

h. Data management

To maintain confidentiality, all participants will be assigned an identification number (ID). Only the ID appears on the questionnaire and other study documents. There is no identifying information on the questionnaire. The ID and participant's name are kept on a password protected computer.

Screening, tracking of participants, etc. will be done using Study360 software described in detail in the Initial Review Application. In short, Study 360™ (Almedtrac, Inc.) is a multi-component, web accessible software system designed to reduce management burden, increase efficiency and improve visibility of clinical trials. It is a highly secure application that uses a 128-bit SSL with third party certificate authority encryption mechanism. Data are maintained and stored in an Oracle 10g RDBMS running in a secure environment on a Dell PowerEdge server running Windows Server 2003 in Entity-Attribute-Value (EAV) format. Data in the Oracle database are maintained in original and unedited format and the research team has the ability to connect to a view that is custom-designed for the project for the purpose of downloading a snapshot of the data into SPSS via an ODBC connection.

The hardcopy Informed Consent documents will be kept in a locked drawer in Dr. Marquez' Lab (room 611 or 516, Applied Health Sciences Building). Questionnaires will be administered and answers recorded electronically using Pendragon software on iPads. The electronic data collected using iPads will be kept on a password-locked computer in Dr. Marquez' lab and on two secured College of Applied Health Sciences (AHS) servers: (1) Information collected on the iPads will be synced with a designated secured server, Host: AHS-KN-PENDRAG.ad.uic.edu, Security Measures: Access restricted by netid and subnet; (2) Data will be backed up on the department virtual server hosted by ACCC called "ahs-kn-nas." The research data is stored on a share called "MarquezLab." Authorization, that is Access to the share is controlled via an Active Directory group. Only members of the group can access this directory. Authentication is handled by ACCC's AD. Additionally, access is limited to college-controlled IP ranges - and these ranges are Private IP ranges. Only the PI and Key Research Personnel have access to data. Key Research Personnel will need access to the files in order to analyze data. All access to data will be granted by the PI, Dr. Marquez. Hard copies of any data will be kept in a locked storage room of Dr. Marquez' lab for 5 years after the completion of the study. At that time all data will be destroyed.

5. For multi-site protocols

Not applicable

6. References

1. FederalInteragencyForumonAging-RelatedStatistics. Older Americans 2010: Key Indicators of Well-Being Washington, DC: Federal Interagency Forum on Aging-Related Statistics, July 2010.
2. Rejeski WJ, Brawley LR, Haskell WL. The prevention challenge: an overview of this supplement. American Journal of Preventive Medicine. 2003;25(3 Suppl 2):107-9.
3. McAuley E, Blissmer B. Self-efficacy determinants and consequences of physical activity. Exercise and Sport Sciences Reviews. 2000;28(2):85-8.
4. Keysor JJ. Does late-life physical activity or exercise prevent or minimize disablement? A critical review of the scientific evidence. Am J Prev Med. 2003;25(3 Suppl 2):129-36.
5. Marquez DX, Neighbors CJ, Bustamante EB. Leisure time and occupational physical activity among racial/ethnic minorities. Medicine & Science in Sports & Exercise. 2010;42(6):1086-93.
6. Dornelas EA, Stepnowski RR, Fischer EH, Thompson PD. Urban ethnic minority women's attendance at health clinic vs. church based exercise programs. Journal of cross-cultural gerontology. 2007;22(1):129-36.
7. Jette AM, Crawford SL, Tennstedt ST. Toward understanding ethnic differences in late-life disability. Research on Aging. 1996;18:292-309.
8. Ostchega Y, Harris TB, Hirsch R, Parsons VL, Kington R. The prevalence of functional limitations and disability in older persons in the US: Data from the National Health and Nutrition Examination Survey III. Journal of the American Geriatrics Society. 2000;48(9):1132-5.
9. Waldrop J, Stern SM. Disability status: 2000, U.S. Census Bureau, Census 2000 Brief Series. Washington, DC U.S. Department of Commerce, 2003 C2KBR-17.
10. Novak K, Riggs J. Hispanics/Latinos and Alzheimer's Disease. Alzheimer's Association, 2010.
11. Clark CM, DeCarli C, Mungas D, Chui HI, Higdon R, Nunez J, et al. Earlier onset of Alzheimer disease symptoms in latino individuals compared with anglo individuals. Archives of neurology. 2005;62(5):774-8.
12. Crespo CJ, Keteyian SJ, Heath GW, Sempos CT. Leisure-time physical activity among US adults. Results from the Third National Health and Nutrition Examination Survey. Archives of Internal Medicine. 1996;156(1):93-8.
13. King AC. Interventions to promote physical activity by older adults. J Gerontol A Biol Sci Med Sci. 2001;56 Spec No 2:36-46.
14. Ramirez AG, Chalela P, Gallion K, Velez LF. Energy balance feasibility study for Latinas in Texas: a qualitative assessment. Preventing chronic disease. 2007;4(4):A98.
15. Wood FG. Leisure time activity of Mexican Americans with diabetes. Journal of Advanced Nursing. 2004;45(2):190-6.
16. Delgado CF, Munoz JE. Everynight Life: Culture and Dance in Latin/o America. Durham, NC: Duke University Press; 1997.
17. Lewis D. Introduction: Dance in Hispanic Cultures. Choreography and Dance. 1994;3(4):1-5.
18. Dunn AL, Andersen RE, Jakicic JM. Lifestyle physical activity interventions. History, short- and long- term effects, and recommendations. American Journal of Preventive Medicine. 1998;15(4):398-412.