

*THE RHYTHM
EXPERIENCE AND
AFRICANA
CULTURE TRIAL
(REACT!)*

Study methodology for a multi-site study examining the effects of an African Dance intervention on cognition, mood, quality-of-life, and physical fitness in a sample of older African Americans.

TABLE OF CONTENTS

1	Participant Screening
100.1	Recruitment
100.2	Inclusion/Exclusion Criteria
100.3	Pre-Screening
2	African Dance Session
200.1	Handling Dance Session: Set-up
200.2	Handling Dance Session: Duration
200.3	Handling Dance Session: Closing
3	Africana Culture and Education Session
300.1	Handling Education Session: Set-up
300.2	Handling Dance Session: Duration
300.3	Handling Dance Session: Closing
4	Research Intern Training
400.1	Training Checklist
5	Post-Testing
500.1	Procedure
6	Retention
600.1	Elements of a Successful Retention Strategy
600.2	What to Do if a Participant Leaves the Study
	Appendix
Appendix A	List of Neuropsychological Battery Assessments
Appendix B	Alternate Fitness Assessment



Title:

Recruitment

100.1

Participants are recruited from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) Registry in the Philadelphia community and additional prospective participants are identified from the community.

Letters from the Director of PACE and site Principal Investigator are sent to randomly selected African American PACE enrollees aged 65-75.

REACT! Study coordinators follow-up the letter with a telephone call

REACT! Study coordinators provide further information, ascertain interest, and assess eligibility

Promotional flyers are distributed within each community

Eligible subjects are scheduled for baseline cognitive and fitness assessments



Title: Inclusion and Exclusion Criteria**100.2**

Inclusion Criteria

- Must report English as their primary language
- Not have dementia or any other neurological or severe psychiatric disorder
- Between 65 and 75 years of age
- Be mobile and ambulatory
- Report no history of balance problems, falls, or any other physical condition that would preclude minimal risk of an exercise-related injury;
- Not have had any serious cardiac or cardiovascular event within the past 2 years;
- Score at least 21 points (i.e., normal to mildly-impaired range) during administration of the Telephone Interview of Cognitive Status (TICS)
- Be available at the times classes will occur and be able to coordinate their own transportation to the class and test sites
- Must successfully complete baseline cognitive assessment
- Must successfully complete and pass cardiovascular fitness test (submaximal VO₂ test performed on a treadmill)

Exclusion Criteria

- Individuals with Type 2 diabetes
- Individuals with hypertension



Title: Pre-Screening

100.3

Eligible subjects are randomized to one of the two groups through a computer program following pre-intervention cognitive and fitness assessments. Subjects are compensated for completion of the pre-intervention cognitive and fitness assessments.

To measure cognitive abilities such as memory, attention, executive function, and spatial reasoning study coordinators administer neurocognitive, mood, and fitness measures including:

- Self-reported demographic information
- Current and past history of cigarette smoking
- Family history of age related cognitive issues
- Submaximal VO₂ fitness test*
 - This test requires walking between 2.0–4.0 mph with increasing grade increments of 1% every 1 min. The test is terminated when the subject reaches 85% of his/her age-predicted heart rate, a rating of perceived exertion (RPE) of 15 or greater in subjects taking beta-blocking medication, or at volitional exhaustion
- Cognitive and mood tests:
 - POSITIVE AND NEGATIVE AFFECT SCHEDULE (PANAS)
 - STATE MEASURES
 - NATIONAL ADULT READING TEST (NART)
 - SATISFACTION WITH LIFE SCALE (SWLS)
 - UCLA LONELINESS SCALE
 - INSTRUMENTAL ACTIVITIES OF DAILY LIVING (ADL/IADL)
 - RBANS
 - DIGIT SPAN BACKWARD
 - GLOBAL HEALTH SCALE (QOLS)
 - CENTER FOR EPIDEMIOLOGIC STUDIES DEPRESSION SCALE (CES-D)
 - GERIATRIC DEPRESSION SCALE (GDS)
 - TRAIL MAKING A & B

Upon completion of the baseline assessments and randomization, subjects are provided a study folder containing contact information to enable communication with research personnel. The folder also contains the assignment information to either the African Dance or Culture Education group, along with relevant addresses, maps, and parking instructions. Additionally, there is a calendar of class dates (including expected topics to be taught for the education group). Other content in the study folder consists of an introduction letter from the lead researchers, biographies of the instructors, and an outline of the research protocol.

*If submaximal VO₂ fitness test is unavailable alternate method of fitness assessment is required.



Title: Handling Dance Session: Set-up

200.1

PROCEDURE: Classes are taught by trained African Dance instructors, and research coordinators are also present at both sites for all sessions to monitor heart rate, exertion, and safety.

- Levels of exertion during dance are prescribed and monitored based on baseline assessments of heart rate and cardiorespiratory fitness.
- Heart rate monitors are calibrated and assigned at baseline for each participant randomized to the dance class.
- To monitor heart rate and intensity of the dancing, each participant is equipped with a Bluetooth-enabled Polar H7 Heart Rate Sensor at the start of each class.
- Research coordinators ensure that the Polar Team app is properly calibrated to the heart rate sensor of each participant.
- Participants' vital signs are measured and recorded at the beginning and end of every session

At each class instructors track attendance on appropriate attendance forms.

Title: Handling Dance Session: Duration

200.2



The African Dance group receives moderate-intensity dance instruction for **one-hour per day (including warm-up and cool down), three days per week for twenty-four weeks.**

For the first two weeks of the intervention, the target heart rate is maintained at 50%–60% (light-moderate intensity) of the age-based maximum heart rate ($220 - \text{age}$). For the remaining 22 weeks, dance instructors and research coordinators use a target heart rate of 60%–70% (moderate intensity) of the age-based maximum heart rate.

- Each exercise session begins with a warm-up of 5–10 min at an intensity below the target heart rate, and the sessions conclude with an instructor-led cool-down period of stretching for 5–10 min.
- Using the Polar Team App, research personnel are able to continuously monitor the heart rates and percent of maximal heart rates in real time of all participants simultaneously.
- Screen shots of the Polar Team App are taken at **15 min intervals** throughout each exercise session, thus providing data for each participant at **0, 15, 30, 45, and 60 min** of exercise.



Title: Handling Dance Session: Closing**200.3**

At the conclusion of each exercise session, the Polar Team App automatically calculates the average percent time in the heart rate zone, maximum heart rate percent, and number of calories burned for all participants.

- Ensure all necessary data has been collected and properly recorded
 - Attendance
 - Screenshots for each participant at intervals of 0, 15, 30, 45, and 60 minutes of exercise
 - Rating of perceived exertion (RPE)
 - Vital signs pre-and post-dance exercise session

Participants are monitored until heart rate and blood pressure have returned to resting levels (HR < 100 bpm; systolic BP < 190; diastolic BP < 100). Frequent assessment of heart rate and RPE help to ensure appropriate levels of intensity during each session.



Title: Handling Education Session: Set-up, Duration, Closing 300.1 – 300.3

The Culture Education control group receives materials focused on Africana culture, history, geography, religion, and politics, as well as art interpretation and creation. Participants also are instructed about healthy lifestyles, behaviors, and risks for disease. Culture Education classes are designed to be as useful, interactive, and entertaining as the African Dance classes to increase the likelihood of adherence as well as promotion of well-being.

The educational sessions are led by instructors with expertise in each particular topic area and are conducted in a group format similar to the dance sessions. Participants receive handouts at the start of many classes to help maintain engagement. After a few weeks of classes on pre-planned topics, participants are asked to rate various subject matters according to their interest, and the content of future classes is planned based on the feedback.

- Instructors will ask these questions during preparation of the lessons:
 - What is the learning objective?
 - How might the participants identity shape how they perceive the curriculum?
 - How might the instructor's identity shape how they perceive the curriculum?
 - How is racism, sexism, classism, and culture informing my circulation of the content selection?
 - Am I fulfilling my goal as a clinical trial research team member abiding by Institution Review Board (IRB) guidelines to do no harm, ensuring the rights and welfare of human subjects are protected during their participation?



Title: **Research Intern Training**

400.1

PROCEDURE:

During their first week on the study, new student interns will:

Complete all required human subjects training

Shadow at least two African Dance sessions and two African Culture and Education sessions

Review Protocols & Good clinical Practices (GCP)

Orientation: Polar Team App configuration, Heart Rate monitor placement, proper Blood Pressure rate monitoring

Review and learn proper data documentation for vital signs, heart monitoring, rating of perceived exertion (RPE) and attendance sheets.



Title:

Post-testing

500.1

PROCEDURE: A series of cognitive and mood tests as well as a submaximal VO₂ fitness test is administered by the study coordinator **within 2 weeks of completion** of the 24-week study.

Participants are compensated for completion of the cognitive and fitness assessments.

- Submaximal VO₂ fitness test*
 - This test requires walking between 2.0–4.0 mph with increasing grade increments of 1% every 1 min. The test is terminated when the subject reaches 85% of his/her age-predicted heart rate, a rating of perceived exertion (RPE) of 15 or greater in subjects taking beta-blocking medication, or at volitional exhaustion
- Cognitive and mood tests:
 - POSITIVE AND NEGATIVE AFFECT SCHEDULE (PANAS)
 - STATE MEASURES
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 - TRAIL MAKING A & B

*If submaximal VO₂ fitness test is unavailable alternate method of fitness assessment is required.



Title: Elements of a Successful Retention Strategy**600.1**

Most trial participants view the experience positively and would be open to participating in another trial if asked. Gaining acceptance to contact a participant for future studies is often part of the informed consent document and process. In order, not to squander this potential resource, keep participants who have completed a study informed to the extent possible of the study's status and findings and let them know that their participation was valuable. Such efforts can also serve as "word-of-mouth" advertising. A thank-you card or certificate of appreciation can indirectly serve as a recruitment tool for the study, as well as for future studies.

- Recruitment and retention of participants are key to the success of any clinical study.
- A successful recruitment and retention strategy requires informed and detailed planning, commitment of adequate resources, careful monitoring, and timely identification and resolution of problems.
- Recruitment of participants may not begin until the Institutional Review Board (IRB) has approved the protocol, informed consent documents, and proposed recruitment and retention strategies.
- Advertisements, fliers, and brochures that are prepared to recruit potential participants and inform them about a study are considered part of the informed consent process. As such, they must be reviewed and approved by the IRB.
- Recruitment for a study has two major elements:
 - Defining a population of appropriate participants to answer the research question.
 - Recruiting appropriate participants in an ethical manner.
- Recruitment of an adequate number of participants, although essential, does not in itself assure the success of a study. Unless an adequate number of participants are retained for the duration of the study, investigators will not obtain enough data to answer the research question they posed, which was the reason for performing the study in the first place.
- Research participants may be offered rewards such as monetary payments or medical care at no cost. Such rewards are not considered benefits of study participation but rather incentives for participation.
- Because incentives for participation are potentially coercive, the amount, form, and conditions of such incentives must be reviewed and approved by the IRB. (Clinical Trials Network 2017)



Title: What to do if a Participant Leaves the Study**600.2**

- When and how to withdraw participants:

Participants can opt to withdraw from the study at any time by notifying a research coordinator that they will no longer be attending the classes.

Participants may be removed from the study if they are not able to complete the study procedures, or if the research staff determine that it is in their best interest to stop participating. For instance, if an injury, illness or other condition at any time during the course of this study occurs, they would be removed from the study to ensure safety and well-being.

- What type of data, if any, will be collected for withdrawn participants:

Any identifiable research information resulting from the participants involvement in the research study will be immediately removed from our database and research team will be properly notified.

- Whether follow-up of some or all participants who have stopped attending classes may occur:

Even if participants decide to stop attending the classes, at the end of the study they will still be invited to complete the same tests that they do at the beginning of the study (the walking test and paper-and-pencil tasks) and receive compensation for doing so. However, they do not have to return to complete these tasks if they do not want to.



Appendix A

List of Neuropsychological Battery Assessments

1. DEMOGRAPHIC FORM
2. MINI MENTAL STATE EXAM (MMSE)
3. POSITIVE AND NEGATIVE AFFECT SCHEDULE (PANAS)
4. STATE MEASURES
5. NATIONAL ADULT READING TEST (NART)
6. SATISFACTION WITH LIFE SCALE (SWLS)
7. UCLA LONELINESS SCALE
8. INSTRUMENTAL ACTIVITIES OF DAILY LIVING (ADL/IADL)
9. RBANS
10. DIGIT SPAN BACKWARD
11. GLOBAL HEALTH SCALE (QOLS)
12. CENTER FOR EPIDEMIOLOGIC STUDIES DEPRESSION SCALE (CES-D)
13. GERIATRIC DEPRESSION SCALE (GDS)
14. TRAIL MAKING A & B

- **Label each page with Subject's ID, date, and administrator initials before beginning each session**
- Note the time each assessment takes
- Note the time the full cognitive session takes (should be less than 2 hours)



Appendix B

Alternate Fitness Assessment

REACT STUDY – UNIVERSITY OF PENNSYLVANIA
BLOOD PRESSURE AND HEART RATE SAFETY CHECK FOR EXERCISE:

To offset the safety concerns that would be gathered in a graded sub-maximal exercise test, the following protocol will be put into place at the University of Pennsylvania site. This protocol should be completed prior to randomization similar to the sub-maximal exercise test in the first cohort of subjects. The total time to complete this procedure is approximately 20 minutes. It can therefore be added to the backend of the baseline cognitive session. Please note that this is a safety check for participation in the intervention and does not provide any measurement of fitness level.

- I. Required Equipment:
 - a. Quiet Room with space to move
 - b. Blood pressure and heart rate measuring system
 - c. Watch
 - d. Data form
 - e. Protocol

- II. Resting measurement:
 - a. Subject enters room and is seated
 - b. Staff completes top portion of data form (Appendix I)
 - c. Subject is to remain seated with both feet flat on the ground and remain silent for full 5 minutes.
 - d. After 5 minutes, the staff takes resting reading #1
 - e. After 1 minute, the staff will take resting reading #2
 - f. If the two blood pressure readings have either a systolic or diastolic difference > 20mmHg, then a third reading is required after another minute of rest. (Example: 145 / 80 first reading and 120 /72 second reading).
 - g. If a third reading is required, the two closest readings will be maintained as the resting readings.
 - h. If no third reading required, write N/A on data form for #3 measurement
 - i. Resting Contraindication Values, session is stopped and subject should be referred to PCP:
 - i. Systolic Pressure: <80 mmHg or > 190 mmHg
 - ii. Diastolic Pressure: < 45 mmHg or > 100 mmHg
 - iii. Heart Rate: > 100 beats per min.



- III. Light Intensity Movement:
- a. Subject will be led through the following stretching and warm-up exercises: See Appendix II for exercise photos.
 - i. Head turns (5 second hold, 3 times each side)
 - ii. Calf Stretch (5 second hold, 3 times each side)
 - iii. Lat. Stretch (5 second hold, 3 times each side)
 - iv. Arm Circles (10 forward and 10 backward)
 - v. Leg Swings (10 front to back and 10 side to side)
 - b. After above exercises are completed, subject is seated and vital signs are measured immediately.
 - c. Repeat reading if necessary, (Example: reading is extremely high or low)
 - d. Exercise Values in which session is stopped and subject referred to PCP:
 - i. Systolic Pressure: > 250 mmHg
 - ii. Diastolic Pressure: > 110 mmHg
 - iii. Heart Rate: = or > than maximal Heart Rate (on Data form)
 - iv. Drop in either systolic or diastolic > 25 mmHg from resting reading
- IV. Walking measurement:
- a. Subject will do the following walking exercises and then have blood pressure measured one final time:
 - i. walk across room (normal walking speed): 5 times
 - ii. walk across room while swinging arms up and down: 5 times
 - iii. walk across room while swinging arms side to side: 5 times
 - b. After the three walking exercises are completed, have subject seated and get immediate blood pressure reading.
 - c. Follow same values as with the light intensity movement step.
- V. After completing the three phases of readings, review with subject if they are eligible to continue or need referred to PCP based on readings. Have 5 minutes of dialogue with subject before obtaining one final post reading. In NOTES box, enter if subject eligible or need referred to PCP along with any other pertinent information.



Appendix I**REACT STUDY**

Subject ID: _____ Gender: _____ Date: _____
Age: _____ Max HR (220 – Age): _____

RESTING:

Resting HR #1: _____ Resting Blood Pressure #1: _____
Resting HR #2: _____ Resting Blood Pressure #2: _____
Resting HR #3: _____ Resting Blood Pressure #3: _____

CONTRAINDICATIONS:

- i. Systolic Pressure: <80 mmHg or > 190 mmHg
- ii. Diastolic Pressure: < 45 mmHg or > 100 mmHg
- iii. Heart Rate: > 100 beats per min.

LIGHT INTENSITY MOVEMENT:

Light HR: _____ Light Blood Pressure: _____

WALKING MOVEMENT:

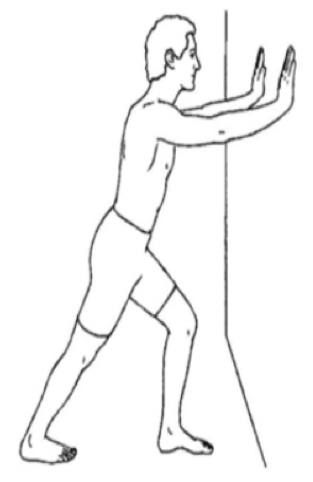
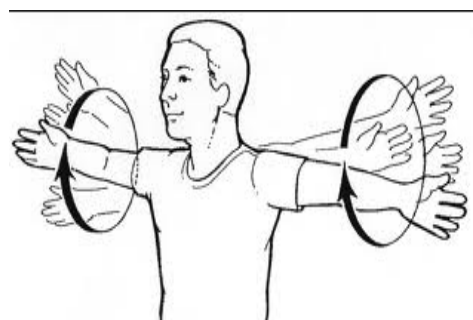
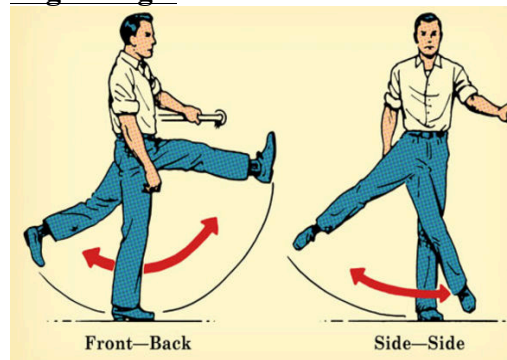
Walking HR: _____ Walking Blood
Pressure: _____

CONTRAINDICATIONS:

- i. Systolic Pressure: > 250 mmHg
- ii. Diastolic Pressure: > 110 mmHg
- iii. Heart Rate: = or > than maximal Heart Rate (on Data form)
- iv. Drop in either systolic or diastolic > 25 mmHg from resting reading

POST HR: _____ POST Blood Pressure: _____



Appendix II**Head Turn Stretch:****Calf Stretch:****Lat. Stretch:****Arm Circles:****Leg Swings:**

References

Lukach, Alexis J., et al. "Rhythm Experience and Africana Culture Trial (REACT!): A Culturally Salient Intervention to Promote Neurocognitive Health, Mood, and Well-Being in Older African Americans." *Contemporary Clinical Trials*, vol. 48, 2016, pp. 41–45., doi:10.1016/j.cct.2016.03.010.

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