

REACT!

Participant Handbook



TABLE OF CONTENTS

Welcome	1
Contact Information	2
Study Timeline	3
Overview of Assessments	4
Study Locations	5
Meet the Team	7
Frequently Asked Questions	10
Glossary	14
Thank you	18

WELCOME TO REACT!

The Rhythm Experience and Africana Culture Trial

We're so glad you decided to join our research community! Here at the Brain Aging & Cognitive Health (BACH) Lab, we're committed to new research that advances our understanding of brain health and function as we age.

Past research shows that African Americans are more likely to develop dementia than other groups. But little is known about why. In addition, history shows that African Americans are poorly represented in research. The REACT study aims to address both of these challenges.

During REACT, some people will go to an Africana cultural immersion class and some will go a class on African dance. The goal is to see whether attending these classes will improve physical and mental health.

Thanks to your commitment, we will show why investing in this kind of research is important. We hope that the results of our study will transform health care recommendations. Your participation is an investment in yourself and your community. We hope you have some fun too!

Everyone on the REACT team is committed to making your time in the study as smooth and enjoyable as possible. If there's anything we can do to help, please don't hesitate to contact a team member. Contact information is on page 2.

We're looking forward to meeting you soon!

Sincerely,
The REACT Team

This handbook is your one-stop shop to all things “REACT.” It is meant to be a reference guide as you navigate the early stages of participation. The handbook includes key information about what’s involved in the study. Check out the FAQ and glossary sections to learn more about the research process. See the table of contents for a full list of what’s included.

CONTACT INFORMATION



Phone

412-648-7060



Email

reactpgh@pitt.edu



Website www.bachlab.pitt.edu



Facebook [/TheBACHLab](https://www.facebook.com/TheBACHLab)

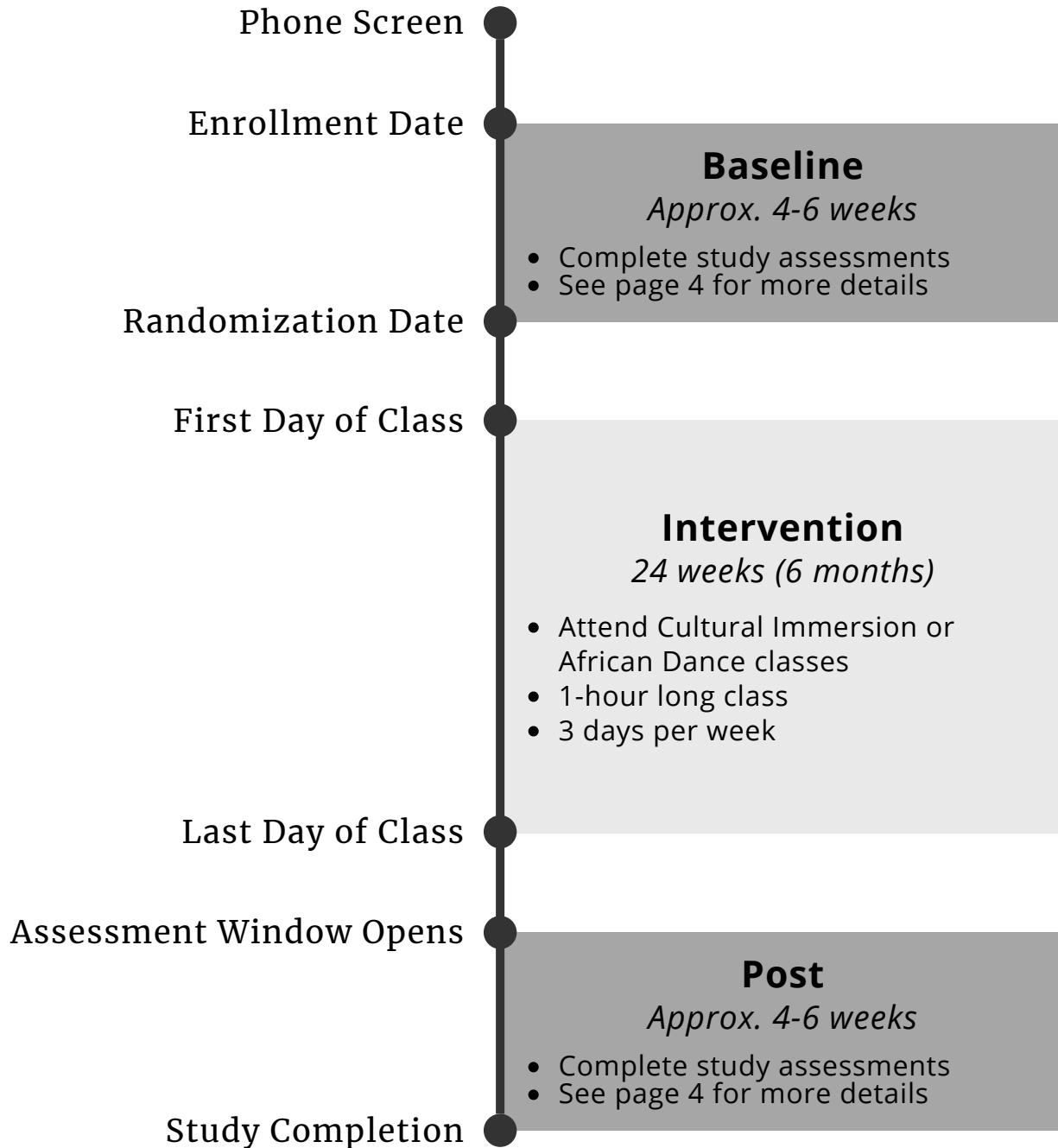


Twitter [@TheBACHLab](https://twitter.com/TheBACHLab)



Instagram [@thebachlab](https://www.instagram.com/thebachlab)

STUDY TIMELINE



Check out the glossary on page 14 for more info on what these terms mean.

OVERVIEW OF ASSESSMENTS

At both the beginning and end of the study, you have four appointments called study assessments. Doing each assessment twice allows us to compare your progress over time. Completing these assessments allows us to make conclusions about the research.

Cognitive Assessment

During the cognitive assessment, you complete several mental and memory tasks. Some of the tasks are completed on paper and pen, and some are completed on a computer. Prior computer experience is NOT required. The tasks are designed to test aspects of your brain health and cognitive abilities. A staff member is present to administer and help guide you through the tasks. This is the first assessment and typically lasts about 2.5 hours.

Fitness Assessment

The fitness assessment is conducted by a trained exercise physiologist. First, we test your flexibility and strength with some physical activity movements. Then, you walk on a treadmill for about 5-20 minutes while wearing a heart monitor. While on the treadmill, the staff member increases the steepness until you reach a certain goal. You wear a face mask that collects the air you breathe out. This test estimates your overall heart health. This is the second assessment and typically lasts about 2 hours.

MRI Scan

A magnetic resonance imaging (MRI) scan creates pictures similar to an x-ray, but does not use any radiation. During the scan, you lie down in a tunnel-like machine. We ask you to stay as still as possible, and the movement of your head is restricted. This allows the machine to record images of your brain and how it's functioning. The scan itself is 1-hour, but the entire session is about 2 hours to account for practice time and safety screening. It is either your third or fourth assessment, depending on schedule availability.

Blood Draw

During the blood draw, a trained phlebotomist collects approximately four (4) tablespoons of blood. We are looking at a protein that helps regulate nerve cell function, which is important for learning and memory. We'll also look at other proteins involved in the healthy aging process. The blood draw requires fasting for 10 hours beforehand. The session lasts about 1 hour. It is either your third or fourth assessment, depending on schedule availability.

STUDY LOCATIONS

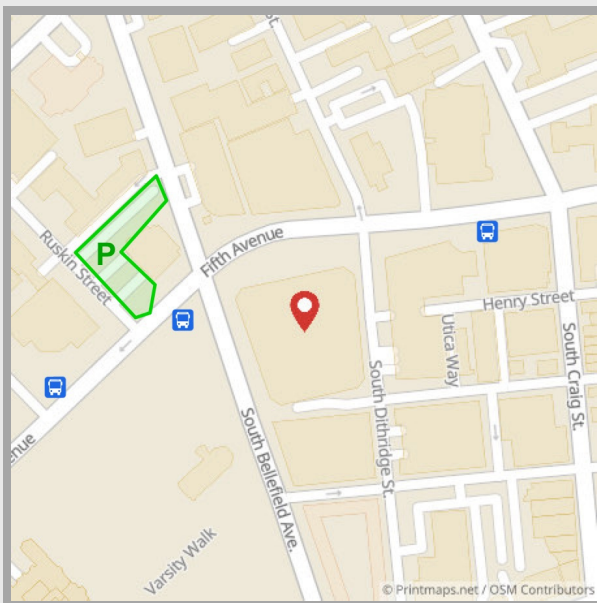
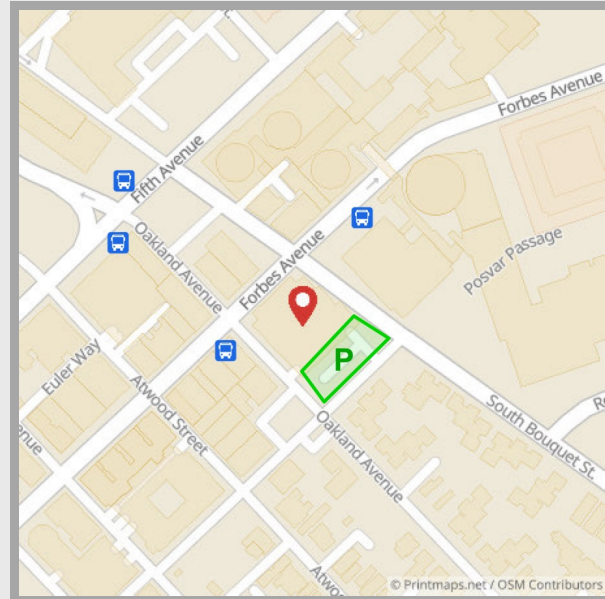
Sennott Square

210 S Bouquet St
Pittsburgh, PA 15213

Location for study assessments:
cognitive, fitness, and blood draw.

Parking available behind building.
Staff will provide a parking pass.

Nearest bus lines: 54, 58, 61A-D, 67,
69, 71A-D, 75, 93, P3



BRIDGE Center

4400 Fifth Ave
Pittsburgh, PA 15213

Location for study assessment:
MRI scan.

Parking available in nearby parking lot.
Staff will provide a parking pass.

Nearest bus lines: 28X, 54, 58, 61A-D,
67, 69, 71A-D, 75, 81, 83, 93, P3

STUDY LOCATIONS

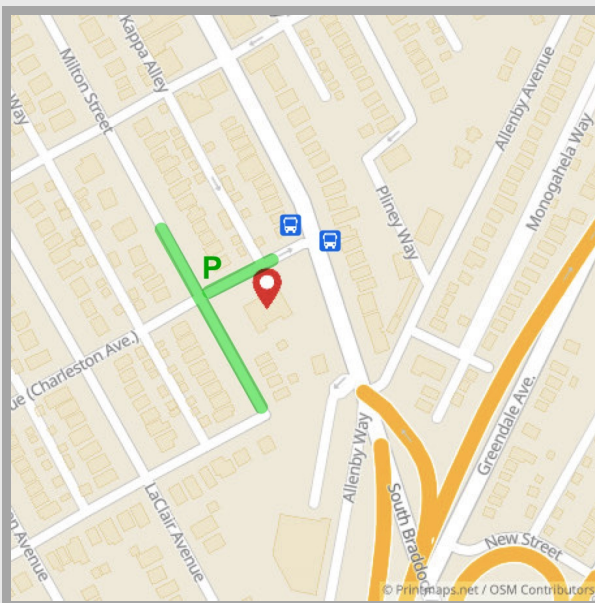
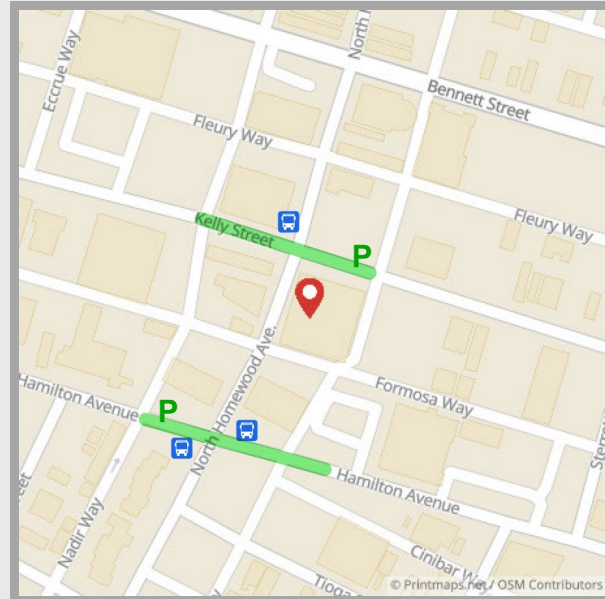
Community Engagement Center

622 N Homewood Ave
Pittsburgh, PA 15208

One of the available locations to take classes.

Free on-street parking available close to the building.

Nearest bus lines: 71D, 74



Wilkins School Community Center

7604 Charleston Ave
Pittsburgh, PA 15218

One of the available locations to take classes.

Free on-street parking available close to the building.

Nearest bus lines: 61B, 71, P71

MEET THE TEAM

Leadership Team



KIRK ERICKSON

Hometown: Pittsburgh, PA

The Principal Investigator for REACT; responsible for overseeing the entire project.



MIHLOTI WILLIAMS

Hometown: Tzaneen, South Africa

The Study Coordinator for REACT; manages all day-to-day operations for the project.

Intervention Team



CHRISALA BROWN

Hometown: Pittsburgh, PA

Responsible for facilitating one of the Africana culture classes.



RONALD LWANGA

Hometown: Kampala, Uganda

Responsible for facilitating one of the Africana culture classes.

Assessment Team



GABRIELLA NUTTER

Hometown: Johannesburg,
South Africa

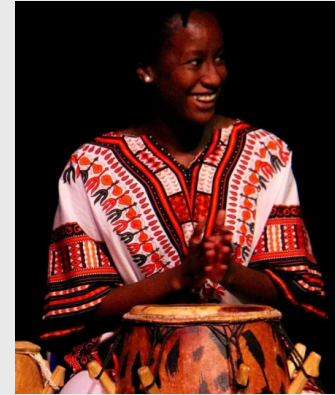
In charge of running the MRI testing session and helps with eligibility screening.



GEORGE GROVE

Hometown: Johnstown, PA

Oversees exercise-related activities and assists with running the fitness testing session.



HAWAH KALLON

Hometown: Greeley, CO

In charge of running the cognitive testing session and oversees the consent process.



JEFF PICONE

Hometown: Pittsburgh, PA

Assists with running the MRI testing session and helps with data entry.



RAYMOND SCALISE

Hometown: Monroeville, PA

Assists with running the fitness testing session and helps with data entry.



REBECCA CLEAVER

Hometown: West Mifflin, PA

In charge of running the blood draw testing session and helps with data entry.

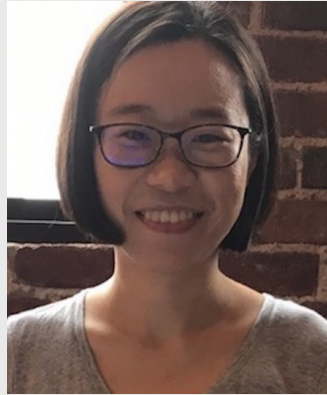
Support Staff



ALLY GILMORE

Hometown: Greenville, PA

Assists with database management and helps perform data quality checks.



LU WAN

Hometown: Tai'an, China

Manages all databases for the project and routinely checks for data quality.



SAMANTHA ROSENBERG

Hometown: Olney, MD

Responsible for participant recruitment and oversees eligibility screening.

Not pictured:

KRISTIN DUDLEY - (Assessment Team) In charge of running the fitness testing session and helps with data entry.

FREQUENTLY ASKED QUESTIONS

What do I get from participating in this study?

In addition to receiving compensation, you have the opportunity to participate in new research on brain health in late adulthood. We designed our classes to be fun and engaging, and we hope to create an environment that promotes community. You have the chance to meet new people, hear their perspectives, and share your own, all while learning about the rich history and culture of Africa. Our goal is to show that this kind of program can have a meaningful impact on mental and physical health. The results will help inform new health care policies and recommendations. Your participation is an investment in yourself and future generations.

Will you share the results of the study?

Yes! Currently, we're still in the data collection stage. Once all the data is collected, we'll begin data analysis. We expect to publish several papers with the results of our research; however, it'll likely be another 2-3 years before we're ready for that. We plan to make our results freely available to all participants at that time.

Can you send my doctor the results of my tests?

Only in very rare circumstances. During the course of the study, you will complete a total of 8 study assessments (4 at baseline and 4 at post). It is not standard practice to share the results of individual tests with you or your doctor. However, if we see anything out of the ordinary, we will let you know, and we will make the results of your test available to your doctor with your permission. In this case, no news is good news!

FREQUENTLY ASKED QUESTIONS

Are there any risks I have to worry about?

No. Our study is low-risk for those screened eligible. After a dance class or the fitness assessment, you may have some muscle soreness or fatigue. We minimize this by starting at a low level and increasing the intensity as you tolerate. In addition, the MRI scan uses a strong magnetic field, which could be dangerous for a person with certain electronic implants. We minimize this risk by asking you detailed questions about metal in the body at several times throughout the study. Some of the other tests, like the blood draw, might cause some minor discomfort. If you are uncomfortable with any study activities, please alert a staff member right away – remember you can choose to stop at any time.

Who has access to the information that I provide?

During the study, staff members for REACT will have access to your information. Only a select few have access to all the data, while most staff have limited access. Every staff member must complete training on data security, which requires renewal regularly. See page 7 for an introduction to our staff.

How are you protecting my personal information?

We take great care to keep your personal information private. Instead of using your name in our records, we identify you with a case number. We store all paper records in a locked filing cabinet in a locked room that only staff have access to. We keep all electronic records on a password-protected server behind multiple walls of encryption. Only authorized users have access to the server and it's actively monitored by the University of Pittsburgh IT department.

FREQUENTLY ASKED QUESTIONS

How do you determine which group I'm in?

It is completely random which group you're assigned to. Since there are only two groups, it's like flipping a coin to decide whether you're in the Cultural Immersion class or in the African Dance class. The process of picking your group is called randomization. In reality, we don't actually flip a coin; we let a computer program do the heavy lifting. Since we won't know which group you're in until right before classes start, it's important that you're interested and willing to participate in either of the two groups. We cannot change your group assignment once the computer makes its choice!

Who is overseeing this research project?

Our leadership team includes our study coordinator, Mihloti Williams, and our Principal Investigator, Dr. Kirk Erickson. Mihloti manages all day-to-day research activities and handles any participant concerns. Dr. Erickson is responsible for managing the budget and all regulatory reporting of study progress. More info on the organizations we report to is found in the glossary on page 14.

Who do I contact if I have a question?

Please reach out to Mihloti Williams, our study coordinator, with any questions or concerns. Her contact information is on page 2.

How is this study being funded?

We received a grant from the National Institutes of Health (NIH) for REACT. NIH is committed to funding research projects that advance medical science and address public health needs.

FREQUENTLY ASKED QUESTIONS

What do I do if I no longer want to be in the study?

That's okay! Participation in this study is completely voluntary. If, for any reason, you no longer wish to participate, you have every right to withdraw from the study. There are no consequences to withdraw, and it will not impact your ability to join other studies in the future. We do, however, ask that you let us know if you choose to withdraw so we can keep an accurate record. Also, we will still ask you to come back for post sessions, if you're willing.

Is there compensation?

Yes! We will compensate you up to \$595. There are two types of payments you will receive: 1) payment for completing study assessments, and 2) payment for attending classes. See the chart below for a breakdown.

Reason	Time Period			TOTAL
	Baseline	Intervention	Post	
Cognitive Assessment	\$35	-	\$35	\$70
Fitness Assessment	\$30	-	\$30	\$60
MRI Scan	\$80	-	\$80	\$160
Blood Draw	\$10	-	\$10	\$20
Take Home Questionnaire	\$20	-	\$20	\$40
Diet History Questionnaire	\$10	-	\$10	\$20
Physical Activity Watch	\$5	\$15	\$5	\$25
Class Attendance*	-	\$200	-	\$200
TOTAL	\$190	\$215	\$190	\$595

*Every 3 weeks, we pay you \$25 (8 total payments), as long as you attend at least 80% of classes.

GLOSSARY

Assessments	For REACT, assessments are the research activities where most data are collected. There are four (4) assessments. You complete each assessment twice: once during baseline and once during post. Completing study assessments allows us to make conclusions about the research. See page 4 for detailed information about each assessment.
Assessment window	The timeframe for completing study assessments. For REACT, the window opens on the date of enrollment and closes, ideally, six (6) weeks later. While six (6) weeks is the goal, sometimes the window is longer; we will work with you to solve any scheduling challenges.
Baseline	In REACT, study participation consists of three (3) time periods. Baseline refers to the first time period, before intervention. During this time, you complete study assessments. We also review your eligibility. Baseline is typically six (6) weeks long.
Cognition	Refers to the mental process of gaining and understanding knowledge. It includes processes like perception, memory, and thinking.
Consent form	A written document that details everything you need to know about what's involved in the study. When you sign the document, you confirm that we obtained your informed consent. It marks your voluntary agreement to participate.
Data and Safety Monitoring Board (DSMB)	A committee made up of scientific experts from universities outside the University of Pittsburgh, as well as the federal government. The DSMB reviews data from an ongoing study and evaluates if any changes need to be made. Their goal is to make sure we meet all safety standards and handle study data responsibly. We submit progress reports to the DSMB regularly.

GLOSSARY

Eligibility criteria	A set of guidelines for who can or cannot participate in a study. There are two (2) main reasons to use this. First, it ensures that all participants share similar factors like age, medical history, and current health status. When this happens, it's more likely that our results are due to research activities, and not due to chance. Second, using eligibility criteria keeps people safe by not including people with increased risk of a serious health problem.
Eligibility screening	The process of determining whether someone is a good fit for a study. It starts at the phone screen and continues throughout the baseline period.
Enrollment	The process of joining a research study and agreeing to participate. Enrollment is official when you sign the consent form.
Enrollment date	The day you sign the consent form. For REACT this is the same date as your first study assessment: the cognitive session. You will sign consent before starting any research activities.
Informed consent	A core principle of research ethics. During this process, a staff member provides a detailed explanation of what's involved in the study. The staff clarifies what we expect from you and gives you time to ask questions. If you agree to participate, we ask you to sign a consent form. The whole process usually takes 20-30 minutes.
Intervention (1)	In REACT, study participation consists of three (3) time periods. Intervention refers to the second time period, between baseline and post. During this time, you attend cultural immersion or African dance classes, three (3) days per week for 1-hour each. Intervention is six (6) months (24 weeks) long.

GLOSSARY

Intervention (2)	Refers to the type of study design used for REACT. An intervention study involves making a change and testing whether that change had an effect on some outcome. For REACT, the change is attending classes three (3) days per week, and the primary outcome is memory function.
Institutional Review Board (IRB)	A committee within the University of Pittsburgh whose purpose is to protect the rights of research participants. The IRB reviews a study to make sure it follows all federal regulations. Members come from varying backgrounds, including at least one community representative. We submit progress reports to the IRB regularly.
National Institutes of Health (NIH)	A government agency for the U.S. that is responsible for advancing biomedical and public health research. The NIH conducts its own research, and it distributes federal funds to outside projects. REACT receives its funding from the NIH. In turn, we submit progress reports to NIH regularly.
Phone screen	A phone call between a staff member and a potential participant. During the call, we explain what's involved in the study and answer any questions you might have. If you're interested in joining, we will also start the eligibility screening process. The call is usually 15-30 minutes.
Post	In REACT, study participation consists of three (3) time periods. Post refers to the third time period, after intervention. During this time, you complete study assessments. These assessments are exactly the same as the ones you complete as baseline, which allows us to make before-and-after comparisons. Post is typically six (6) weeks long.
Pre-enrollment	The period of time after completing a phone screen but before enrollment.

GLOSSARY

Principal Investigator (PI)	The person responsible for overall study design. The PI is in charge of getting funding, managing the budget, and reporting progress to governing bodies. The PI is responsible for the integrity of the study.
Randomization	The process of determining which intervention group you're in. For REACT, this refers to either the 1) Cultural Immersion class, or the 2) African Dance class. During randomization, you are randomly assigned to one of these classes. You have an equal chance of being in either group, like flipping a coin for heads or tails. Doing this allows us to make sure the group are divided fairly.
Randomization date	The day we determine which group you're assigned to. While the process is just like flipping a coin, we actually let a computer program do the work for us. Our study coordinator will contact you after randomization to tell you which group you're in and to give you details on starting your class.
Research ethics	Refers to the guidelines on how to do research responsibly. We commit to being honest and open in our research activities. We value the unique perspective of every participant and treat you with respect. We hold ourselves accountable and strive for integrity.
Study coordinator	The person responsible for managing all day-to-day research activities. They make sure that the assessments run smoothly. They also talk to participants regularly to make sure we meet your needs.

THANK YOU

FOR PARTICIPATING IN THE REACT STUDY!

This handbook was created by Samantha Rosenberg. If you have any questions about anything printed here, please contact her at SLR113@pitt.edu

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