Lifestyle Physical Activity and Cognitive Training Interventions: Preventing Memory Loss in Older Women With Cardiovascular Disease

NCT04556305

01.26.2021

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Lifestyle Physical Activity and Cognitive Training Interventions: Preventing Memory Loss in Older Women with Cardiovascular Disease

Sponsor(s): NIH/NINR: National Institute of Health, National Institute of Nursing Research, Washington, DC

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University System for Health will not change or be affected.

The purpose of this study is to see if women with cardiovascular disease who participate in the 24-week combined *MindMoves* intervention, which combines lifestyle physical activity and cognitive training have better improvements to memory and other markers of brain health compared to women who participate in *Mind* (cognitive training) or *Move* (lifestyle physical activity), or do not receive any intervention. We will be assessing memory and other health factors at the start of the study, 24 weeks, 48 weeks, and 72 weeks.

If you agree to participate in this study, your participation may last up to 72 weeks and you will be asked to complete 4 data collection study visits at baseline, 24 weeks, 48 weeks, and 72 weeks

post-baseline. You will also be asked to complete an intervention orientation after you are randomized (assigned by chance) to your intervention group after your baseline visit.

Data collection visits will either occur in the clinic/research office setting, or on the phone. During the data collection visits, you will be asked to complete questionnaires about your sociodemographics, health, physical activity, cognitive activity, and other health behaviors. You will also complete 30 minutes of neurocognitive testing and wear an ActiGraph accelerometer (activity tracker device) for 7 consecutive days on your right hip. You will also have your blood drawn in the outpatient laboratory or in your home by our trained data collector. You will also have your finger pricked to obtain 4 spots of blood. For both of these blood samples (blood draw from your vein in the laboratory or your home, and the finger prick blood spot), we will use the blood to look at biomarkers found in the blood that may be related to the brain, and also to look at genetic factors that may be related to how people respond to interventions that target memory. Each visit will take about 2 hours.

If you are considered eligible for the study, you will be randomized (assigned by chance) to one of the following groups: (1) *Mind*: a cognitive training program that consists of participating in 3 weekly 30-minutes sessions of cognitive training games on an iPad that is provided to you, (2) *Move*: a lifestyle physical activity program that consists of individualized goal-setting and 5 group meetings that aim for you to increase your physical activity participation, (3) a combination of both the *Mind* and *Move* intervention (*MindMoves*), or (4) usual care, or whatever your cardiology provider normally recommends at your normal visits. All conditions will receive healthy lifestyle educational materials at the beginning of the study and a Fitbit at the end of the study. For more information, please see the *"What are the activities you will be doing if you participate in this study?"* section below.

You may benefit from taking part in this study, but there is no guarantee that it will help you. Based on experience with lifestyle physical activity and cognitive training in healthy older adults, researchers believe it may improve memory in people with high cardiovascular risk. However, because individuals respond differently to interventions, no one can know in advance if it will be helpful for you. For more information, please see the *"What are the benefits of participating in the study?"* section below.

This study includes little risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. For details and a list of risks you should know about, please see the *"What are the risks and discomforts of participating in this study?"* section below.

If you are assigned to the usual care condition, you should not expect to improve memory as a result of participating in this study.

Instead of participating in this study, there may be other opportunities for improving your memory. You should discuss these other opportunities with your study doctor. Some of these opportunities may include improved medication management of chronic health problems or other lifestyle behaviors or programs that can support memory, such as learning a new language, puzzles, or other cognitive activities. You have the option to not participate in this study.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to be a subject in a research study that is a lifestyle physical activity program for older women with cardiovascular disease (e.g., coronary artery disease, hypertension).

You are being asked to take part in this study because you are:

- A woman
- Aged 65 years or older
- Able to speak and read English
- Have a diagnosis of cardiovascular disease (e.g., coronary artery disease, hypertension), and are a patient seen by a provider at the Rush Heart Center for Women
- Have a Bluetooth-compatible device (tablet, cell phone)
- Not currently doing regular moderate or vigorous physical activity
- Not currently doing a cognitive training program
- Have no disability that would prevent you from being more physically active
- No self-reported hearing loss that interferes with normal conversation
- Do not have signs or symptoms of cardiopulmonary disease
- Do not have current cognitive impairment, dementia, or significant neurological disease
- Do not have current Stage 5 renal disease on dialysis

How many participants will take part in this study?
Approximately 254 participants are expected to take part in this study at Rush University Medical Center and Rush Oak Park Hospital.

What are the activities you will be doing if you participate in this study?
If you are reading this, you have already completed a preliminary screening interview, either in person or over the phone with yes/no questions and you have received an informed consent in the mail or email. You also have received provider approval from your cardiology provider at the Rush Heart Center for Women to participate in a lifestyle physical activity program. If you agree to be in the study, you will complete the secondary screening either in person at Rush University Medical Center or Rush Oak Park Hospital in a private conference room, or over the phone with a study staff member. The secondary screening takes about 15 minutes. If you are eligible for the study, then you will complete the baseline assessment. The baseline assessment can either be completed in person at Rush, or over the phone. You will also have the option of having your blood drawn in your home instead of coming into the outpatient laboratory. We may provide you with the supplies to prick your own finger to obtain the 4 drops of blood at home. The baseline assessment usually takes about 2 hours.

Screening

Secondary Screening

1. You will be asked to read this informed consent form, and either sign it or verbalize your consent if you are willing to be in the study. You may read the consent form on your own or have it read to you. You will need to say your date of birth to verify your identity.
2. You will complete a short cognitive screening questionnaire.
3. You will be asked permission for the research staff member to access your Electronic Health Record (EHR) to confirm screening criteria, including diagnosis of cardiovascular disease [CVD] or hypertension, blood pressure, hemoglobin A1C (a diabetes measure), neurological disease (such as Alzheimer's disease or Parkinson's), stroke within the past 3 months, anti-psychotic medications, and on dialysis for renal disease. The research staff member will view your EHR to see your past labs and history regarding these items.
4. You will have the baseline assessment scheduled if you meet the complete criteria for the study and agree to participate.

During the Study

Baseline Assessment

The baseline assessment will either be completed in the clinic/research office setting, or you will complete the assessment over the phone. If you complete the baseline assessment over the phone, you can have your blood drawn in your home.

1. Your blood pressure, height, and weight will be measured either in the clinic or your home.
2. You will be given the results of your blood pressure, height, weight, and Body Mass Index (BMI).
3. You will complete study questionnaires. If you are completing the assessment in the clinic, then you will be given a snack. The questionnaires will include demographic questions (for example your age and gender), health history (for example, menopausal status or pregnancy history), your physical activity and sedentary behavior, self-reported cognitive activity (like reading and doing puzzles) and psychological health and memory. You may have the questionnaires read to you or you may answer them yourself.
4. You will complete the 2-minute step test, where you step in place at a designated height for 2 minutes.
5. You will have about 2 tablespoons of blood drawn at either the outpatient laboratory or drawn in your home from one of your veins in your arm to measure biomarkers of brain health and genetic factors.
6. You will be asked to prick your finger to obtain 4 drops of blood that will be smeared on a card at either the outpatient laboratory or in your home. You may need to prick more than one time to get 4 total drops. If you choose to complete this step at home, you will be trained by our research staff on the finger prick and blood collection. the research team

will provide you with the card and materials needed and you will be asked to mail back the sample in a prepaid envelope that is provided. These drops of blood will also measure biomarkers of brain health found in the blood.

7. You will be given an activity monitor to wear around your waist for seven days during waking hours. You will return the monitor during your intervention orientation.
8. You will be given a $40 Target gift card for the assessment. This total baseline assessment should take 2 hours or less. If it is more convenient for you, this can be completed over two or three visits.

Intervention Conditions

After you have returned the activity monitors, we will assign a Study Identification number for you. You will be randomized (assigned by chance) to one of the following groups: (1) Mind: a cognitive training program that consists of participating in 3 weekly 30-minutes sessions of cognitive training games on an iPad that is provided to you, (2) *Move*: a lifestyle physical activity program that consists of individualized goal-setting and 5 groups meetings that aim for you to increase your physical activity participation, (3) a combination of both the *Mind* and *Move* intervention (*MindMoves*), or (4) usual care, or whatever your cardiology provider normally recommends at your normal visits. All conditions will receive healthy lifestyle educational materials at the beginning of the study, and a Fitbit at the end of the study (or can keep your study Fitbit if you receive one in your intervention condition). You will have equal chances of being assigned to any of the 4 conditions.

1. *Mind*
   a. Study Orientation
      i. You will be given and taught how to use an iPad tablet to complete a cognitive training program.
      ii. You will be instructed to complete the cognitive training program (BrainHQ) 3 times per week for 30 minutes each session on the iPad tablet. The cognitive training program will be downloaded onto the iPad tablet, which you will use during the study period.
      iii. You will receive a Participant Manual on how to use the iPad tablet to complete the cognitive training program.
      iv. You will receive weekly tech support phone calls to help with any questions you have.

2. *Move*
   a. Study Orientation
      i. You will be given a physical activity prescription. Our goal is to increase physical activity above your baseline by a minimum of 3,000 steps per day, or about 30 minutes of physical activity, over the 24-week intervention. We also strive for you to achieve 150 minutes of moderate physical activity per week. You will gradually increase your physical activity and receive an individualized goal at each of the 5 group visits.

ii. You will be given and taught how to use a physical activity monitor (Fitbit) to monitor your steps. The Fitbit will be worn at your wrist during waking hours. The Fitbit will sync with your Blue-tooth capable device and you can monitor your progress on the Fitbit application.
iii. You will receive a Participant Manual that will provide instructions on using your Fitbit.
iv. You will receive weekly tech support phone calls to help with any questions you have.

b. Group Meetings
i. You will attend 5 group meetings every 5 weeks. The group meetings will either be held virtually using Zoom software, or they will be held in a private conference room at Rush University Medical Center or Rush Oak Park Hospital. If the group meetings are held virtually, you will be given an iPad to use in order to access the group meetings. Group meetings consist of five 90-minute visits held every five weeks. Group meetings are led by a trained interventionist with a health-related degree. Group meetings include an individual visit with the interventionist about your physical activity goals, followed by the group component.
ii. Group meetings may be audio-recorded for training purposes, and so participants can access the recordings if they miss a session.

3. *MindMoves*
a. If you are randomized to *MindMoves* you will complete both the *Mind* and the *Moves* interventions simultaneously over 24 weeks.
4. Usual Care
a. The usual care group will continue to receive care from their cardiology provider.

Follow-up Assessments at 24 weeks, 48 weeks, and 72 weeks (all Intervention groups)
The follow-up assessments will either be completed in the clinic/research office setting, or you will complete the assessment over the phone. If you complete the baseline assessment over the phone, you can have your blood drawn in your home.

1. Your blood pressure, height, and weight will be measured either in the clinic or your home.
2. You will be given the results of your blood pressure, height, weight, and Body Mass Index (BMI).
3. You will complete study questionnaires. If you are completing the assessment in the clinic, then you will be given a snack. The questionnaires will include demographic questions (for example your age and gender), health history (for example, menopausal status or pregnancy history), your physical activity and sedentary behavior, self-reported cognitive activity (like reading and doing puzzles) and psychological health and memory. You may have the questionnaires read to you or you may answer them yourself.
4. You will complete the 2-minute step test, where you step in place at a designated height for 2 minutes.
5. You will have about 2 tablespoons of blood drawn at either the outpatient laboratory or drawn in your home from one of your veins in your arm to measure biomarkers of brain health and genetic factors.

6. You will be asked to prick your finger once to obtain 4 drops of blood that will be smeared on a card at either the outpatient laboratory or in your home. You may need to prick more than one time to get 4 total drops. If you choose to complete this step at home, you will be trained by our research staff on the finger prick and blood collection. the research team will provide you with the card and materials needed and you will be asked to mail back the sample in a prepaid envelope that is provided. These drops of blood will also measure biomarkers of brain health found in the blood.
7. You will be given an activity monitor to wear around your waist for seven days during waking hours. You will return the monitor during your intervention orientation.
8. You will be given a $40 Target gift card for the assessment. This total baseline assessment should take 2 hours or less. If it is more convenient for you, this can be completed over two or three visits.
9. For participants in the *Move* or *MindMoves* group, you will keep your study Fitbit at the end of the study. If you were in the *Mind* or the usual care group, you will be given a Fitbit to keep at the end of the study.

You may call the study office at (312) 947-3870 and leave a message at any time (24 hours 7 days per week) if you have questions or concerns. There will be a telephone voice mail so you can leave a message. Also, we will be available during the day to talk with you.
Your name will never be used on any paper reports. In this research there will be a number used instead of a name. There may also be times when a research team member may observe the interactions between you and staff members. You will be asked in advance if you mind having the observer there. You may refuse. If you do agree to have the observer in the room, they will be out of the way, and you will be asked to interact as usual. This is the research teams' method of evaluating how well the visits are going.

Does this study involve genetic testing?
Yes, this study involves *BDNF* Val66Met polymorphism and *APOE-ε4* candidate gene analysis with DNA extraction from whole-blood samples. The *BDNF* Val66Met polymorphism affects how BDNF, a protein related to the brain, is secreted into the blood. The *APOE-ε4* allele is a genetic risk factor for Alzheimer's dementia. These genetic factors may be related to how interventions, such as lifestyle behavioral intervention or drugs, affect memory.

The use of genetic material in research to study the causes of disease and to help understand how individuals respond to drug treatments is called genetic research. The cells of your body contain a molecule called deoxyribonucleic acid (DNA). DNA is received from your parents and carries a code in the form of genes, which determine your physical characteristics such as the color of your hair and eyes. Ribonucleic acid or RNA for short also acts as a messenger to tell your cells to produce certain features. Just as differences in our genetic codes help explain why we all look different, these differences can also help explain why some people develop certain diseases and others do not. They may also help explain why some drugs or interventions are safe and effective for some people but not for others.

We will not be examining individual genetic factors. We will be looking at genetic factors from the entire group as a whole. We will not be providing genetic information to participants. If you

no longer wish to have genetic information used in this research, we will remove and destroy the samples at any time during or after the study.

What do you need to know regarding the collection of biospecimens?
Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect blood.

Most biospecimens contain DNA. We will not use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA.

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or biospecimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

Will your cells, tissues, blood or other biological materials (biospecimens) be used to develop commercial products?
No, your biospecimens will not be used to develop a commercial product.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

- You may experience some discomfort, bruising, minor bleeding and, very rarely, infection at the site the needle enters the body, and in rare cases, fainting or infection.
- At the screening, you will be asked to report any history of heart disease, chest pain, severe dizziness or joint pain that is increased by becoming more physically active. A positive response to any of these will mean that you cannot take part in the study.
- There may be a risk of injury or falling related to physical activity and falling. During study orientation, topics in injury prevention will be reviewed, including proper walking form, warming up, cooling down, and increasing physical activity slowly over a period of time
- You may feel uneasy talking about yourself and your personal behaviors. You can talk about any uneasy feelings with a research team member. Your ability to answer research questions honestly is based on your comfort with the information so if you alert the

research team to your uneasy feelings, they will do everything possible to make you more comfortable.

There may be other risks that may happen that we cannot predict.

What are the risks involving genetic information?

While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. Genetic information is considered health information and is protected under the Health Insurance Portability and Accountability Act (HIPAA) as is your other health information. While very rare, information could be misused by employers, insurance companies and others. For example, life insurance companies may charge a higher rate based on this information. A federal law called the Genetic Information Non-Discrimination Act (GINA) should help lower the risk from unfair health insurance or employment policies. To learn more about the GINA Law, please go to http://www.ginahelp.org/GINAhelp.pdf or ask the study staff.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. There are no consequences to your care for leaving the study.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Shannon Halloway, her study team, and other Rush personnel involved with the conduct and review of this study

(which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Shannon Halloway and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- During the in-person screening process, we will confirm your diagnosis of cardiovascular disease using the medical record, as well as any diagnosis that would prevent you from being eligible in the study (e.g., neurological disease, stroke within the last 3 months, uncontrolled blood pressure greater than 160/100 mmHg).
- Results from questionnaires and neurocognitive tests
- Results from blood tests, including serum neurotrophin biomarkers and *APOE-ε4* candidate gene analysis

Dr. Shannon Halloway and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers;
- The study Sponsor, the National Institutes of Health, and its representatives (the Safety Monitoring Committee);
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Shannon Halloway is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. Any audio tapes obtained during the study will not have identifying information recorded (e.g., names).

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Shannon Halloway at 600 S Paulina, Suite 1080, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All of your questionnaires and physical information will be maintained using an identification number and will be kept separate from your name at all times.

After all information collected from you has been analyzed (within 2 years after the end of study), the identification number will be removed from the data, which will remain completely anonymous thereafter. The hard copies of the data will be kept for 3 years, and then destroyed.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected. Whenever we use the information you give us, only a code number will identify you. Only you and the people working on the study here will know your code number. Your name will never be used. You will not be named in any publication or presentation from this study. Your answers on the questionnaires or your lab results will not be shared with your provider. Nothing you say will influence your treatment or services at any clinic or agency. The information will not become a part of your medical records or any other records or files.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs to participate in this study?

All costs for the required study, including questionnaires, blood tests for the study, and interventions will be paid by the National Institutes of Health

You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not, unless you are told that such item or services will be supplied at no cost. If you have health insurance, the insurance may or may not pay for the costs associated with your participation in this study. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. Before you decided to be in this study, you should contact your insurance provider to verify coverage.

Will you be paid for your participation in this study?
You will be paid $40 Target gift card for each completed study visit ($160 total for the 4 data collection study visits). If you do not finish this study, you will be paid for the study visits you have completed. You will be paid within approximately 30 days after each data collection study visit either in person or in the mail. You will also receive a parking pass at each study visit, including the 4 data collection visits and study orientation. You will also receive a Fitbit at the end of the study or get to keep your study Fitbit if you received it as part of your intervention.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Shannon Halloway or Dr. Charlene Gamboa (project director) at telephone number (312) 947-3870.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.
You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Charlene Gamboa (project director) at (312) 947-3870 or email her at Charlene_Gamboa@rush.edu. You may also contact the principal investigator, Dr. Shannon Halloway, at 312-563-9594 or email her at Shannon_Halloway@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you

must inform Dr. Shannon Halloway in writing at the address on the first page. Dr. Shannon Halloway may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature