Reducing Disability Following Hospital Discharge in Vulnerable Older Adults: The CAPABLE Intervention

NCT:

Date: Ocotber 19, 2017

	Approved on:	
	Expires on:	
Visiting Nurse Service of NY Institutional Review Board (IRB) FWA#00001885	Study number:	

Research Participant Informed Consent Form – CAPABLE Study

Johns Hopkins IRB#:
VNSNY IRB #:
Participation Duration: 12 months
Anticipated Number of Participants: 268

Contact	Title / Contact Type	Phone Number / E-mail
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Melissa Trachtenberg	Project Manager	212-760-3112/Melissa.Trachtenberg@vnsny.org

WHAT IS THE PURPOSE OF THIS CONSENT?

This form describes a research study and what you can expect if you are in the study. We will read the form together and talk about any questions you have before you decide to take part in this study. This study is being run by researchers working together from the Visiting Nurse Service of New York (VNSNY) and Johns Hopkins University School of Nursing. You are being asked to be in this study because you have trouble with some daily activities such as getting dressed, taking a bath, and/or walking.

WHAT IS THE PURPOSE OF THIS STUDY?

This study is being done to test out a new program with VNSNY patients. We want to know if receiving more visits from an occupational therapist, registered nurse and handy man will make it easier for you to walk around and take care of yourself at home. The program we are testing is called the Community Aging in Place, Advancing Better Living for Elders (CAPABLE), program. This program helps people with their medications, their pain, and help them put together an exercise plan. You may also be asked to make some changes to your house or apartment to help you be more comfortable at home. We will test this program by asking patients to be part of one of two study groups: one group will get visits from an occupational therapist and registered nurse as part of the CAPABLE program and the other group will not get any extra visits. If you agree to take part in this study you will be randomly placed in one of the two groups. You have a 50:50 chance of getting into either group. At the end of the study, we will look at the information we collect from each group to see if one group does better than the other. The information that we get from you and other people in the study will help the project team to figure out if these programs should continue or if they should be changed.

WHAT WILL I BE ASKED TO DO?

You are being asked to take part in one interview now, a second interview in 5 months and a possible third interview in about 12 months. Each survey visit will last about 1 hour. During each visit, we will ask you questions about your regular activities, your pain and we will ask you other questions about your general health. At the very end of the study, after all of the interviews are done, someone may call you and ask you questions about how the study went.

After the first interview, all study participants will be randomly placed in either the CAPABLE program group or the usual care (control) group. You have a 50:50 chance of getting into either group. This means that you may be placed in the CAPABLE program group or you may not and the interviewer does not know which group you will be in.

IF you are placed in the CAPABLE program group:
In addition to the usual care you receive from the VNSNY CHOICE staff, you will get 10 home visits with the study staff for the next 5 months. This includes about 6 visits from a study occupational therapist and about 4 visits from a study registered nurse. You may also receive handy man services during your time in the program.

The study occupational therapist assigned to you will:

1) Fill out an assessment in your home to see how well you are able to walk, get around in your home and complete your normal activities of daily living.
2) Look around your home for safety and mobility problems. Your occupational therapist will work with you to create a list of safety risks to be given to the handy man service for repair. Such repairs may include: fix holes in floors, stabilize shaky banisters, or lower cabinets for easier access.
3) Review any changes to your home with you and the handy man service to make sure that you are satisfied with the changes.

The study registered nurse assigned to you will:

1) Fill out an assessment about your general health.
2) Work with you to organize and manage your medications.
3) Create an exercise and strengthening plan if needed.
4) Help you find a primary care physician if needed.

IF you are placed in the Usual Care (Control) Group: your care will be the same as you usually receive, with your VNSNY CHOICE Advantage services unchanged and providing care as before. You will not be visited by a study nurse, occupational therapist or handy man if you are in this group. If you are still getting VNSNY home health care services, you will continue to receive those visits as part of your usual care.

It is important for you to know that your usual VNSNY CHOICE care will not change as part of this study. The study team will not make any changes to your VNSNY CHOICE health plan and this study will not have any effect on your insurance.

By taking part in this study, you agree to give the study team permission to review your VNSNY CHOICE health records and health status information, and information about your VNSNY home care services. This information includes your activities of daily living, service use information, medication changes and referrals made to other services.

By taking part in in this study, you give the study team permission to collect information about the healthcare services that you receive through your VNSNY CHOICE plan. You are giving us permission to look at your health records from the time you start the study plus 2 years later. You also give the study team permission to look at your Medicare healthcare services for the same time period even if you change your Medicare healthcare plan.

We are asking your permission to audio record the interviews. You do not have to agree to this part of the study and your decision does not affect your participation in the rest of the project. Audio

recording the interviews will help us with training and to make sure we collect all of your information. We are also asking for your permission to contact you about future research studies that you may be interested in.

HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?
We are asking about 268 VNSNY CHOICE members to take part in this study.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF PARTICIPATION?
There is low risk to you for taking part in this study. Patients who are in the CAPABLE program group may be given new exercises from their occupational therapist. Because we might be asking you to get up and move around, there is a possible risk of having a fall but the study nurse and therapist will work closely with you to keep this risk low.

We will be asking you for some personal information such as your name and questions about how you feel. The only people who have access to the information will be the study team members. We will use a study ID number instead of your name on all of the information that we get from you. The study team will do everything we can to protect your private information. All of your private information will be put in locked cabinets and password protected computers.

You may not gain anything from being in this study but your participation is very important to the success of the project. The information that you give us will help us continue to create better programs for adults like you.

ARE THERE ANY COSTS?
You do not have to pay anything to take part in this study.

WILL I BE PAID?
Yes, you will receive $25.00 after each survey as a thank you for your time. This means that every time you meet with the study interviewer and complete the questionnaire, you will receive $25.00 as a thank you. There is no payment for meeting with the study occupational therapist, study nurse or handy man as part of the CAPABLE program group.

WHO CAN SEE MY INFORMATION?
This study is being run by staff at 2 organizations: the VNSNY and Johns Hopkins University College of Nursing. If you decide to take part in this study, your study information will be shared with team members at both of these organizations.

CAN I CHANGE MY MIND?
The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use information from the 3 study interviews, your VNSNY CHOICE and VNSNY home care electronic health record, your VNSNY CHOICE Medicare claims, and other Medicare claims if you change programs. If you are in the CAPABLE program group, we will use the health information that we collect about you to conduct the study. We will use your health information to help us analyze the study data and to report results of the research to our sponsors and federal regulators. The data collected may be audited to make sure we are following regulations, policies and study plans.

We will do everything we can to keep information we learn about you private. Sometimes, other people may need to see the information. For example, if we found your safety or health was at risk, we would have to follow through to be sure that you are protected.

The study investigator may share a copy of this consent form and/or records that identify you with the following people: The VNSNY Institutional Review Board, the Johns Hopkins Institutional Review Board, the National Institute of Health, the Office of Human Research Protections or other government agencies.

If you decide to take part in this study, your Authorization for this study will not expire unless you cancel it. Authorization means that you are giving us permission to use the data we collect about you for the research. You can always cancel this permission by writing to the study investigator. If you cancel your permission, you will also be removed from the study. Your other medical benefits will not change even if you decide to stop the study. Canceling your permission will keep us from sharing your information after the study investigator gets your written request. Information gathered before then may need to be used and given to others for research purposes.

You can also refuse to sign this consent form and not be part of the study. If you agree to take part in this study now, you may also tell us you want to leave the study at any time, for whatever reason. By signing this consent form, you give us permission to use and/or share your health information as stated above.

DISCLOSURE STATEMENT

A researcher and Johns Hopkins have a financial or other interest in this study. In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Dr. Bruce Leff at 410-550-2654 or bleff1@johnshopkins.edu. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins

WHAT DO I DO IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have questions about this study, you can call the project director, Dr. Szanton, at 410-502-2605. You can also call the project manager, Melissa Trachtenberg, at 212-760-3112.

If you have questions about your VNSNY CHOICE heath plan, you can call Member Services at 1-866-783-1444.

PARTICIPANT'S RIGHTS AND VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary. You are free to stop or to withdraw at any time, for whatever reason. Your decision to take part in this study will not affect any of the services you are getting from VNSNY or from any other healthcare provider. If you do withdraw from this study, the information you have already provided will be kept private.

STATEMENT OF CONSENT

I have read the purpose of the study and understand what I have to do to take part in the study. I volunteer to take part in this research. I have had the chance to ask questions. By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in the study. If I have questions later about the study, I can contact the person in charge of the study, Dr. Szanton at 410-502-2605 or the project manager, Melissa Trachtenberg at 212-760-3112. I understand that I may stop or withdraw from this project at any time. The study managers may withdraw me from this study as they see fit.

If I have questions about my rights as a research participant, I can call the VNSNY IRB Administrator, Christopher Murtaugh at (212) 609-5777. I verify that I am 21 years of age or older and freely give my consent to take part in this study. I understand that I will receive a copy of this document for my records.

Participant name:

Print Name:_____ Signature:_____ Date: _____

Person obtaining consent:

Print Name:_____ Signature:_____ Date:_____

Thank you for taking part in this study!