Title: PreHabilitation for patients undergoing Transcatheter Aortic Valve Replacement (TAVR PreHab)

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Version: January 26, 2022

Prinicipal Investigator: James Harvey, MD, MSc

WELLSPAN
Cardiology

## INFORMED CONSENT AND HIPAA AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY

**Title:** PreHabilitation for patients undergoing Transcatheter Aortic Valve Replacement (TAVR PreHab)

**Protocol Version:** January 26, 2022

**Principal Investigator:** James E. Harvey, MD, MSc
1001 S. George St
York, PA 17403
717-851-2441

**Sub Investigator:** Stewart Benton Jr. MD

**Sponsor:** York Hospital Heart & Vascular Research Fund

### WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH?

You are asked to participate in a research study because you have severe aortic stenosis and you are scheduled or will be scheduled for a transcatheter aortic valve replacement (TAVR). TAVR has emerged as an alternative therapy to surgery for patients with severe, symptomatic aortic stenosis. Individuals undergoing TAVR are often older with more underlying health conditions than patients undergoing open Aortic Valve Replacement. It has recently been shown that patients who undergo TAVR benefit from rehabilitation after their procedure and that this helps to maintain their independence. In addition, it has been shown that people who participate in physical therapy before undergoing open-heart surgery have a shorter amount of time in the intensive care unit (ICU) and a shorter hospital length of stay after their surgery.

### WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to determine the safety and effectiveness of pre-procedural physical therapy in patients undergoing TAVR. We want to learn if physical therapy prior to the TAVR procedure will improve physical functioning before the TAVR procedure and if this will result in a sustained improvement out to 30 days after the procedure. We also want to learn if a physical therapy program prior to surgery will have an effect on post-procedural length-of-stay, clinical outcomes, and quality of life.

### WHO IS DOING THE STUDY?

The person in charge of this study is James Harvey, MD, MSc of WellSpan Health, and the Department of WellSpan Cardiology. There will be other people on the research team assisting at different times during the study.

## WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at York Hospital and Gettysburg Hospital Physical Therapy Departments and in the Heart & Vascular Research Department.

If you agree to participate in this study, you will be one of seventy participants. You will have a 50% chance of being randomized (like a flip of a coin) to physical therapy before the procedure. This will be the treatment group. The other 50% of participants (the control group) will not participate in physical therapy prior to the TAVR procedure.

## WHAT WILL I BE ASKED TO DO?

If you are in the control group (the group that is not participating in physical therapy prior to the TAVR procedure), you will undergo all items including the physical therapy evaluation but you will not participate in physical therapy sessions.

### Intake (Initial) Assessment

At this visit, you will meet with a member of the Physical Therapy staff who will perform an assessment of your exercise capacity, mobility, and balance through the following:

a. 6MWT (6 minute walk test) measures the distance you are able to walk in 6 minutes.
b. TUG Test (Timed Up and Go) measures the time it takes you to rise from a chair, walk a short distance, turn around, walk back to the chair and sit down
c. FSST (Four Square Step Test) assesses your balance
d. KCCQ (Kansas City Cardiomyopathy Questionnaire) to assess your quality of life.

### Prehabilitation (treatment group only)

Based on the results of the Intake Assessment, the physical therapist will determine a course of conditioning specific to you; however, you will receive a maximum of 12 visits over the 3 to 5 weeks prior to the surgery date.

### Pre-operative Assessment

This visit will occur within a week prior to your TAVR procedure.

You will have the same assessment as you had at the initial assessment.

a. 6MWT
b. TUG Test
c. FSST
d. Kansas City Cardiomyopathy Questionnaire

### 30-day Follow-up Assessment

Your electronic health records (EHR) will be monitored for thirty days from the discharge date for the following:

a. Information regarding any hospital readmissions after your procedure
b. Cost of your hospital stay (assessed by total charges accrued during any readmission hospitalization)
c. Any adverse events that may occur

You will also perform the following:

a. 6MWT
b. TUG Test
c. FSST
d. Kansas City Cardiomyopathy Questionnaire

**1-year Follow-up Assessment**

Your electronic health records (EHR) will be monitored for one year from the discharge date for the following:

a. Information regarding any hospital readmissions after your procedure
b. Cost of your hospital stay (assessed by total charges accrued during any readmission hospitalization)
c. Any adverse events that may occur
d. Serious adverse events, including those that require hospitalization

You will also perform the following:

a. 6MWT
b. TUG Test
c. FSST
d. Kansas City Cardiomyopathy Questionnaire

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may experience the following risks or discomforts: dizziness, fainting, chest pain, ventricular tachycardia (fast heart rate from the lower chambers of your heart), or sudden cardiac death. Ventricular tachycardia has been reported in early studies of patients with severe aortic stenosis undergoing exercise stress tests but this has not been reported in any modern recent studies. Other potential physical risks include falling or pain due to exercise.

## HOW ARE THESE POTENTIAL RISKS BEING MINIMIZED?

You will undergo a complete history and physical examination by a cardiologist prior to enrollment. If you are determined to be at high risk for an adverse clinical event by your cardiologist, you will be excluded. Also, you will undergo standard TAVR non-invasive and invasive testing; this includes: transthoracic echocardiography, transesophageal echocardiography, right and left heart catheterization, and Computer-Assisted Tomography (CAT scan) of the chest, abdomen, and pelvis. If you are found to have coronary artery disease that has not been treated either by a stent or bypass graft, you will not be enrolled.

In addition, if you undergo pre-procedural physical therapy, you will do so under the close supervision of the physical therapist and research RN. The physical therapist and RN will continually assess you, ask you how you are feeling, and ask if you are experiencing any negative

symptoms in accordance with the American College of Sports Medicine (ACSM) guidelines. If you experience any significant negative symptoms or exhibit any significant adverse signs, you will have your current activity stopped and will be clinically assessed and observed. If the adverse symptoms have not resolved within 20 minutes, you will undergo immediate clinical evaluation and treatment.

## WILL I BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will directly benefit from taking part in this study. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have your condition.

## DO I HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer and you will receive appropriate standard medical care including your planned TAVR. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

## IF I DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, you may proceed with usual care.

## WHAT WILL IT COST ME TO PARTICIPATE?

WellSpan Heart & Vascular will be responsible for the costs of all physical therapy visits and visits with the Research Staff. WellSpan Health will not bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. If you have questions or concerns, you should call your healthcare insurance provider.

WellSpan will not cover the costs of your TAVR procedure. Any costs related to your TAVR procedure will be billed to your insurance, or Medicare or Medicaid.

## WHAT IF I GET SICK OR HURT BY PARTICIPATING?

If you believe you are hurt or if you get sick because of something that is due to your participation in the research study, you should call Dr. James Harvey at 717-851-2441 or contact Heart & Vascular Research at 717-851-3472.

If you are hurt or get sick because of something that is due to the research study, it is important for you to understand:

- In the event that you suffer a research related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.
- WellSpan may pay for the medical costs related to your care and treatment for the injury you experience as a result of your participation in this research study.

- WellSpan Health has no plans to pay for any wages you may lose if you are harmed by the study.
- You may need to pay a co-payment or deductible even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of the co-payment/deductible may be substantial.
- Medicare or Medicaid may pay medically necessary costs (if you have questions regarding Medicare/Medicaid coverage you should contact them by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570 before volunteering to participate.)
- You do not give up any of your legal rights by signing this form.

## WHAT PERSONAL HEALTH INFORMATION WILL BE USED OR COLLECTED?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter this research study, the following information will be created, collected, used, and/or shared ("disclosed" or "released").

- Past and present medical records
- Research records
- Records about your study visits
- Records about your TAVR procedure

All records identifying you are kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Your name will not be shared outside of WellSpan York Hospital. Only your assigned number is recorded in the case report forms, and if your name appears on any other document (e.g. angiogram or echo), it must be obliterated before a copy of the document is supplied outside of York Hospital.

## WHO WILL BE ABLE SEE, USE, COLLECT, SHARE OR RECEIVE MY PERSONAL HEALTH INFORMATION?

The information in this study will be used only for research purposes and in ways that will not reveal who you are. Federal or state laws may require us to show information to government officials who are responsible for monitoring the safety of this study. However, an assigned number will be used to designate your study record with your answers and not information that personally identifies you. You will not be identified in any publication from this study or in any data files shared with other researchers.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

You should know, however, that there are some circumstances in which we may have to show your information to other people.

Individuals or organizations who may look at, copy, share, or receive pertinent portions of records that identify you for the purpose of research include:

- The Principal Investigator (Dr. James Harvey)
- The research staff at York Hospital Heart & Vascular
- The physical therapists
- The WellSpan Health Institutional Review Board and staff
- Data Safety Monitoring Board (Heart & Vascular physicians not directly involved in this study)

When your information is shared outside of WellSpan Health for the purpose of this study, WellSpan Health may not be able to prevent others from disclosing your Protected Health Information.

When your Personal Health Information is disclosed to others not subject to the Privacy Rule, WellSpan Health cannot promise that information will definitely be protected.

## HOW LONG WILL THIS PERMISSION LAST?

If you agree, by signing this form, that researchers can use your personal health information, your permission **does not expire**. This means that, although you may have completed some or all of the research activities, the Researcher may combine your health information with the health information every other research study volunteer to analyze and report the results of this research study. Remember, however, as stated above, you can change your mind and withdraw your permission at any time.

## CAN MY TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study at any time. If during the preprocedure testing it is determined you do not need a TAVR, you will be removed from the study. If you are removed from the study, study-related treatment will no longer be provided by the investigator. This may occur if you are not able to follow the directions they give you, if they find that your being in the study offers more risk than benefit to you, or if the study stops early for a variety of scientific reasons.

## HOW DO I STOP PARTICIPATION IN THE STUDY?

You can stop being in the study at any time. If this happens, tell your study physician/nurse that you want to withdraw your permission and/or send it in writing to:

**Name: James Harvey, MD, MSc**
**Entity and/or Department: WellSpan Cardiology**
**Address: 1001 S. George Street**
**City, State. Zip: York, PA 17403**

S/he will make sure your request to withdraw your permission is correctly processed. You will not be penalized and the care you get from your doctor will not change.

Beginning on the date you withdraw your permission, no new personal health information will be used for research purposes. However, researchers may continue to use the health information that was provided before you withdrew your permission, or if the information is used to follow up on adverse events or has already otherwise been relied upon.

## WHAT ARE MY RIGHTS REGARDING ACCESS TO MY PERSONAL HEALTH INFORMATION?

You have the right to review and/or copy records of your personal health information kept by your provider, consistent with your provider's standard Privacy Notice.

## CAN I PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

It is important to let the investigator/your doctor know if you are currently participating in a research study. If you are participating in a research study, you may not be able to participate in this study. You also may not be able to participate in any research study while you are enrolled in this study.

## WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study. You will receive $20 for each completed on-site visit to help cover your expenses for attending study visits. These expenses include:

- Your local travel/parking expenses to and from office visits and tests.

You do not need to keep receipts for these expenses.

The payments will be issued by WellSpan York Hospital. In order to receive the payments, you must complete the provided IRS Form W-9 and supply your Social Security number. If you receive $600.00 or more per year from WellSpan York Hospital for any reason, federal regulations require that we report it to the IRS and issue an IRS Form 1099. If you choose not to complete the IRS Form W-9 you may still participate in the study but you will not be eligible to receive financial compensation.

## WHAT IF I HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide to take part in the study, please ask any questions that might come to mind now. If you have questions about the study, you can contact the investigator Dr. James Harvey at 717-851-2441. If you have any questions about your rights as a volunteer in this research, contact the WellSpan Health IRB Staff 717-851-2223.

## WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT MY DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to

sign a new informed consent form if the information is provided to you after you have joined the study.

## WHAT ELSE DO I NEED TO KNOW?

You have the right to refuse to sign this permission form. If you do not sign the form, you will not be able to participate in the study.

You will receive a copy of this consent form to take with you.

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

The York Health Foundation Heart & Vascular Research Fund is providing financial support for this study.

**Participant**

| | |
|---|---|
| I have read and understand the information describing this study. All my questions have been answered to my satisfaction. This form is being signed voluntarily to indicate my agreement to be in the study. I will be given a copy of this form for my personal records after all individuals sign and date it. I authorize the release of my research related medical records to the study investigators and their representatives. | |
| Participant's Name (Print): | |
| Participant's Name (Signature): | Date: |
| **OR** if participant is unable to provide informed consent a Legal Representative (spouse, parent, adult child of parent, legal guardian, power-of-attorney) may provide informed consent on behalf of the participant. | |
| Legal Representative's Name (Print): | |
| Legal Representative's Signature: | Date: |

**Principal Investigator or Designee**

| | |
|---|---|
| I Confirm that the study has been explained to the subject above and that the consent to participate has been given. | |
| Name of person conducting the consent discussion (Print): | |
| Signature of person conducting the consent discussion | Date: |