The Ohio State University Consent to Participate in Research

Study Title: ABVENTURE-P: Pilot Trial of Abdominal Core Rehabilitation to Improve Outcomes After Ventral Hernia Repair

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Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Hernias can affect abdominal core health by causing pain and problems with core function. Surgery is often needed to repair hernias. Recovery after surgery can often involve a lot of pain and restriction of activity.

In this study, we want to test if supervised rehabilitation with a physical therapist helps patients get better faster after hernia surgery and reach a higher level of comfort and ability than with standard precautions. We know this is beneficial after orthopedic surgery, but the benefit after hernia surgery is not known.

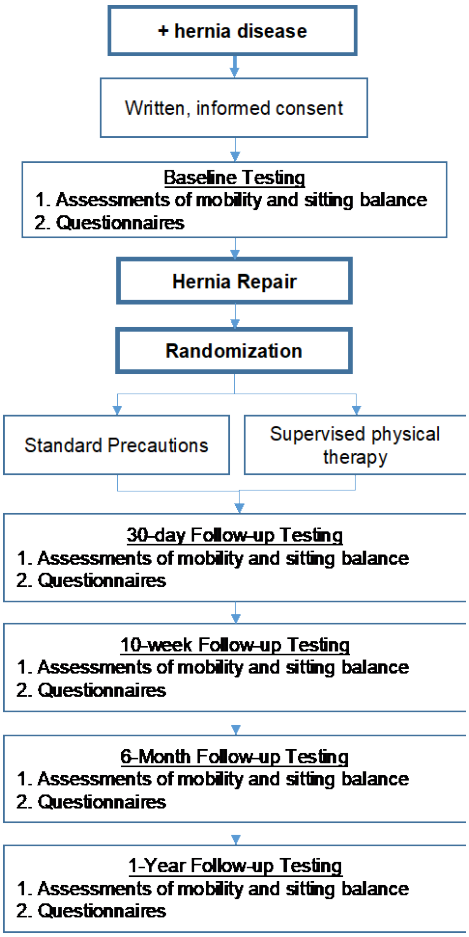
1. Why is this study being done?

Hernia disease affects the structure and function of the abdominal wall, also known as the abdominal core. Individuals affected by hernia disease often have difficulty with daily activities like breathing, personal hygiene and moving around their home and community. Surgical repair of the affected area is the most common treatment for hernia disease, but unlike other similar surgical procedures, few individuals go on to have physical therapy. We are trying to understand whether physical therapy that focuses on training the abdominal core is more beneficial than the current, standard post-surgical instructions and abdominal brace.

2. How many people will take part in this study?

We will enroll 94 individuals scheduled to undergo hernia repair.

3. What will happen if I take part in this study?



If you provide your consent to participate, you will complete questionnaires about your function and take part in brief assessments of your mobility and sitting balance prior to your hernia repair. In these assessments, we may attach motion sensors to your body or record video to help us measure how your body moves during the tests. This baseline testing will be done during your medical visit.

Immediately after surgery in the recovery area, you will be randomly assigned to receive either standard post-operative instructions following hernia repair with or without supervised physical therapy. You will receive this information in a packet on the day of surgery.

If you are randomly assigned to receive physical therapy, a research team member will help coordinate your first physical therapy visit. The first visit will be scheduled approximately 2 weeks after surgery. Physical therapy treatments will be focused on restoring the function of your abdominal core through exercises to retrain and strengthen your muscles and training to move effectively. You will be asked to attend these sessions 2x/week for 8 weeks and you can schedule them at your convenience.

You will repeat the same assessments of function, mobility and sitting balance at 30 days, 10 weeks, 6 months, and 1 year after hernia repair.

There are several questionnaires we will ask you to complete electronically. You may skip any questions that you feel uncomfortable answering. We will also access your electronic medical records to record and retain information about your medical care that is relevant to your hernia repair. This includes basic demographic information (i.e. your age, biological sex), information about your diagnosis (i.e. medical imaging), operative notes, and physical therapy notes (if you are randomized to that group).

4. How long will I be in the study?

You will be in the study for approximately 13 months. This includes the time involved in testing prior to surgery and up to the 1 year follow-up testing. Each testing session will take about 30 minutes.

If you are randomly assigned to received physical therapy, you should anticipate that each session lasts between 30-60 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may experience muscle soreness as a result of the physical testing involved with this study. The risk is minimal, and similar to that experienced during your activities of daily living. There is a risk of loss of balance during the sitting balance task. To reduce this risk, you will be supervised and assisted by trained research personnel to ensure you do not fall.

If you receive physical therapy, you may experience muscle soreness. The risk is minimal, and similar to that experienced during physical activity and strength training.

Because we are using the Internet to collect your questionnaire responses and to store sensor data or videos, there is a chance that someone could access your online responses or the data without permission. In some cases, this information could be used to identify you. Your data will be encrypted and protected with a code to reduce the risk that other people can view the responses or data.

You will receive routine care after your hernia surgery which may include management of complications after the surgery. Some pain can be expected after the surgery. If you experience a complication, this may make participating in the study more painful. If this happens, you may choose to continue being part of the study or stop being in the study.

There is minimal risk of breach of data confidentiality because we will be accessing and recording information from your medical records. Electronic medical records and the electronic database where we will store those data, are user restricted, accessible only by trained and approved members of the research team.

7. What benefits can I expect from being in the study?

Participants who are randomized to receive post-operative physical therapy may experience reduced pain and greater mobility and function than that of the standard precautions group.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs to taking part in this study. If you are randomly assigned to the physical therapy group, your physical therapy visits will be paid for by the study.

10. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income. You will be eligible to receive up to $175 over the course of the study. You will received $25, $50, and $100 for completion of the 10-week, 6-month, and 1-year testing, respectively. We will provide these payments as Amazon electronic gift cards emailed to the address you provide.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent. If another researcher requests access to the data from this study in writing with a plan regarding how they will use the data, we may provide de-identified data from all consenting research participants. Your identity will be completely removed so that the researcher would have no way of determining which data comes from you instead of other participants.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this

study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If we find information that significantly impacts your health, we **will** share it with you. As part of this trial, we will be tracking medical conditions that are commonly evaluated following surgery. We whether physical therapy may provide more benefits than standard instructions alone, so we will be studying how frequently these medical conditions occur in both groups. You will be notified if one of these conditions affects you personally.

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 the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Stephanie Di Stasi, PT, PhD and Benjamin Poulose, MD via email to abventuretrial@osumc.edu**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Stephanie Di Stasi, PT, PhD and Benjamin Poulose, MD via email to abventuretrial@osumc.edu**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time