Microbreaks and Intraoperative Exercises for Gynecologic Surgeons (MIGS Trial)

May 24, 2022

Consent to Participate in Research

Basic Study Information

Title of the Project: The Effect of Intraoperative Exercises on Gynecologic Surgeons
Principal Investigator: Rachel High DO FPMRS, University of Texas at Austin Dell Medical School, Austin, TX
Faculty Advisor: Rachel High DO FPMRS, University of Texas at Austin Dell Medical School, Austin, TX

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to evaluate the effect of intraoperative microbreaks and exercises on surgeon body discomfort.
- In order to participate, you must be a resident, fellow, or attending performing gynecologic surgery. You must be able to perform the exercises. Surgery days must contain at least one gynecologic surgery with two hours of total operating time in one day. Surgeons will need to have operated on average at least 2 days per month over the last 12 months.
- If you choose to participate, you will be asked to perform intraoperative exercises during an intraoperative microbreak on at least 10 surgery days. You will also be asked to complete surveys on at least 20 surgery days.
- The intraoperative exercises will take approximately 2 minutes each time they are performed. The exercises will be performed multiple times across at least 10 surgery days. The surveys will be administered across at least 20 different surgery days (10 surgery days with intraoperative exercises and 10 surgery days without intraoperative exercises).
- Risks or discomforts from this research include risk for musculoskeletal injury from the exercises and stretches that are performed in this study.
- The possible benefits of this study include decreased work-related pain or discomfort
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of this study is to evaluate the effect of intraoperative microbreaks and exercises on surgeon body discomfort by conducting a multicenter randomized trial. We hypothesize that gynecologic surgeons will experience decreased pain on surgery days with intraoperative microbreaks and exercises without compromising overall surgical performance.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

1. Complete a "Baseline Surgeon Questionnaire": The baseline surgeon questionnaire asks about surgeon characteristics including surgeon age, gender, weight, height, dominant hand, surgical volume, and years practicing surgery. The baseline questionnaire also includes a survey which assesses for history of trouble (ache, pain, discomfort) in body part regions. This will take approximately 10 minutes to complete and will only be done one time at the beginning of the study.
2. Perform the intervention on at least 10 surgery days: Surgery days randomized to intraoperative microbreaks and exercises will include standardized breaks lasting approximately 2 minutes. During these breaks, surgeons will perform a set of targeted stretches or exercises while remaining sterile. The exercises will be performed just before surgical time-out, at a surgically convenient time 45-75 mins after the start of the case, and at the end of the case. This task will take approximately 15-25 minutes for each of the 10 surgery days that include the intervention.
3. Complete "Surgery Day Questionnaire": This questionnaire incorporates the Body Part Discomfort (BPD) scale and the Surgery Task Load Index (SURG-TLX). The BPD scale is a scale that measures discomfort in different body parts on a scale of 1 to 10. At the beginning and end of the surgery days, the participating surgeon will complete the BPD scale. The SURG-TLX measures mental demands, physical demands, temporal demands, task complexity, situational stress, and distractions during surgery. At the end of surgery days, the surgeon will complete the SURG-TLX. This questionnaire (containing the BPD scale and SURG-TLX survey) will be completed on 10 surgery days with the intervention and 10 surgery days without the intervention. This will take approximately 10 minutes to complete each day.
4. Complete the exit survey: This survey includes 6 questions about your experience in the study. This will take 5 minute to complete.

How long will you be in this study and how many people will be in the study?

If you agree to take part in this study, you will participate for at least 10 surgery days with and 10 surgery days without the intervention. The total duration of participation may vary among participants. There will be at least 20 participants in the study.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. There is a risk of musculoskeletal injury from the exercises and stretches that are performed in this study.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

Possible benefits of this study include decreased work-related pain or discomfort.

What will happen to the data we collect from you?

As part of this study we will collect data from the surveys described above in addition to information about the surgeries performed. We will remove any identifiers that link your name or

identity to the information we collect. We will destroy the information collected at the end of 6 years.

How will we protect your information?

We will protect your information by recording data into a secure and encrypted data collection system. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.** We will not share your data with other researchers.

We plan to publish the results of this study. To protect your privacy, we will/will not include any information that could directly identify you in this study or future studies.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for 6 years. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

How will we compensate you for being part of the study?

You will not receive any type of payment for your participation.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin.

You are not waiving any of your legal rights by participating in this study.

What are the costs to you to be part of the study?

To participate in the research, there will be no costs.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, you should let the principal investigator/study coordinator know as soon as possible. You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record. If your information has already been used, and de-identified, it may not be possible to remove them. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information".

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, or feel you may have been harmed due to participation, you may contact:

Principle Investigator: Rachel High, DO
Mail: Ascension Medical Group Seton Women's Health at 911 W 38th St #202, Austin, TX 78705
Phone: 512-324-8670

Or

Secondary contact person: Laura Kent, MD
Mail: Ascension Medical Group Seton Women's Health at 911 W 38th St #202, Austin, TX 78705
Phone: 512-324-8670

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date