Protocol for Patient-Centered versus Physician-Centered Counseling Video for Midurethral Sings An RCT: **MU-Vi: M**id**U**rethral Sling **Vi**deos

Acronym: MU-Vi

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PROTOCOL TITLE:

Protocol for Patient-Centered versus Physician-Centered Counseling Video for Midurethral Sings An RCT: Mid**U**rethral Sling **Vi**deos

PRINCIPAL INVESTIGATOR:

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Obstetrics & Gynecology, Division of Urogynecology

VERSION NUMBER:

4

DATE:

5/3/17

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
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☐	EPA (Environmental Protection Agency)
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☐	VA
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Is this a clinical trial under ICH-GCP E6? ☐ Yes ☒ No

If yes, please confirm that the research team is familiar with and agrees to comply with the investigator requirements cited in ICH-GCP E6. ☐ Yes ☐ No

ICH-GCP E6 can be accessed by copying and pasting this URL into your browser: http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

Table of Contents

1. Objectives

Management of Pelvic Floor Disorders (PFDs) is individualized according to a patient's symptomatology and quality of life. Although conservative measures exist, patients may elect for surgical management. The decision making process for surgery is complex. It is well documented that patient's lack understanding prior to their surgical procedures[1, 2]. Preparedness for MUS surgery is related to a patient's comprehension of the purpose, risks, benefits, and complications[3]. Patients who are more prepared prior to surgery have been proven to have greater postoperative satisfaction[3]. Therefore, it is essential to improve patients' preparedness and enhance patients' understanding of realistic expectations of post-operative outcomes.

Our long-term goal is to improve patient-centered preparedness and satisfaction when considering surgery. Previous studies by the Preliminary Study of Peer Support Groups and Pelvic Floor Disorders have demonstrated trends in improvement for preparedness and decision conflict with the use of peer focus groups. However, peer support groups are a costly process and there may be many barriers to participate.

A key gap in the literature is how to improve patient preparedness for surgery and improve satisfaction through the use of peer counseling in a manner that is convenient for patients, reproducible and low cost. Technological advances with multimedia may assist in bridging this gap. With ease-of-access to mobile electronic devices, videos are effective tools to prepare patients for surgery. The purpose of this randomized controlled clinical trial is to determine if a patient-centered video improves satisfaction and preparedness compared to a physician-centered video.

The *first objective of this research* is to develop two videos to counsel patients who have elected to undergo a MUS procedure. One video will be created from a physician-centered approach. The second video will be a patient-centered perspective. The *second objective of this research* is to compare the impact of video counseling between women randomized to a physician-centered versus a patient-centered video. Our *central hypothesis* is that women randomized to a patient-centered video will report higher scores of satisfaction and preparedness than women randomized to the physician-centered video.

Specifically, our aims for this study are:
Aim #1: To create two videos to be used to counsel patients who have elected to undergo a MUS procedure. One video will present the risks, benefits and alternatives to MUS surgery by a physician, mimicking traditional counseling prior to surgery. The second video will also explain the risks, benefits and alternatives to the MUS surgery utilizing a patient mentor who has undergone the MUS procedure will describe the patients' perception of the information. The patient-centered video will also include topics that have previously been identified by focus groups as important patient-centered aspects of pre-surgical counseling.

Aim #2: To compare the impact of video counseling between women randomized to a physician-centered video and a patient-centered video. **Hypothesis:** Women randomized to a patient centered-video will report higher satisfaction and preparedness as measured by validated scales. They will have higher scores on the Post-operative preparedness questionnaire (PPQ), Preparedness Scale and the Surgical Decision Satisfaction (SDS-PFD) questionnaire; and lower scores on the Decision Regret Scale (DRS-PFD) questionnaire than women randomized to view the physician-centered video prior to undergoing midurethral sling surgery.

Aim #3: To compare a women's decisional conflict post-operatively in women randomized to the physician-centered video and the patient-centered video. **Hypothesis:** There is a reduction of decisional conflict in women randomized to the patient-centered video.

Aim #4: To determine if there are differences in anxiety scores in women who watch the patient-centered video versus the physician centered video. **Hypothesis:** Anxiety scores measured by the State Trait Anxiety Inventory (STAI: Y-6 Item) questionnaire are decreased by a pre-operative patient-centered counseling video.

2. Background

Patients poorly understand or retain information given to them by physicians. Patient preparedness for surgery has been shown to influence a patient's perception of surgical success[4]. Patient satisfaction is of increasing importance and is likely linked to preparedness. Realistic surgical expectations have been shown to be associated with higher postoperative satisfaction[5]. In addition, what patients feel is important to know about surgery may not correlate with what physicians feel is important. Recognizing inconsistencies, which may exist between a patient-based versus a physician-based framework for comprehension, may improve a patient's preparedness and ultimate satisfaction with surgical care.

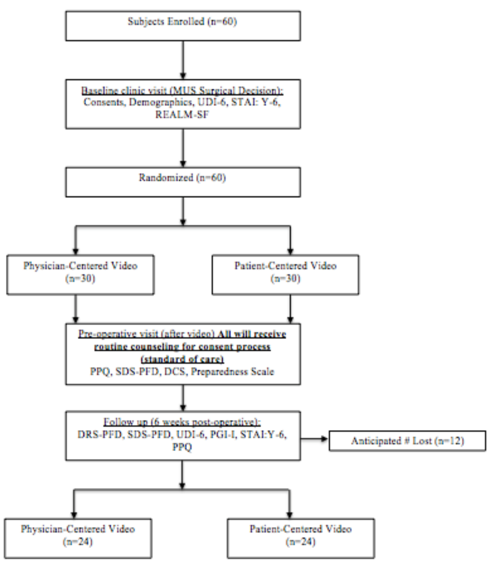
Previous work from the Preliminary Study of Peer Support Groups and Pelvic Floor Disorders indicates that women desire peer support in the peri-operative period. Group shared appointments before sacral nerve stimulation showed a greater likelihood of preparedness preoperatively, which was associated positively with the patient's perception of outcome[6]. Furthermore, pilot peer support groups have indicated an improvement in preparedness.

Stress urinary incontinence, or loss of urine with cough and sneeze, affects nearly 13 million women in the US[7]. Mid-urethral (MUS) slings are an effective treatment and are the standard surgical treatment for stress urinary incontinence (SUI)[8]. Approximately 30% of women with SUI in the United States select surgical treatment. The risks, benefits and alternative to MUS are well described[9-12], nonetheless patients do not recall key steps in the procedure or long-term risks of the procedures. Poor risk recall of MUS surgery was associated with increased decision regret from the procedure[9]. Length of counseling prior to surgery did not improve recall of the procedure or its risks[9].

While we have found that patients feel that peer counseling improves their preparedness for surgery, and others have published similar results, peer to peer counseling is difficult and costly to arrange. Barriers to participate in peer support include transportation and scheduling conflicts. One-on-one counseling is costly and difficult to arrange. A key gap in the literature is how to improve patient preparedness for surgery and improve satisfaction through the use of peer counseling, in a manner that is convenient for patients, reproducible and low cost.

Digital videos are inexpensive, reproducible, can be easily displayed, and are time regulated. With ease-of-access to mobile electronic devices, videos are effective tools to prepare patients for surgery. A previous study by Ellet et al. has demonstrated that patients prefer a consent process that is enriched with multimedia presentations as preferred to solely receiving information from the physician[13]. A study evaluating educational videos created for radiation treatment for prostate cancer noted that increased patient satisfaction, preparedness, and reduced anxiety[14].

3. Study Design



This is a randomized controlled clinical trial to determine if a patient centered-video improves satisfaction and preparedness compared to a physician centered-video. The target population is women with stress urinary incontinence who are planning to have a mid-urethral sling performed. Women will be randomized during their pre-operative visit to watch the physician centered-video or patient centered-video before they are counseled regarding their upcoming MUS surgery in the usual manner during the clinic visit and prior to signing surgical consent.

4. Inclusion and Exclusion Criteria

We will recruit patients who present to the University of New Mexico Urogynecology practice at UNMH, Sandoval Regional Medical Center, or the UNM Westside clinic with stress urinary incontinence who elect to undergo a MUS procedure. We selected a MUS procedure because there is well-described literature of the risks, benefits, and alternatives to MUS that we will utilize to create the videos. Patients who have elected to proceed with a MUS procedure will be offered study enrollment if they meet the inclusion and do not meet the exclusion criteria.

The *inclusion criteria* are:

1. Subjects are ≥ 18 years of age
2. Planning to undergo a midurethral sling procedure
3. Either stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) with a positive cough stress test or SUI documented on urodynamic testing
4. English speaking

Exclusion criteria are as follows:

1. Those who desire a concomitant POP Surgery
2. Inability to speak/understand English
3. Prior midurethral sling performed

5. Number of Subjects

Power Analysis: We will compare the percent of patients that feel completely prepared (strongly agree on the Patient Preparedness Questionnaire, a 1-6 Likert scale) between the two intervention groups, those randomized to a Physician-centered vs Patient-centered video. Firoozi et al. found 30% were "completely prepared" in the standard office counseling group.[6] However, we expect a "floor effect" where a higher percentage of completely prepared at 40%. As there is high satisfaction in this population that will be undergoing mid-urethral sling surgery. A sample size of 24 patients per group would be adequate to detect a difference of 40% (Physician-centered video) versus 78% (Patient-centered video) in those being "completely prepared" with 80% power and an alpha of 0.05. This is a feasible power analysis since Firoozi et al found an improvement to 79% using the shared appointments.[6] Therefore our recruitment goal will be to increase randomization to a total of 60 subjects, 30 patients per group, which will also allow for a 20% loss to follow up.

6. Study Timelines

Based on the current surgical volume in the UNM division of urogynecology, it will take 12 months to recruit the 43 patients; it would take 18 months to recruit~ 60 patients. Then, for data analysis and composition of the manuscript, we estimate that this will take 6 months.

Timeline	Feb. 2017- May 2017	June 2017- Dec. 2018	Jan 2019-March 2019	April 2019- June 2019
Video Development	⟷			
Subject recruitment, surgery, through 6 week follow up		⟷		
Data analysis			⟷	
Manuscript preparation				⟷

7. Study Endpoints

First, the physician-centered and patient-centered video will be created. Once developed, the **primary endpoint** of our study is to determine if there is a difference in patient preparedness and satisfaction in those women undergoing a MUS procedure who have watched a patient-centered versus a physician-centered video watched at their pre-operative visit. Our **secondary endpoints** include differences in preparedness, satisfaction and decisional conflict scores. Our **exploratory endpoint** is to investigate differences in anxiety 6 weeks after corrective MUS surgery in those who undergo a pre-operative patient-centered video compared to a physician-centered video.

Given that a MUS surgery is routinely performed currently, we do not have any **safety endpoints**.

8. Research Setting

The study will be performed at the University of New Mexico (UNMH), Sandoval Regional Medical Center (SRMC)urogynecology clinics in Albuquerque, New Mexico.

All patients planning to undergo surgery will have a complete history and physical taken and undergo a physical exam. After recruitment, they will undergo the consent process, and fill out initial questionnaires in the outpatient offices.

There are no laboratory tests in this trial other than what would be routinely collected prior to surgery

There will be no involvement of any community advisory board.

9. Resources Available

Yuko Komesu, MD is a board subspecialist in Urogynecology and will serve as the PI for this study. She is an experienced researcher at UNM. She has been the PI on multiple research trials and has successfully completed multiple randomized control trials at UNM.

The University of New Mexico (UNM) urogynecology division operates at two main locations. *UNM Women's Health Urogynecology Center (UNMH)* located in downtown Albuquerque provides a full range of services for women with pelvic floor disorders. At UNM, the clinic at University of New Mexico's Health Sciences Center consists of 8 exam rooms, 2 treatment rooms and 3 consult rooms with a separate entrance for urogynecology patients. Our second location is at *Sandoval Regional Medical Center (SRMC),* a community based facility located in Rio Rancho, New Mexico, a large suburb located outside of Albuquerque. The UNM Westside clinic is located in the western side of Albuquerque where there are 3 examination rooms devoted to urogynecologic patients

Timeline	Feb. 2017- May 2017	June 2017- Dec. 2018	Jan 2019-March 2019	April 2019- June 2019
Video Development	⟷			
Subject recruitment, surgery, through 6 week follow up		⟷		
Data analysis			⟷	
Manuscript preparation				⟷

Clinical Research Nurse Coordinator/Research Staff**:** The Urogynecology Division employs 5 research coordinators, two student research assistants and a full time research administrative assistant. We also employ two research nurses through our NIH-funded Clinical and Translational Research Center. Our research staff has extensive experience conducting multi-center investigations and recruiting patients to clinical studies, with special expertise in community-based research and quality of life studies.

Research Experience: The Urogynecology Division at UNM has a strong history of conducting high quality research and collaboration with other investigators in the US and abroad, and had consistently met or exceeded recruitment goals on time. We are currently members of the NICHD-sponsored PFDN, and have met recruitment goals with high rates of follow-up and accurate data collection. In addition to PFDN research, Dr. Komesu is currently funded with an R01 through NCCAM (National Center of Complementary and Alternative Medicine), an NIH Institute. She is evaluating hypnotherapy versus medications in the treatment of urgency urinary incontinence and is evaluating their effect on brain activation and connectivity on fMRI. The Division has collaborated with investigators both as the coordinating and a contributing site; recent work includes the IUGA-sponsored Sexual Function Group as well as collaboration with Brown University.

Our group is well versed in the importance of adherence to protocols, timely completion of regulatory requirements, effective recruitment strategies, and the importance of the inclusion of minority subjects. Research is integral to all aspects of Divisional work; importantly, all members of the clinical team participate in research efforts. There are weekly research meetings to discuss the progress of the ongoing studies within the department, and it is an excellent forum to ensure that all involved are adequately informed of their duties, of the protocol, and of the procedures.

We do not anticipate that emergency care will be needed for this study, however as the patients are getting surgery, the urogynecology physicians are available on a 24-hour basis, 7 days per week for their patients requiring emergency care.

10.Prior Approvals

There will not be any approvals obtained prior to commencing the research. The study was presented for approval by the Departmental Chair. The signed Departmental Review form can be found in the "supporting documents"

This study does not include any ionizing radiation, biologic specimens, or drugs.

11.Study Procedures

1. First, two videos will be created to counsel patients who have decided to undergo a MUS procedure. One video, the physician-centered video, will be developed with well-described literature involving the risks, benefits, and alternatives to MUS. Physicians from the urogynecology division will be videotaped explaining these risks. The second video will be the patient-centered video. We will meet with the patient mentors who were a mentor in the Preliminary Study of Peer Support Groups and Pelvic Floor Disorders. We will create a script with the patient mentors that will include the risks, benefits, and alternatives in lay terms as well as topics that have previously been identified by focus groups as important patient-centered aspects of counseling. This will include aspects of quality of life factors such as catheterization and when patients can return back to work. Once we have created the script with the mentors who agree to be filmed; the mentors will be videotaped explaining these topics. All participants involved in the creation of the video will sign an informed consent prior to the development of the video. The participants will include the physicians counseling on the video and women acting as mentors on the video.

2. Once the videos are complete, we will perform a randomized clinical trial clinical trial to determine if a patient-centered versus a physician-centered video will increase preparedness and satisfaction. The target population is female subjects with stress urinary incontinence who are planning to have a MUS procedure. All subjects will be given written study consents during their clinic visit when they are scheduled for their MUS. After enrollment, subject's data collected include *Patient Demographics*: Age; self-reported race and ethnicity; body mass index (BMI); vaginal parity, education level, socio-economic status. Also, *Medical/Surgical History:* Medical comorbidities; prior POP surgeries or incontinence procedures, prior hysterectomy. They will also perform a health literacy assessment utilizing the validated REALM-SF questionnaire. They will also complete the PGI-I and STAI: Y6 questionnaire at the baseline clinic visit.

Once this is performed, patients will return for their standard pre-operative clinic visit. Patients will then be randomized once they check-in to the waiting room.

Randomization: Randomization assignment will be generated by a computer based randomization table and assigned by a research coordinator not otherwise involved in the study. Assignments will be kept in sealed opaque envelopes numbered sequentially. As an adjunct to standard pre-operative counseling, the physician will call the research coordinator and the next envelope in the sequence will be opened randomizing the patient to the patient-centered or physician centered video.

Once randomized, patients will view the video they are assigned to in the waiting room utilizing video viewing devices with headphones. Once the video is complete, patients will receive standard pre-operative counseling for the midurethral sling procedure by their provider. The pre-operative counseling will be scripted. They will then complete the PPQ, preparedness scale, SDS-PFD, DCS.

At the 6 week post-operative visit, they will fill out the questionnaires: SDS-PFD, DRS-PFD, and STAI: Y6, UDI-6, PGI-I will be completed (Table 1). The physician will also complete an adverse events form at that time.

Table 1: Outcomes collected at various time points

	Baseline Clinic Visit	Immediately after consents and video	6 weeks postoperatively
PPQ		X	X
Preparedness Scale		X	
DCS		X	
DRS-PFD			X
SDS-PFD		X	X
UDI-6	X		X
Demographics	X		

The primary outcome is preparedness for surgery with an adjunct patient-centered versus a physician-centered video at their pre-operative visit. After they watch the video in the waiting room, all patients will receive standard pre-operative counseling for the midurethral sling procedure by their provider. They will then fill out the preparedness questionnaires. Our secondary outcome is satisfaction, which will also be evaluated using the SDS-PFD at her pre-operative visit after consents and the video as well as their 6 week visit.

The midurethral sling will be performed by surgeons in the standard fashion.

Outcome Measures:

1. Patient Preparedness Questionnaire (PPQ): Assess the level of pre-operative preparedness according to each preparedness question. Measured by question 11 on the Patient Preparedness Questionnaire (PPQ): "Overall, I feel prepared for my upcoming surgery." The 11-question PPQ contains questions on both knowledge and preparedness for the planned surgical procedure. The PPQ has demonstrated construct validity properties in previous studies.

2. Decision Regret Scale- Pelvic Floor Disorders (DRS-PFD): Validated pelvic floor disorder questionnaire. It is designed to measure regret after health care decisions. This is a modified scale that is specific for women making decisions regarding surgical therapy for PFDs.

3. Satisfaction with Decision Scale-Pelvic Floor Disorders (SDS-PFD): Validated pelvic floor disorder questionnaire. This is a modified 6-item questionnaire with a 5-point response scale to measure patient satisfaction.

4. Urinary Distress Inventory 6 (UDI-6): This is a validated shortened version of the UDI questionnaire to assess symptom distress and the impact of daily life of urinary incontinence. It is a 6-question instrument that correlates well with the longer version.

8. Decisional Conflict Scale (DCS): A questionnaire that has been adapted and validated for Pelvic Floor Disorders. This contains 16 questions with a five-point response scale. The mean score is multiplied by 25 to report it on a 100-point scale with 0 correlating to no decisional conflict and 100 with extremely high decisional conflict.

9. Preparedness Scale: Measures extent to which a subject that she was prepared pre-operatively for their surgery on a 0 to 10 scale.

12.Data Analysis

Data Analysis: The main comparison is of the overall preparedness questionnaire item on the patient preparedness questionnaire (PPQ) between the two intervention groups of patients (physician- vs. patient- centered videos) using the Chi-Squared test for categorical data, since the questionnaire item responses are on a Likert scale. Other analyses will be done by a 2-way ANOVA with both intervention groups and the item members considered to be 2 grouping factors.

Power Analysis: We will compare the percent of patients that feel completely prepared (strongly agree on the Patient Preparedness Questionnaire, a 1-6 Likert scale) between the two intervention groups, those randomized to a Physician-centered vs Patient-centered video. Firoozi et al. found 30% were "completely prepared" in the standard office counseling group.[6] However, we expect a "floor effect" where a higher percentage of completely prepared at 40%. As there is high satisfaction in this population that will be undergoing mid-urethral sling surgery. A sample size of 24 patients per group would be adequate to detect a difference of 40% (Physician-centered video) versus 78% (Patient-centered video) in those being "completely prepared" with 80% power and an alpha of 0.05. This is a feasible power analysis since Firoozi et al found an improvement to 79% using the shared appointments.[6] Therefore our recruitment goal will be to increase randomization to a total of 60 subjects, 30 patients per group, which will also allow for a 20% loss to follow up.

13. Provisions to Monitor the Data to Ensure the Safety of Subjects

There is no DSMB or individual that will be monitoring safety as these procedures, MUS is a common surgical procedures included in the standard of care for stress urinary incontinence. Additionally, there will be a form to report all adverse events throughout the study so this can be reported on.

We do not anticipate any conditions that would trigger a suspension or termination of the research.

14. Withdrawal of Subjects

Any participant may withdraw from the study at any time without penalty and will continue to receive the clinical standard of care. A subject may be withdrawn from the study without her consent at the discretion of the physician and study staff if they believe she no longer meets study inclusion criteria or if she meets exclusion criteria, or if they believe that it is not in her best interest to continue study participation. Investigators may withdraw a subject if the subject is not following the study protocol. If a woman is withdrawn from the study either at her own discretion or that of the research staff, she may continue with the planned surgical procedure performed in the usual fashion.

To minimize withdrawal from the study, patients will be randomized just before the procedure. According to the 2010 CONSORT guidelines, we will analyze all participants assessed for eligibility within the study. We will document reasons for withdrawal from the study including failure to meet eligibility criteria or participant declining enrollment into the study. We will report eligibility criteria not met or reasons for declining participation in the study. The withdrawal procedure is clearly documented in the study consent.

15. Data Management/Confidentiality

Randomization assignment will be generated by a computer based randomization table and assigned by a research coordinator not otherwise involved in the study. Assignments will be kept in sealed opaque envelopes numbered sequentially, and on the day of the patient's pre-operative visit, the surgeon will call a research coordinator who will open the next envelope in the sequence. This de-identified study subject number will then be assigned to the patient. All data collection sheets and questionnaires will contain the subject number and day of the hospital or clinic visit. No other patient identifiers will be collected. PHI including patient name, date of birth, phone number, medical record number will need to be collected to track for appointments.

The data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. The offices have the additional security of being badge-access only for OBGYN department employees. A key matching study number to subject's name will be secured in a locked file cabinet in the OBGYN research administrative area.

The only PHI collected will be patient name, date of birth, medical record number and telephone number for site use only and to ensure patient follow up. This will not be entered into the database, but it will be kept with the other identifying information.

The data does not include sensitive information or information requiring additional protection.

All data will be kept in a locked file cabinet in the research administrative area. In order to further ensure patient confidentiality, the identifying information will be kept separately from the numbered study files in a locked cabinet.

Electronic data entry will be performed in the OBGYN administrative offices at UNM A REDCAP database will be created through UNM to collect, store and manage the data. REDCAP databases are reposed securely. The REDCAP database is only accessible using a individual unique login and password and access is only provided to co-investigators. Access is restricted to co-investigators and will be protected using the unique REDCAP login and password provided to each co-investigator.

A Certificate of Confidentiality will not be used to protect data from forced release. No data will be transported to outside locations. There will be no audio or video recordings or photographs taken.

16.Data and Specimen Banking

As stated above, the data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. A key matching study number to subject's name will be secured in a locked file cabinet in the OBGYN research administrative area. In order to further ensure patient confidentiality, the identifying information will be kept separately from the numbered study files in a locked cabinet. The data will be maintained for 5 years after completion of the study and then destroyed.

No specimens will be collected. .

17.Risks to Subjects

Risks of enrollment in the study include the risk of breach of confidentiality. We will take every measure to try to ensure the security and confidentiality of participants. This may result in stigmatization or hardship. Participants will be recruited in a private room and will have ample time to consider whether they want to participate in the study. Also, locked filing cabinets will be used to protect patient consent information and collected data. The link identifying patients and their study numbers will be also stored in a locked cabinet. There are risks of stress, emotional distress, and inconvenience. There are unknown risks of being randomized to either a physician-centered video or a patient-centered video.

Additionally, each patient who will be offered enrollment will already have agreed to a MUS surgery. There are risks inherent to these surgical procedures including bleeding, risk of infection, injury to surrounding organs, especially bladder perforation. We attempt to minimize the possibility of unrecognized injuries by performing cystoscopy with all of these procedures to ensure bladder integrity and to note efflux from each ureteral orifice. Each patient will be provided with informed consent regarding these risks and offered a blood transfusion in the event of life-threatening blood loss. Giving informed consent for these procedures is our practice's standard of care and will not be altered in the study population. The patient and physician-centered videos are an adjunct to routine pre-operative visits.

Pregnant women will not be included in the study, so there is no risk to embryos/fetuses. All women who are of reproductive age routinely get a pregnancy test the day of surgery. If they are pregnant, the patient meets exclusion criteria.

There are no risks to those who are not subjects.

18. Potential Benefits to Subjects

The patients enrolled are already opting for surgical correction of their stress urinary incontinence. Participation in this study may help to improve an individual participant's condition, but it is also possible that the condition may not improve. There is no guarantee that any individual will personally benefit by participating in this research study. Participation in this study may provide information that may help other people who have a similar medical problem in the future. It is unknown as to whether watching the physician-centered or patient-centered videos will increase satisfaction, preparedness, knowledge, knowledge-recall, and decrease anxiety.

19. Recruitment Methods

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The urogynecology clinic at UNMH, Westside, SRMC have a large referral population of patients with pelvic organ prolapse. Participants will be identified in the clinics at investigators. The patients will be counseled about possible treatment options for stress urinary incontinence including non-surgical and surgical techniques. If the patients surgical management by a midurethral sling procedure, they will be introduced to the study and provided with written information that may help them decide if participation in the study is right for them. Subjects are encouraged to consult with family, friends, and primary health care providers, as well as communicate any questions they may have before beginning the written consent process.

If a woman is withdrawn from the study either by her desire or that of the research staff, or does not desire to participate, she will be offered the same treatment options, but she will not watch the videos during her pre-operative visit. Her follow up times for after surgery are the same regardless of participation in the study.

There will be no other additional materials to recruit subjects.

20. Provisions to Protect the Privacy Interests of Subjects

Privacy concerns are taken into account with every patient. Participants approached and/or interviewed in the clinic setting will be in private offices or examination rooms where all staff, including research staff, are well-versed in sensitive health care discussions and procedures. Telephone interviews for recruitment and study data gathering are conducted in the research staff area or private physician offices, where all staff have received CITI Training. The office area designated for the entire urogynecology research staff is isolated from the clinical administrative staff area, providing protection for participants and potential participants during screening, recruitment, study-designated calls, and data entry.

Additionally, the operating rooms at UNM, SRMC, and SMCA hospital are places where patient privacy is respected and observed. All study sheets used to collect patient information will be de-identified.

At all times throughout the clinical investigation confidentiality will be observed by all parties involved. All data will be secured against unauthorized access. Privacy and confidentiality of information about each subject will be preserved in study reports and in any publication. Each subject participating in this study will be assigned a unique identifier. An IRB-approved HIPAA authorization is required to be signed. All documents containing personal health information (screening logs, consent documents, data forms) are maintained in locked file cabinets with access available only to research staff and investigators. Data is entered into a password-protected system. No individual identifiers are entered into the system. The sole link with personal information is maintained by the research team in locked files with access limited to authorized research staff and investigators. This information is only to be used at the study center.

21. Economic Burden to Subjects

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
Midurethral Sling Surgery	1	☐	☒
______	______	☐	☐
______	______	☐	☐

_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Midurethral Sling Surgery	1	☐	☒
Pre-operative visit	1	☐	☒
Urodynamics	1	☐	☒
1-2 week post-operative visit	1	☐	☒
6 week post-operative visit	1	☐	☒
3 month post-operative visit	1	☐	☒
_____	_____	☐	☐
_____	_____	☐	☐

A Midurethral Sling (MUS) surgery is the most common type of surgery to correct stress urinary incontinence. The sling is a narrow strap made of synthetic mesh that is placed under the urethra and acts as a hammock to lift or support the urethra.

There are no study related costs to the participants. Whether enrolled in the physician-centered video or the patient-centered arm of the study, participants will not be billed for the study materials. They have already chosen to undergo surgery, and they will receive prior authorization from their 3rd party payers, or they will have worked out financial assistance, if needed, with the hospital prior to their surgical date. These costs will be billed to their insurance provider and costs may range from copay only to full cost of treatment.

22. Compensation

For enrollment in the study, each patient will be compensated with a $60 merchandise card. They will receive a $20 merchandise card at their pre-operative evaluation and a $40 merchandise card at their 6-8 week post-operative visit. The merchandise card is reasonable compensation for the inconvenience of participating in a research study due to the multiple questionnaires evaluating preparedness, satisfaction, knowledge, and anxiety after watching a physician or patient-centered video.

23. Compensation for Research-Related Injury

If participants are injured or become sick as a result of this study, UNMHSC will provide emergency treatment at the study participant's cost. No commitment is made by the University of New Mexico Health Sciences Center to provide free medical care or money for injuries to participants of the study. Reimbursement for treatment for all related costs of care will be sought from the participant insurer, managed care plan, or other benefits program. The participant will be responsible for any associated co-payments or deductibles required by the insurance. Participants will be encouraged to report any illness or injury they believe to be related to the study to the investigator or research staff. Participants will be given telephone contact information for the urogynecology office for the purpose of asking any questions or stating any concerns about the study or treatment as a research subject. They may also be directed toward the HRPO. This language will be stated in the written consent document, and reviewed during the informed consent process. Again, the patient undergoes an informed consent process for the surgical procedure regardless of enrollment in the study; hence, there is no additional risk to participate in this study.

24.Consent Process

Patients will be approached about the research study at the urogynecology clinics during a discussion for the management of stress urinary incontinence. Each patient undergoes counseling in a private room with a closed door to ensure privacy. All of the physicians in the urogynecology division will obtain consent, given that they are the ones providing the surgical care. They routinely perform this procedure and thus are highly qualified to counsel patient regarding the risks, benefits, and alternatives to the procedure. Those recruited will have already decided to undergo a corrective mid urethral sling procedure. Study consent will be obtained by one of the research team members. Additionally, care will not be withheld if they decide not to participate.

The patients who would like to participate in the study will be consented during their pre-operative visit in the urogynecology clinic. There is a variable amount of time between the decision to undergo surgery and their next visit for their pre-operative assessment, but it ranges from a few days to months. Hence, the patient will be counseled on the study upon the decision to undergo surgery, during their pre-operative visit, and again during the day of surgery. They will have these multiple opportunities to ask any questions that they may have, and they will also be provided with the clinic’s contact information to get in touch with research investigators to address any additional questions or concerns.

Subjects will be reassured that participation is completely voluntary and does not affect their treatment, their relationship with their providers, or the university to minimize the possibility of coercion or undue influence. The patients will be asked that they understand the opportunity to participate and their complete freedom to decline. This will also be asked if they understand and if they have any questions. There is no minimum time period needed between informing the patient of the study and time of consent. Subject will all be encouraged to take as much time as they need.

This study will obtain HIPAA authorization prior to enrollment. HIPAA authorization is embedded within the study consent form, which will be reviewed with all participants by the physician obtaining consent. Specific information that will be obtained includes prior medical history, surgical history, reproductive health history including child bearing, drug allergies, age, and ethnicity. This information will obtained by health care providers, not research coordinators, as deemed necessary for a more complete and accurate medical history of the patient.

Subjects not fluent in English

Given that the primary outcome is measurement with the PPQ questionnaire and it is only validated in English, non-English speaking patients will be excluded.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

Cognitively Impaired Adults will not be included in the study.

Subjects who are not yet adults (infants, children, teenagers)

All subjects will be 18 years of age or older. No infants, children or teenagers will be enrolled in the study.

25.Documentation of Consent

We plan to document consent, and the Consent form is attached. We do not plan on collecting/storing tissue samples. We will not obtain consent verbally. We will not be using a script, information sheet, or other mechanism.

26.Study Test Results/Incidental Findings

26.1. ***Individual Results:*** Patients will be randomized to watch either a physician-centered or patient-centered video. Therefore, the patients will be aware which study arm they are randomized to. Study results for individual participants will not be shared.

26.2. ***Incidental Findings:***

We do not anticipate that the research being conducted will result in incidental findings. Every patient will receive the practice's standard of care regarding a pre-operative work up, which may include different laboratory tests and imaging studies, as determined by their other active medical issues. These results are not directly a part of the research being conducted, and will hence be disclosed to the patient. They will not, however, affect randomization.

27.Sharing Study Progress or Results with Subjects

The patients will be aware which arm of the study they are randomized to. Therefore, we will not require to provide subjects with a summary of the trial. We do not intend to seek out study participants to disseminate information once the study is complete. Women who are interested in the results will be provided the information where to read the manuscript once it is published. Study results for individual participants will not be shared.

28.Inclusion of Vulnerable Populations

There will not be any vulnerable populations included in this study. Those electing for surgery will not be coerced into doing so, nor will they be coerced into participating in this trial.

29. Community-Based Participatory Research

There will be no involvement of the community in this research.

30. Research Involving American Indian/Native Populations

This research does not specifically target this population. If a Native American female is a candidate for this study she will be offered participation.

31. Transnational Research

This study is not transnational

32. Drugs or Devices

No drugs or devices will be utilized in this study.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

A. Partial Waiver of Consent for Screening/Recruitment
We are not requesting a partial waiver of consent

Partial Waiver of HIPAA Authorization for Screening/Recruitment
We will not be reviewing records to identify potential subjects

B. Waiver of Documentation of Consent
NA, We are not requesting a waver of documentation of consent. We do not intend to obtain consent verbally. We will be obtaining signatures from subjects on a consent form to document consent.

C. Alteration of Consent
NA. We are not intending to obtain consent by eliminating or altering one or more of the required elements of consent.

D. Full Waiver of Consent/Parental Permission
We are not requesting a full waiver of consent for all subject or certain subject groups.

E. Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)
We are not requesting a full waiver of consent for all subjects or certain subject groups

F. Full Waiver of HIPAA Authorization
We are not requesting a full waiver of the requirement to obtain HIPAA authorization for all subjects or certain subject groups.

G. Other Waiver Types
We are not requesting alterations of consent, assent, or HIPAA authorization.

II. Vulnerable Populations

A. Adults with Cognitive Impairments
Adults with cognitive impairments will not be included in this study.

B. Children
The subject population will not include children

C. Pregnant Women and Fetuses
The subject population does not include pregnant women or fetuses.

D. Neonates of Uncertain Viability or Nonviable Neonates
The subject population does not include neonates of neonates of uncertain viability

E. Nonviable Neonates
The subject population does not include nonviable neonates

F. Biomedical and Behavioral Research Involving Prisoners
The subject population will not include prisoners

III. Medical Devices

A medical device will not be utilized in this study

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