

Protocol Title:

Educating Women about Pelvic Floor Disorders during Pregnancy From the 1st to the “4th trimester”

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change (Yes/No)
1	7/1/20	Addition of virtual version of workshops	Yes
2	10/8/20	Addition of postpartum phone follow up	No

1. Study Summary

Pelvic floor disorders (PFDs) are common and significantly affect the quality of life of many women as they age. Pregnancy has been identified as a major risk factor for developing PFDs later in life. Educating women about PFDs is essential to ensuring that they present to care in a timely manner. No study has investigated different education tools during pregnancy. The proposed study is a randomized controlled trial in pregnant patients comparing two educational tools: written materials about PFDs versus an educational workshops led by pelvic floor physical therapists (PFPTs). Pregnant patients will be recruited in the first and second trimester and randomized at that time. Knowledge will be assessed at baseline and again 6 weeks postpartum using the validated Prolapse and Incontinence Knowledge Questionnaire. Secondary outcomes will be evaluating referral patterns to urogynecology and to PFPTs from general OBGYNs and assessing any pelvic floor symptoms with the pelvic floor disability index (PFDI-20) at baseline and at 6 weeks postpartum.

2. Purpose of the Study / Objectives

Hypothesis: Patients attending an educational workshop from pelvic floor physical therapist (PFPT) on pelvic floor anatomy, physiology, and disorders will have improved knowledge of pelvic floor disorders (PFDs) as measured by the Prolapse and Incontinence Knowledge Questionnaire (PIKQ) than those in the written education group.

Primary aim:

To determine the change in knowledge regarding PFDs as measured by the PIKQ in pregnant patients attending education compared to written education alone.

Secondary aims:

To determine whether pregnant patients receiving written education or attending an educational workshop on PFDs increases referral rates to either PFPT or urogynecology.

To evaluate the incidence of PFD symptoms among pregnant patients throughout their pregnancy, including the “4th trimester” postpartum period (or the 12 weeks following delivery) using validated Pelvic Floor Disability Index (PFDI-20).

3. Background

Pelvic floor disorders (PFDs) in females can occur in many phases of life some of which are better understood than others. Pregnancy and delivery have been well established as major risk factors for developing PFDs.¹ The American College of Obstetrics and Gynecologists (ACOG) has made a renewed effort to bring attention to many health issues women experience due to pregnancy and the postpartum period by focusing on the “fourth trimester”, referring to the 12 weeks following delivery. In May of 2018, the ACOG committee opinion focused on redefining the postpartum visit. One of the areas described in the physical recovery is assessment of the perineum and the presence of PFDs such as fecal or urinary incontinence.² There are a wide variety of physical and mental health topics that need to be discussed in each perinatal visit and pelvic floor issues may not be addressed.

Prior studies have evaluated the information that patients receive during pregnancy and the most neglected area was educating patients on PFDs. Obstetricians cite their concern about patients developing PFDs in the future as a factor that they consider in their obstetric management during delivery.³ Patients are not well informed on their risk of developing PFDs and would be more equipped to participate in their care during pregnancy, during their delivery, and after pregnancy if they were better informed. Furthermore, many women have misconceptions about PFDs and are unaware of what their risks are and that there are prevention strategies and treatment options available to them.⁴ When patients have been asked about their perception of PFDs in one-on-one interviews, the findings suggested that younger women were less educated about PFDs while older women were more embarrassed to discuss these issues with others.⁵ The goal of this study is to investigate the best method for educating patients in the antepartum period and following them into the postpartum period to assess their retention of knowledge from the education they received.

Previous studies have examined this issue by various means of educating patients in different stages of the postpartum period. One such study examined immediate postpartum education on

perineal lacerations using a 3-D anatomical model and the effect it had on changing patient anxiety and knowledge. Patient anxiety decreased and patient knowledge increased after education using this model.⁶ Gagnon, et al. approached this issue by offering postpartum patients direct interaction with pelvic floor physical therapists in a group and one-on-one setting.⁷ Both of these studies showed that educating women about PFDs can lead to an improved understanding of their symptoms. In Gagnon's study, the patients that were educated in a group workshop setting led by PFPTs showed similar satisfaction and improvement in PFDI-20 scores to those patients that met with PFPTs in one-on-one sessions. This study would seek to continue the efforts of prior studies by further comparing patient education tools. The innovation of this study lies in the patient population and intervention comparison. The interventions that we will compare are written educational material versus an educational workshop setting with PFPTs. By intervening earlier in pregnancy, we hope to capture a unique patient population and intervene earlier to try to improve their knowledge of PFDs throughout pregnancy, the postpartum period, and beyond into the remainder of their life. There are no prior studies that have taken this approach of educating patients during pregnancy using the PIKQ as a validated measure of knowledge.

4. Study Design

The study design is a randomized controlled trial. There will be two study groups with 60 participants in each (total study population of 120 participants.) The participants will be randomized into: Group 1- written education group and Group 2-PFPT workshop group. Patients will be recruited from the obstetric population at our institution in the first and second trimester during their scheduled prenatal visit.

Statistical Analysis:

Patients' baseline characteristics will be summarized according to the two groups. All data will be presented as mean \pm SD or median (interquartile range) for continuous variables, and number (percentage) for categorical variables. Chi-squared or Fisher's exact test (categorical variables) and Student's t-test or Mann-Whitney test (continuous variables) will be used to compare patients between PFPT and written education group at baseline. Paired t-test or Wilcoxon signed-rank test will be used to compare questionnaire scores between baseline and the follow-ups within each group. Student's t-test or Mann-Whitney test will be used to compare the paired difference between the two groups. The Shapiro-Wilk test will be used to check the normality. Pearson's correlation coefficient or Spearman's rank correlation coefficient will be used to analyze the relationships among variables. All analyses will be performed with STATA version 16 (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC). Statistical significance will be defined as two-tailed $p < 0.05$ for all tests.

Sample Size Calculation:

Our primary objective of the proposed study is to evaluate the hypothesis that patients attending an educational workshop from PFPTs will have improved knowledge of pelvic floor disorders (PFDs) as measured by the Prolapse and Incontinence Knowledge Questionnaire (PIKQ) as compared to patients in the written education group. We will use the 24-point PIKQ questionnaire composite score as our primary endpoint. Based on the PIKQ validation study, a composite score of 0.45 (45%) is expected in women of this age at baseline.⁸ Assuming in our study population at baseline a score of 0.45, we would expect an increase in the composite

score to 0.8 in the PFPT group and an increase in composite score to 0.54 in the written education group. Therefore, a sample size of 96 patients will be needed to detect the difference with 80% power and a significance level of 0.05 based on the two-sided Z-test with pooled variance. After considering 20% dropout rate from the study, the total sample size will be 120 patients (60 per group). PASS 2015 (PASS 15 Power Analysis and Sample Size Software (2017). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass) was used for sample size calculation.

Study Timeline:

The obstetrics practice that we will be recruiting from has approximately 75 obstetrics patients per month. Assuming approximately 50% recruitment each month, we anticipate being able to complete recruitment in 6 months. We will start educational workshops once 10 patients are enrolled into the educational workshop arm of the study. In order to offer adequate availability to patients, we will plan to offer four workshops per month. As scheduling the workshops may pose a logistical challenge, we will assess patient availability and adjust timing of the workshops to maximize the number of patients at each workshop. We will continue to follow these patients through their pregnancy so the timeline of data collection will continue for approximately 9 months after the recruitment period ends. We estimate that data collection will be completed by August 2021.

2020			
July	Recruitment period		
Aug			
Sept		Educational workshops four times per month	Data collection period will continue until 3 months after the completion of the intervention to capture both questionnaire and referral pattern data.
Oct			
Nov			
Dec			
2021			
Jan			
Feb			
Mar			
Apr			
May			
June			
July			
Aug			

Inclusion criteria:

- Patients in the first or second trimester of pregnancy
- English speaking
- Greater than 18 years old

Exclusion criteria:

- Non-English speaking or unable to provide informed consent

5. Study Intervention

At the first research visit, patients will be consented and randomized. Patients may be approached regarding the study by phone. The research consent form will be sent to them via e-mail for them to review and they will sign the consent at their next in-person visit. They will complete the PIKQ and PFDI-20 questionnaires (Appendix A).^{8,9} After their baseline questionnaires are completed, they will receive written educational materials.

Patients randomized into the written education group will only receive written materials. They will receive these materials at the first study visit and again when leaving the hospital after delivery. The written materials will consist of three one-page handouts with information on pelvic organ prolapse (POP), stress urinary incontinence (SUI), and pelvic floor exercises. These handouts will be created in collaboration with Dr. Jennifer Vardeman and Alaina Spiers who have experience in the study of patient's perceptions of PFDs and have collaborated with the American Urogynecology Society to create written educational materials in the past.⁴ We plan to seek feedback from patients regarding their impressions of our newly developed handouts prior to use.

The PFPT workshop group will both receive the written handouts and attend an in-person education workshop that will be led by a PFPT with approximately 5-10 study participants in each workshop. Patients will be allowed to attend the workshop after being randomized during pregnancy or during the postpartum period to maximize participation. The session will last approximately 1 hour and will review similar information to the content of the handouts. It will focus on educating the patients about pelvic floor anatomy, etiology of PFDs, prevention strategies, and informing them about urogynecologists and PFPTs. The educational workshops will be offered in either in person or virtual format to accommodate group gathering restrictions of COVID-19. The web-based meeting will be password protected and participants will have the option to share their video and do not have to provide their name as the participant if they do not want to. They have the option to verbally participate but this is not required.

Patients will be reassessed and complete the PIKQ and PFDI-20 questionnaires at their 6-week postpartum visit. We will also record delivery type. If patients do not attend their postpartum visit, they will be reached by phone or e-mail to complete the postpartum assessment. Referral patterns to PFPT and urogynecology will be assessed using electronic medical records during the study period and up to 3 months postpartum.

Patients from the workshop group will receive a follow up phone call to perform a brief phone survey on their perceptions of the two forms of educational materials: written versus workshop format. No medical information will be discussed in this phone call. Please see interview guide attached in appendix ***.

6. Drugs, Biologics, Devices

No drugs, biologics, or devices will be used for this study.

7. Collaborative / Multi-site Research

This study will take place at one site within the Methodist system.

8. Data Privacy / Confidentiality

Houston Methodist polices for Protected Health Information (PHI) will be followed in access patient charts. PHI will be used to identify patients that are eligible for the study by reviewing clinical schedules. Patients will be assigned a subject ID number that is deidentified. There will be a master data sheet that will have patient MRNs associated with their subject ID number that is separate from the RedCap database. This data sheet will be stored on an encrypted password protected USB drive. No PHI will be disclosed. The data will be maintained for 6 years after the completion of the study and then destroyed.

The web based virtual workshop will not include the patient's personal information, including their name, unless they want to provide their name. They have the option to share their video or participate verbally in the workshop but it is not required. All participants will be muted and their video off on entry to the virtual meeting and they can choose to disable these features if desired. The virtual workshop meeting room will be password protected. This password will be provided to the participants via e-mail the day of the workshop. There will be a phone number to a study team member provided to them to call for any technical support if needed. None of the sessions will be recorded.

Identifier (or parts of)	Recorded	Disclosed	Comment
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and elements of dates (including year) indicative of such age	X		
Medical record numbers	X		
Phone number			Used for recruiting patients after virtual visits with their doctor.
Email address			Used to send questionnaires and consent forms if recruited virtually. Used to send password for virtual workshop.

9. Data and Specimen Banking

Patient demographic data will be collected from the medical record and the PIKQ survey, including age, race, obstetrics history, marital status, household income, and education level. Delivery type will also be recorded at the 6 weeks postpartum visit. The patients will be asked to give responses to the PIKQ and PFDI-20 surveys. Data collected in the study will include referral patterns within the OBGYN group at Methodist to the urogynecology group and pelvic floor physical therapy group. The referral information will be collected for the 6 months

preceding the study and compared to the data collected during the study period. This data will be recorded on recruitment paperwork with a de-identified subject ID and recorded into a RedCap database.

10. Study Population

We will recruit female patients in the first or second trimester of pregnancy who are 18 years of age or older.

11. Screening and Recruitment ^{S R}

Patients will be identified by reviewing the clinical schedule of the general obstetrics providers at Houston Methodist Hospital. The patients will be approached either in the waiting room prior to their appointment or while they are awaiting their physician visit in the clinic room. Patients may also be approached by phone after their visit with a physician if they are attending virtual visits. Recruitment flyers will be posted around the clinical area and waiting room of the Smith 2221 OBGYN clinical area.

12. Withdrawal of Subjects

Subjects may withdraw from the study at any time with no change to their routine obstetric care. Patients who experience a miscarriage or intrauterine fetal demise prior to viability will be withdrawn from participation.

13. Provisions to Protect the Privacy Interests of Subjects

Subjects will be required to provide minimal demographic information at their recruiting visit and this will not need to be repeated at any point. Their primary interaction with the research study team will be at recruitment, at the PFPT group workshop, and at their postpartum visit for the follow up questionnaire administration. The educational workshop will include females only and female PFPTs in small groups of 5-10 subjects. We plan to offer the workshops in either an in-person or virtual format to accommodate for current group gathering constraints due to COVID-19.

14. Risks to Subjects

There are minimal risks associated with this study. The cost of parking in the medical center may pose a burden to some subjects and so we plan to compensate the cost of parking to try to offset this. Otherwise, there is no physical, social, legal, or psychological risk to the subjects.

15. Potential Benefits

Regardless of the group to which the subjects are randomized, they will be given education on PFDs that they would not typically receive in their routine obstetric care. This may provide the opportunity to make subjects aware of treatment options for PFDs that they were not aware of and provide them an opportunity to improve their quality of life.

A potential challenge would be ensuring that patients receive their follow up assessment as patients may not show up for their postpartum visit. A strategy to improve follow up would be to consent patients to the option of receiving and completing the PIKQ and PFDI-20 by e-mail if they do not attend their postpartum visit. Another potential challenge may be ensuring that patients attend their assigned group workshop. A strategy to improve attendance and

enrollment would be to compensate patients. We plan to compensate their parking on the dates that they attend the group workshop.

16. Financial and Economic Issues

The only cost to the study subjects will be the cost of parking to attend the group workshop. The remainder of the study visits will occur at the same time as routine care visits. We will plan to compensate the cost of parking at the time of their group workshop with an estimated cost of \$960 (\$16 per participant).

17. Data Safety Plan

Please see above description of Data and Specimen Banking.

18. Informed Consent Documentation and Process

Informed consent will be obtained prior to any of the study procedures with the attached informed consent template. Consent will be obtained from a member of the research team. The consent document may be e-mailed to participants after being recruited by phone for their review. They will then sign the consent form at their next in-person physician visit.

19. Waiver of Informed Consent and /or Authorization

A screening waiver will be requested preparatory for research (waiver requested for feasibility, recruiting, access to charts, pre-screening). We are not requesting a waiver of informed consent.

Appendix A:

Pelvic Floor Disability Index (PFDI-20)

Instructions: Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder, or pelvic symptoms and, if you do, how much they bother you. Answer these by circling the appropriate number. While answering these questions, please consider your symptoms over the last 3 months. The PFDI-20 has 20 items and 3 scales of your symptoms. All items use the following format with a response scale from 0 to 4.

Pelvic Organ prolapse Distress Inventory 6 (POPDI-6)

Do You...	NO	YES
1. Usually experience pressure in the lower abdomen?	0	1 2 3 4
2. Usually experience heaviness or dullness in the pelvic area?	0	1 2 3 4
3. Usually have a bulge or something falling out that you can see or feel in your vaginal area?	0	1 2 3 4
4. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?	0	1 2 3 4

5. Usually experience a feeling of incomplete bladder emptying?	0	1	2	3	4
6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	0	1	2	3	4
	0	1	2	3	4

Colorectal-Anal Distress Inventory 8 (CRAD-8) Do You... NO YES

Do You...	NO	YES
7. Feel you need to strain too hard to have a bowel movement?	0	1 2 3 4
8. Feel you have not completely emptied your bowels at the end of a bowel movement?	0	1 2 3 4
9. Usually lose stool beyond your control if your stool is well formed?	0	1 2 3 4
10. Usually lose stool beyond your control if your stool is loose?	0	1 2 3 4
11. Usually lose gas from the rectum beyond your control?	0	1 2 3 4
12. Usually have pain when you pass your stool?	0	1 2 3 4
13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	0	1 2 3 4
14. Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?		

Urinary Distress Inventory 6 (UDI-6) Do You... NO YES

Do You...	NO	YES
15. Usually experience frequent urination?	0	1 2 3 4
16. Usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	0	1 2 3 4
17. Usually experience urine leakage related to coughing, sneezing or laughing?	0	1 2 3 4
18. Usually experience small amounts of urine leakage (that is, drops)?	0	1 2 3 4
19. Usually experience difficulty emptying your bladder?	0	1 2 3 4
20. Usually experience pain or discomfort in the lower abdomen or genital region?	0	1 2 3 4

Scoring the PFDI-20 Scale Scores: Obtain the mean value of all of the answered items within the corresponding scale (possible value 0 to 4) and then multiply by 25 to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only.

PFSI-20 Summary Score: Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

Prolapse and Incontinence Knowledge Quiz (PIKQ)

1. In what year were you born? _____
2. How many children have you given birth to? _____
3. Which describes you?

Still have regular periods Near menopause Menopausal

4. Do you work in a medical field?
No Yes (If yes, what do you do? _____)

5. Are you currently married?

No Yes

6. What is your yearly household income?

< \$10,000 \$10,000 - \$49,999 \$50,000 - \$100,000 >
\$100,000

7. What is your highest level of education?

8th grade or less High School College Graduate School

8. Have you ever seen a urologist or urogynecologist for any type of medical issue or problem?

No Yes

9. Have you ever had a problem with urine leakage?

No Yes

10. Have you ever had a problem with pelvic organ prolapse (bulging of the vagina, uterus, bladder, and/or rectum)?

No Yes

11. Have you ever been treated for pelvic organ prolapse (bulging of the vagina, uterus, bladder, and/or rectum)?

No Yes

12. Have you ever been treated for leakage of urine?

No Yes

13. What is your race?

Hispanic White (not Hispanic) African American Asian
Other

Below are some statements about urinary incontinence (loss of urine or leaky bladder). Please state if you agree or disagree with each statement, or if you do not know.

1. Urinary incontinence (loss of urine or leaky bladder) is more common in young women than in old women.

AGREE DISAGREE DON'T KNOW

2. Women are more likely than men to leak urine.

AGREE DISAGREE DON'T KNOW

3. Other than pads and diapers, not much can be done to treat leakage of urine.

AGREE DISAGREE DON'T KNOW

4. It is NOT important to diagnose the type of urine leakage before trying to treat it.

AGREE DISAGREE DON'T KNOW

5. Many things can cause urine leakage.

AGREE DISAGREE DON'T KNOW

6. Certain exercises can be done to help to control urine leakage.

AGREE DISAGREE DON'T KNOW

7. Some medications may cause urinary leakage.

AGREE DISAGREE DON'T KNOW

8. Other people start to leak urine, they are never able to control their urine again.

AGREE DISAGREE DON'T KNOW

9. Doctors can do special types of bladder testing to diagnose urine leakage.

AGREE DISAGREE DON'T KNOW

10. Surgery is the only treatment for urinary leakage.

AGREE DISAGREE DON'T KNOW

11. Giving birth many times may lead to urine leakage.

AGREE DISAGREE DON'T KNOW

12. Most people who leak urine can be cured or improved with some kind of treatment.

AGREE DISAGREE DON'T KNOW

Below are some statements about pelvic organ prolapse (bulging of the vagina, uterus, bladder, or rectum). Please state if you agree or disagree with each statement, or if you do not know.

1. Pelvic organ prolapse (bulging of the vagina, uterus, bladder, or rectum) is more common in young women than in old women.

AGREE DISAGREE DON'T KNOW

2. Giving birth many times may lead to pelvic organ prolapse.

- | | AGREE | DISAGREE | DON'T KNOW |
|--|-------|----------|------------|
| 3. Pelvic organ prolapse can happen at any age. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 4. Certain exercises can help to stop pelvic organ prolapse from getting worse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 5. Symptoms of pelvic organ prolapse may include pelvic heaviness and/or pressure. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 6. A good way for a doctor to diagnose pelvic organ prolapse is by examining the patient. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 7. Once a patient has pelvic organ prolapse, not much can be done to help her. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 8. Heavy lifting on a daily basis can lead to pelvic organ prolapse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 9. Surgery is one type of treatment for pelvic organ prolapse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 10. Doctors can run a blood test to diagnose pelvic organ prolapse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 11. A rubber ring called a pessary can be used to treat symptoms of pelvic organ prolapse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |
| 12. People who are obese are less likely to get pelvic organ prolapse. | | | |
| | AGREE | DISAGREE | DON'T KNOW |

20. References

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