Title: Does a Patient Education Video Augment Pelvic Floor Physical Therapy Compliance?

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1. Protocol Synopsis

1.1. Study Premise

Pelvic floor physical therapy (PFPT) is a widely accepted treatment for many urogynecologic diagnoses, such as stress and urge urinary incontinence, pelvic organ prolapse, and myofascial pain of the levator ani muscles[1]. This conservative treatment modality has virtually no risk, unlike medications or surgery[2]. It is especially useful for patients who are otherwise poor surgical candidates. This treatment consists of weekly one hour long physical therapy sessions with therapists specially trained in the pelvic floor musculature. Treatment length depends on severity of symptoms and patient progress, but is usually anywhere from five to fifteen visits at our practice.

Many investigators worldwide have studied what factors influence patient compliance with this therapy[1,3,4]. Some barriers that have been identified including being too busy with work, being afraid of vaginal palpation, feeling ashamed, feeling too old to engage in such therapy, or having symptoms that are minor.[5] Another analysis found that age, distance from home, and diagnosis necessitating PFPT were factors in compliance[6]. We have recently performed an IRB-approved retrospective chart review to determine PFPT compliance within our practice. We found that 66% of patients attended at least one therapy session. Of these women, 73% attended at least half of the recommended visits.

Our practice wants to develop an educational tool to improve PFPT compliance. We designed and created a four minute patient education video with assistance of the marketing department. This video includes physicians, pelvic floor physical therapists, and one of our patients speaking to the most common questions and concerns patients have. Now we aim to assess if patients who use this education tool will have improved compliance to therapy.

1.2. Specific Research Question

Does viewing an educational video augment patient compliance with PFPT compared to standard counseling?

1.3. Study Objectives and Hypotheses

Objective: To determine the impact on PFPT compliance in patients who view an educational compared to standard counseling

Hypothesis: Compared to patients receiving standard counseling, those who receive both the standard counseling and educational video intervention will

1) Be more likely to complete at least half of their recommended PT visits
2) Be more likely to initiate PFPT
3) Will have a shorter time to initiation of PFPT
4) Be more likely to discharge from PFPT
5) Will have greater improvement in urogenital distress following PFPT

1.4. Summary of Study Design

Study Design: Randomized controlled trial

Population: Clinic-based patients seen at the Loyola University Medical Center Urogynecology outpatient clinic who have been prescribed PFPT as a treatment for their condition and agree to such therapy.

Control group: Will read standard PFPT handout (see Appendix 4.1)

Intervention group: Will read standard PFPT handout plus watch education video (see Appendix 4.2)

Study Length: At least three months after the initial PFPT referral for each patient, medical record review will be performed to record therapy attendance, including date of first visit, number of visits recommended by the therapist, number of completed visits, and whether the patient was discharged from PFPT.

Power-calculation: One goal of the proposed study is to test the null hypothesis that the rate of women attending at least half of their required PT visits is identical in the two populations: Those assigned to handout only and those assigned to handout and video intervention. With proposed sample sizes of 96 assigned to handout only and 96 assigned to handout and video intervention, the study will have power of 80% to yield a statistically significant result.

This computation assumes that the difference in proportions of compliance is 20% (specifically, 70% versus 50% compliance for the intervention and control groups, respectively). It also assumes that the criterion for significance (alpha) will be set at 0.05 and that the test will be 2-tailed, meaning an effect in either direction will be interpreted.

This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance. It is also assumed that this effect size is reasonable, in the sense that an effect of this magnitude may be anticipated in this research.

2. Protocol

Patients who have been interviewed, examined, and a plan has been made by the treating physicians in the Female Pelvic Medicine & Reconstructive Surgery practice will be invited to participate at the end of the visit if the patient and physician mutually agree that PFPT is the treatment modality to pursue.

If she agrees to participate, she will be consented and randomized. If she is randomized to standard counseling, she will be given the standard handout to read. If she is randomized to the intervention, she will be both given the standard handout and then view the 4-minute educational video on a clinic iPad.

At the conclusion of the counseling, patients will be asked if they have any additional questions, and these will be recorded and answered. The patient will also fill out a visual analog scale about how informed she feels. (See appendix 4.3 & 4.4)

Follow-up: Patient chart will be monitored following enrollment in the study to measure time to PFPT attendance and PFPT compliance (See appendix 4.5).

2.1. Eligibility criteria

Inclusion criteria

Patients who have prescribed PFPT by a treating physician in the Female Pelvic Medicine & Reconstructive Surgery practice

Exclusion criteria

Patients < 18 years old

2.2. Consent Process

Patients will be identified when they present to the Loyola Urogynecology out-patient clinic for management of their pessary. Consent form will be read to them describing the nature of the trial and potential associated risks and benefits. They will be informed that neither participation nor refusal will influence the care received at either Loyola University Medical Center. A copy of the consent form will be given to them. Participation is completely voluntary and they may discontinue participation in the study at any time.

2.3. Trial Design

Randomized controlled clinical trial

2.4. Randomization

Block randomization strategy will be developed based on a 1:1 allocation of patients in the intervention and control groups. The randomization procedure will take place after informed consent is completed and eligibility status is determined.

2.5. Confidentiality

Following HIPPA guidelines, patient identifiable data will be coded to protect each patient's identity. A unique identification number will be assigned to designate each subject, and all identification numbers identifying information will be removed from the database and stored separately on a secure password-protected network drive in the office of the PI.

Here is an overview of the security of the infrastructure:

Physical

- Servers kept in locked cage
- Entry requires a passcard and biometric recognition
- Digital surveillance equipment
- Controls for temperature, humidity and smoke/fire detection
- Staffed 24/7

Network

- Multiple independent connections to Tier 1 Internet access providers
- Fully redundant OC-48 SONET Rings
- Uptime monitored every 5 minutes, with escalation to SurveyMonkey staff
- Firewall restricts access to all ports except 80 (http) and 443 (https)
- QualysGuard network security audits performed quarterly

Hardware

- Servers have redundant internal power supplies
- Data is on RAID 10, operating system on RAID 1
- Servers are mirrored and can failover in less than one hour

Software

- Code in ASP, running on SQL Server 2000 and Windows 2000 Server
- Latest patches applied to all operating system and application files
- Data backed up every hour internally
- Data backed up every night to centralized backup system, with offsite backups in event of catastrophe

2.6. Statistical analysis

Binary logistic regression will be used to compare the odds of PFPT initiation, PFPT discharge, completion of half of the recommended visits, and having any further questions after counseling between those assigned to the enhanced versus standard counseling groups. In these models, expected frequencies will be monitored and exact logistic regression models will be used when these values are sparse. We will also

stratify the comparison of PFPT initiation by participants' primary language. Because few patients will have Spanish as their primary language, we will make an *a-priori* decision to use an exact binary logistic regression model to compare the two treatment groups among Spanish speaking participants. Subsequently, a Breslow-day test may be used to compare the stratified English and Spanish speaking odds ratios for homogeneity.

A binary logistic regression model will also be used to estimate the odds of being discharged from PFPT as a function of the number of completed visits, and a Kaplan-Meier curve will be used to estimate the probability of not attending a PFPT visit following date of referral for those in the experimental and control cohorts. Using this approach, elapsed time will be measured in days from referral date to date of first visit for those who attended PFPT. Individuals who never attended PFPT will be censored at the last date they were known to be absent from therapy.

For each patient, the change in UDI-6 will be calculated by subtracting the post-treatment score from her pre-treatment score, and an independent samples *t*-test will be used to compare this change score between those assigned to the experimental group versus control group. In this model, normality and influential outliers will be assessed using QQ plots and box plots, respectively. A non-parametric Wilcoxon rank-sum test may be used if the data violate parametric assumptions. Finally, though a Kaplan-Meier method is primarily used to compare days from date of referral to date of first visit between the experimental and control groups, a Wilcoxon rank-sum test will also be used to make this comparison as a sensitivity analysis among those who attend PFPT. All analyses will be completed using SAS version 9.4 (Cary, NC).

2.7. Anticipated findings and use of the data

The findings from this project may result in a new standard counseling for PFPT that includes viewing of the educational video.

2.8. Subject compensation

There is no subject compensation.

3. References

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2. Fitzgerald MP, Anderson RU, Potts J, et al. Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. *J Urol*. 2013;189(1 Suppl):S75-85.

3. Brown HW, Barnes HC, Giles D, McAchran S. Abstract: Compliance with prescribed pelvic floor physical therapy when patients consult with a physical therapist at their initial urogynecologic evaluation. *Female Pelvic Medicine and Reconstructive Surgery*. 2015;21(5):S52.

4. Farahani F, Calloway E, Gibson R, et al. Abstract: Patient compliance to pelvic floor physical therapy for urinary incontinence. *Female Pelvic Medicine and Reconstructive Surgery*. 2015;21(5):S52.

5. Alewijnse D, Mesters I, Metsemakers J, Adriaans J, van den Borne B. Predictors of intention to adhere to physiotherapy among women with urinary incontinence. *Health Educ Res*. 2001;16(2):173-186.

6. Tibaek S, Dehlendorff C. Do women with pelvic floor dysfunction referred by gynaecologists and urologists at hospitals complete a pelvic floor muscle training programme? A retrospective study, 1992-2008. *Int Urogynecol J*. 2013;24(8):1361-1369.

4. Appendix

4.1. Standard care handout

The Role of Physical Therapy in the Treatment of Pelvic Floor Dysfunction:

Physical therapists are trained to evaluate and treat dysfunctions in the joints, muscles, nerves and scar. Physical therapists specifically trained in the area of pelvic health can identify the possible musculoskeletal causes of pelvic pain, bladder and bowel difficulties and develop a treatment plan specific to the individual suffering from this difficulties.

What to expect at your first physical therapy appointment:
Your first visit will include an initial evaluation in a comfortable, private room by a therapist who has undergone advanced education and training in the evaluation and treatment of pelvic muscle dysfunction. The therapist will obtain a detailed history of your health, pain and activity limitations. She will also ask you about any bowel, bladder and sexual difficulties as these are in part controlled by the pelvic muscles. The therapist will then take a look at your posture, mobility of your spine and hips and strength and flexibility of pelvic girdle muscles. She will examine any scar tissue and trigger points in the muscles of your pelvic region.

The therapist will also specifically examine the pelvic floor muscles. Your pelvic floor consists of a group of muscles that attach behind the pubic bone in the front to the tail bone in the back. They are responsible for providing support to the pelvic joints and organs, relaxing to allow the passage of urine, stool and gas and contracting to prevent the loss of urine, stool and gas as appropriate. In order to best examine these muscles you will be asked to undress from the waist down and be covered with a sheet. The therapist will use a lubricated, gloved finger to identify painful muscles around and in your vagina or rectum then instruct you to contract and relax these muscles in order to determine how the muscles are functioning. Care is taken to make you as comfortable as possible with the exam.

Your therapist will discuss the evaluation results with you and provide you with education regarding your specific condition and the expectation of therapy. She will

answer all of your questions and will work with you to establish a treatment plan based on the results of the evaluation and your goals for therapy.

PAC can schedule for any of the locations and the phone number is 708-216-5300.

Loyola Rehabilitation Services provides pelvic floor rehabilitation at the following locations:

Loyola Outpatient Center Urogynecology at Loyola University Medical Center (708) 216-2180

Loyola Center for Rehabilitation on Roosevelt in Maywood (708) 216-5300

Loyola Center for Health at Burr Ridge (708) 327-1050

Loyola Center for Rehabilitation at Hickory Hills (708) 233-5395 (No PT at this location for now)

Loyola Oak Brook and Oakbrook Terrace, 630-953-6778

4.2. English Intervention video link: https://youtu.be/mDMVUQ-2wvY, **and Spanish Intervention video link:** https://youtu.be/R0x4ixhFCqo

4.3. Patient information collected (in clinic)

Circle one: Control Intervention (video)

Age _____ **Vaginal Parity** _____ **BMI** _____

Insurance type: Private Government sponsored Combined Other

Race Caucasian Black Asian Eastern European Hispanic Other

Urogynecologic diagnoses (circle)**:** SUI UUI MUI Urgency-frequency Syndrome

Weak pelvic floor Defecatory dysfunction POP Myofascial pain Other

Stage of Prolapse 0 1 2 3 4 Not Assessed

4.4 Patient questionnaire

Do you have any further questions? No/Yes_____

_____

1) After your visit today, how **well informed** do you feel about the role of pelvic floor physical therapy in treating pelvic floor symptoms?

_____

No change Very Informed

2) How do you rate the **ease of understanding** of information about pelvic floor physical therapy?

_____

Very difficult Very easy

3) How do you rate the **amount of information** about pelvic floor physical therapy that was presented to you?

_____

Not enough information Too much information

4.5 Patient information collected (from EMR < nine months later)

Time to first PFPT visit from day of referral: _____ days

Physician who referred: Fitzgerald Brubaker Mueller Brincat

Number of recommended visits: _____

Number of completed visits: _____

Discharged from PFPT practice (circle): yes no