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2015 MOTIVATIONAL INTERVIEWING IN WOMEN'S PELVIC WELLNESS EDUCATION PROJECT

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Abstract

Pelvic floor disorders can significantly affect a woman's quality of life, yet many feel uncomfortable openly discussing these topics. Treatments include lifestyle modification, medications, and/or surgery. Decisional conflict arises when patients have difficulty choosing between several viable treatment options. Factors contributing to decisional conflict include biased information, poor peer support, and unaddressed fears. Effective counselling may help address these factors. Objectives of this pilot study are to assess: (1) the impact of a small-group workshop on pelvic floor disorders (urinary incontinence (UI), or pelvic organ prolapse (POP)) on decisional conflict regarding treatment options; and (2) participant satisfaction with the workshop in terms of quality of information shared, comfort with discussing pelvic health in a group setting, and perceived benefits of a nurse continence advisor and psychologist. Women ≥ 18 years old with urinary incontinence or pelvic organ prolapse will be randomized at the time of their first urogynecology consultation to usual care or a 90 minute workshop on either UI or POP. Five to 10 women will attend each workshop led by a nurse continence advisor and a psychologist. In both groups, decisional conflict will be measured using the validated Decisional Conflict Scale (DCS) at baseline and at the first follow-up clinic appointment. Satisfaction with the workshop will be assessed by a post-workshop survey. Demographic data will be compared between groups using t-tests for continuous data and chi-square tests for categorical data. Change in DCS score will be compared using t-tests. Linear regression analysis will be performed to identify predictors of decisional conflict. This pilot study will assess the feasibility and acceptability of an educational workshop on pelvic floor disorders and its potential impact on decisional conflict. Results of this study will inform future development of interdisciplinary, patient-centred approaches to enhanced decision making in women's health.

I. Rationale and Background Information

Pelvic floor dysfunction, according to the IUGA (International Urogynecological Association)/ICS (International Continence Society), is a general term encompassing urinary incontinence (UI), pelvic organ prolapse (POP), anal incontinence, sensory abnormalities of the lower urinary tract, defecatory dysfunction, and chronic pelvic pain syndromes. The IUGA/ICS defines the symptoms of pelvic organ prolapse as *a departure from normal sensation, structure or function, experienced by the woman in reference to the position of her pelvic organs*. Objectively, POP is *the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus, or the apex of the vagina*. The IUGA/ICS definition of urinary incontinence is *the complaint of involuntary loss of urine*, or *the observation of involuntary loss of urine on examination*, and can be sub-categorized further as stress, urge, or mixed urinary incontinence. [1]

Risk factors for UI and POP include age, parity, obesity, and history of pelvic radiation. [2,3] Bump et al. (1998) proposed a comprehensive model for the development of female pelvic floor dysfunction. In this model, pelvic support and function is influenced by interactions between *predisposing factors* (i.e. race, connective tissue, anatomic, neurologic, genetic), *inciting factors* (i.e. childbirth, nerve injury, muscle injury, radiation, tissue disruption, surgery), *promoting factors* (i.e. constipation, obesity, smoking, medication, comorbidities), *decompensating factors* (i.e. aging, dementia, poor mobility), and *intervening factors* (behavioural modification, pharmacologic, devices, surgical). [4] This model is useful for both understanding the etiology of pelvic floor dysfunction and for developing both primary and secondary prevention strategies to address them.

Pelvic floor dysfunction is common and occurs more frequently in women. Urinary incontinence and pelvic organ prolapse are the two most common manifestations of pelvic floor dysfunction. The prevalence of UI ranges from 13.1-49.7% while the prevalence of POP of any severity is approximately 41%. Cystocele is the most frequently encountered form of POP (34%), followed by uterine prolapse (14%), and rectocele (13%). [2]

Treatment options for UI and POP fall into two modalities: conservative treatment (behaviour modification, pelvic floor muscle therapy, pharmacologic therapies, pessaries) and surgical intervention. Although an initial trial of conservative management is usually undertaken, many women will eventually have surgery. In 1995, the estimated lifetime risk of undergoing one operation for pelvic floor disorders was 11.1% by age 80. [5] Based on current population demographics and the increasing prevalence of obesity, it is projected that over the next five decades the demand for incontinence and prolapse care will significantly increase. [6]

Despite the high prevalence of pelvic floor dysfunction in women, it is well accepted that far fewer seek treatment for their symptoms. Patient-reported barriers to seeking treatment include lack of knowledge about their condition and available treatments, the perception that their symptoms are a normal part of ageing or childbirth, or are not appropriate for medical intervention. [7] Left untreated, the symptoms of pelvic floor dysfunction, can be debilitating, leading to functional decline, social isolation, sexual dysfunction, withdrawal from employment or leisure activities, and loss of independence. [8]

Lack of knowledge about pelvic floor dysfunction, in addition to being a barrier to appropriate treatment, can undermine decision-making and the process of informed consent.

Many patients do not feel adequately informed about their condition and seek additional resources to supplement the counselling provided by their physician. Of 458 consecutive patients presenting to a urogynecology outpatient clinic, only 20% of patents felt they had sufficient knowledge about their diagnosis, and of the 80% who felt inadequately informed, most consulted their primary care physician or used the internet to obtain more information. [9] Nonetheless, women with pelvic floor dysfunction have a desire both to be well informed and involved in decision-making, and most women seeking care for pelvic floor dysfunction prefer an active or collaborative role in decision-making. [10]

An essential component of patient-centered care, *shared decision-making* promotes active participation of the patient in discussing a care plan. Shared decision-making has been defined as '*an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences*". [11] This approach may be especially applicable in clinical situations such as pelvic floor dysfunction, where quality, not quantity, of life is at stake. In these cases, effective counselling and decision-making support is essential for the development of an acceptable treatment plan.

Women presented with several viable treatment options, each with respective drawbacks and benefits, may experience decisional conflict, which can result in emotional distress, isolation, and vulnerability. Decisional conflict can be defined as "*the uncertainty about which course of action to take when choice among competing actions involved risk, loss, regret, or challenge to personal life values".* [12] Antenatal testing, hormone replacement therapy for menopause, hysterectomy for abnormal uterine bleeding, ovarian cancer screening, and treatment for incontinence are all situations specific to women's health in which decisional conflict may arise. [12] O'Connor et al. (1995) developed the decisional conflict scale (DCS), a validated scale that measures (a) perceived uncertainty between options, (b) factors contributing to uncertainty (feeling uninformed, unclear about values, unsupported in decision making), and (c) factors contributing to effective decision making (feeling the choice is informed, values-based, likely to be implemented, and satisfaction with the decision). [13] A total decisional conflict score from 0 (no decisional conflict) to 100 (extremely high decisional conflict) is given, as well as five sub-scores for each factor listed above.

Designed to facilitate shared decision-making, decision aids are evidenced-based tools that empower patients to make high quality, well-deliberated and informed decisions. A 2014 Cochrane Review reported high-quality evidence that shared decision-making and decision aids increase patient knowledge about treatment options and reduce decisional conflict; increase participation in decision-making and promote of more accurate perceptions of risk (moderate quality evidence); and increase congruence between the chosen option and patient values (low quality evidence). [14] Decision aids have also been shown to significantly reduce the number of patients choosing major elective surgery (i.e. prophylactic mastectomy for BRCA 1/2 gene carriers, cardiac revascularization, orchiectomy). [14] A large randomized controlled trial of 894 British women with benign abnormal uterine bleeding, found that when nurses administered a structured interview to women immediately before their consultation with the surgeon with the goal of clarifying their preferences for treatment, women were more satisfied with their involvement in decision-making and overall costs were reduced, as women were more likely to

choose conservative therapy over hysterectomy. [15]

Among women making treatment decisions for pelvic floor dysfunction, there is limited data on the impact of shared decision-making or decision aids on decisional conflict. In one recent study, in which 103 women with pelvic organ prolapse were randomized to either standard clinician-led, one-on-one counselling or standard counselling plus a decision aid, the addition of a decision aid to standard counselling did not significantly reduce decisional conflict or influence the choice of conservative treatment over more invasive surgery [16].

Shared decision-making may be difficult to implement in a busy office practice where information exchange is time-limited. Most studies on shared decision-making have focused on the physician-patient interaction, and as such, the most commonly reported barrier to implementing this practice is lack of time for effective counselling. [17] Recognizing the importance of the entire healthcare team in patient-centered care, interprofessional models of shared decision making have been developed [18] and validated [19], and may help address this time constraint barrier. Although there is a growing body of evidence to suggest that small-group educational workshops increase patient knowledge about pelvic floor dysfunction and improve symptoms and quality of life [20,21], no studies to date have explored how group counselling sessions lead by non-physician health professionals affect decisional making in women with pelvic floor dysfunction.

The interprofessional model proposed by Légaré et al. [18] takes into account three conceptual levels of shared decision making: the individual level, in which the patient, once presented with a decision, collaborates with various healthcare professionals as she progresses through the phases of making choice. The second level takes into account how the interactions between members of different healthcare professions influence the decision-making process. Finally, the third level considers how the team functions within the environment in which it is embedded (health policies, social context, and professional organizations).

This model also explicitly introduces the concept of a “decision coach”, a health professional (often a nurse, social worker, or psychologist) who’s role involves being an empathetic but impartial team member who guides a patient through the decision making process. [22] Decision coaching involves assessing patients’ degree of decisional conflict and factors contributing to uncertainty, delivering decision-making support by providing evidenced-based information or patient decision-aids, ensuring understanding, clarifying values, monitoring progress in decision-making, and screening for barriers preventing implementation of a chosen decision. In the context of pelvic floor disorders, the decision coach may play an important role in guiding women through the decision making process.

There are few studies on how decision coaching can help women with prolapse and incontinence reach a satisfactory decision about treatment. This study aims to use the principals of shared decision making to address decisional conflict surrounding treatment for pelvic floor disorders. Specifically, we will evaluate the feasibility and acceptability of small group workshops on pelvic organ prolapse and urinary incontinence led by a nurse continence advisor and a psychologist (decision coach). We will also assess impact of the workshop on decisional conflict. Results of this study will inform future development of interdisciplinary, patient-centered approaches to enhanced decision making in women’s health.

II. Study Objectives, Hypotheses

Primary objective: To evaluate how a structured workshop on pelvic floor disorders impacts decisional conflict with regard to seeking treatment for pelvic organ prolapse and urinary incontinence.

Secondary objective: To assess patient satisfaction with the quality of information shared during the workshop, their comfort with discussing pelvic health in a group setting, and the perceived benefits of a nurse continence advisor and psychologist.

Hypotheses:

1. A nurse and psychologist-led workshop on pelvic floor disorders will result in decreased decisional conflict compared to standard individual physician-led counselling.
2. Participants will be satisfied with the quality of information shared and will feel comfortable discussing pelvic health in a group setting

Primary Outcome & Measure: Change in "Decisional Conflict" between baseline and follow-up, as measured by the Decisional Conflict Scale.

Secondary Outcome & Measure: Participant satisfaction with the group workshop. This will be measured using a survey administered immediately following the workshop

III. Study Design and Methodology

This pilot study will be a structured as a randomized control trial in which eligible participants will be recruited at the time of their first urogynecology consultation. Participants will be randomized into two groups: (1) standard care (follow up with urogynecologist as usual) or, (2) a workshop on either urinary incontinence (UI) or pelvic organ prolapse (POP), with a follow-up urogynecologist appointment after attendance at the workshop (Figure 1).

Randomization will be done using a computer generated randomization sequence in blocks of 4 or 6. Sequentially numbered envelopes will contain the randomization result, with the group only revealed at time of randomization. Health care providers will be blinded to the treatment group, but participants will be unblinded to treatment group due to the nature of the intervention.

Patients randomized to the intervention group will be asked to select a workshop on either UI or POP based on which pelvic floor disorder they perceive to be most bothersome. Two identical workshops on different dates will be offered for each topic and participants will be required to attend one to be included in the study.

The workshop will be approximately 90 minutes in length. The first 15 minutes will be an information session on either UI or POP led by a Nurse Continence Advisor. The following 60 minutes will comprise a psychologist-led group discussion. The structured discussion will encourage participants to share experiences, thoughts, and feelings on pelvic floor disorders. Resistances and barriers to seeking treatment will be discussed. Decision-making processes will be explored. During the final 15 minutes, participants will be asked to complete a survey to evaluate the workshop. The survey will assess satisfaction with the information provided, quality of group discussion, comfort level with the group experience, and their satisfaction with the roles of the nurse continence advisor and psychologist.

Using a questionnaire, the following demographics will be collected at baseline: age, marital status, education level, household income, ethnicity, predominant type of pelvic floor dysfunction (urinary incontinence, prolapse, both), and previously attempted treatment modalities. Electronic medical records will also be accessed to confirm the principal diagnosis. The Decisional Conflict Scale (DCS) and the Control Preferences Scale (CPS) will also be administered at the baseline visit.

The DCS is a validated scale that measures (a) perceived uncertainty between treatment options, (b) factors contributing to uncertainty (feeling uninformed, unclear about values, unsupported in decision making), and (c) factors contributing to effective decision making (feeling the choice is informed, values-based, likely to be implemented, and satisfaction with the decision). [13] The CPS is a validated tool that assesses the degree to which patients wish to be involved in treatment decision-making. [10] The CPS is a one-item questionnaire with a five-point scale that describes various degrees of involvement in decision-making. Lower scores on the CPS indicate stronger preferences for an active role in decision making while higher score indicate a preference for a passive or collaborative role.

Analysis of results

Baseline socio-demographic data will be compared between groups using t-tests for

continuous data and chi-square tests for categorical data. Differences in decisional conflict scores between the intervention and control groups will be compared using unpaired t-tests. Linear regression will be done to identify significant predictors of decisional conflict in this population.

IV. Study Population/Recruitment/Consent process

Sample size

For this pilot study, we estimate that recruiting a total of 80 participants will be feasible based on the volume of new consults to the Riverside Hospital Urogynecology Clinic. With a minimum 50 percent participation rate, this would result in a total sample size of 40-80 participants (20-40 per study group).

Inclusion criteria

- Women ages >18 years old
- Urinary incontinence and/or pelvic organ prolapse
- First visit with urogynecologist

Exclusion criteria

- Anal incontinence
- Previous pelvic radiation therapy
- Non-English speaking
- Requirement for a Substitute Decision Maker
- Inability to attend the workshop
- Unwilling to attend an English-language workshop
- Unwilling to complete English-language surveys

Recruitment & Consent

Participants in the study will be patients identified from the Riverside Urogynecology Clinic at their first consultation visit. The day prior to the clinic, the SMS and vOASIS will be checked for participants attending clinic who meet eligibility requirements. Suitable participants agreeing to research contact through the Consent to Research Contact process will be approached in person by the Research Coordinator at the time of their first urogynecological consultation.

For patients who have not previously consented to research but who are deemed suitable for the study by their urogynecologist, the physician will also obtain permission for research personnel to approach the patient to discuss the study. The OBIEE tool will be used to identify patients who have agreed to research contact. Medical charts will be reviewed for eligibility in vOASIS prior to patient approach to potential participants meet eligibility criteria. Informed consent will be obtained by the research coordinator in person. The consent is identical between the treatment and control groups.

The standard of care for pelvic floor disorders is gynecology/urogynecology consultation with appropriate counselling with regard to potential treatments. There will be no additional activities that will be performed on research participants regardless of group assignment. Participants in the intervention group will attend a group workshop during which they may

participate in a discussion on pelvic floor disorders led by a nurse continence advisor and psychologist. Participation in this workshop will not delay treatment for their condition.

Participants in the intervention group risk feeling uncomfortable or embarrassed discussing sensitive information, or hearing other participants' sensitive information, in a group setting. Participants in this research study who are randomized to the intervention group may benefit from the decision-making support and additional knowledge received in the group workshop on pelvic floor dysfunction. Following the workshop they may feel more knowledgeable about their condition and more comfortable with choosing a treatment for their specific condition. They may feel more comfortable knowing that other women may be experiencing the same thoughts and emotions surrounding their diagnosis. If the participant no longer wishes to participate in the study, she may withdraw early.

We will provide participants with reimbursement of parking fees incurred during the initial clinic visit, the follow up clinic visit, and, the group workshop (for participants randomized to this group).

V. Appendix

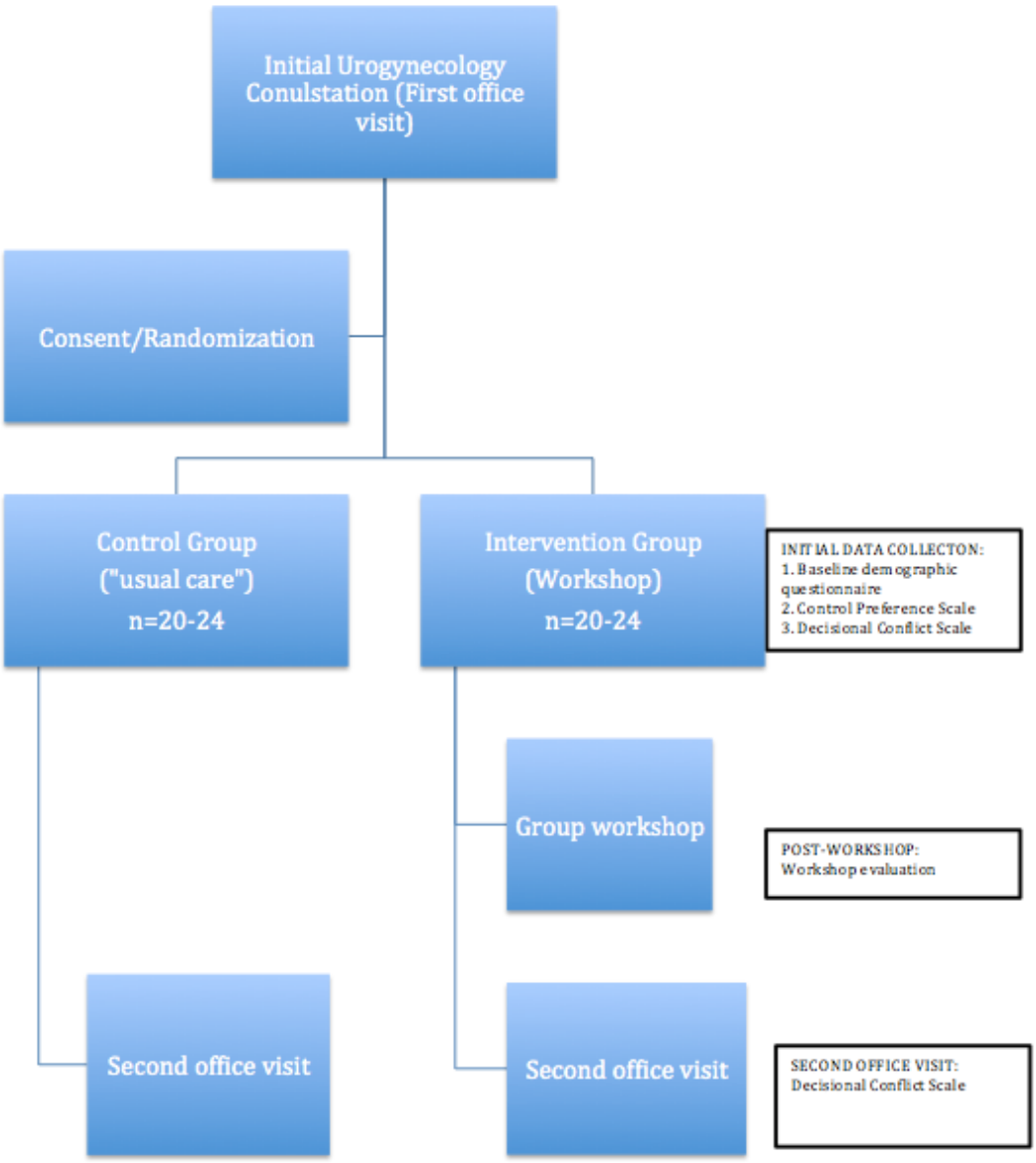

Figure 1: Study Flowchart

Baseline Questionnaire *(Please complete to the best of your ability)*

Age:

18-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61-70 ☐ 71-80 ☐ 81+ ☐

Educational Level:

Grade school ☐ High School ☐ College Diploma ☐

Bachelor's degree ☐ Post-Graduate degree ☐ Professional Degree ☐

Ethnicity:

White ☐ Black ☐ Chinese ☐ Filipino ☐

South Asian (i.e. East Indian Pakistani, Sri Lankan etc.) ☐

Latin American ☐ Arab ☐ West Asian (i.e. Iranian, Afghan etc.) ☐

Southeast Asian (i.e. Vietnamese, Cambodian, Malaysian, Laotian, etc.) ☐

Korean ☐ Japanese ☐ First Nations ☐

Other ☐ _____

Type of Pelvic Floor problem: please check ALL that apply:

Pelvic organ prolapse (cystocele, rectocele, uterine prolapse) ☐

Urinary incontinence (involuntary leaking urine) ☐

Both pelvic organ prolapse and urinary incontinence ☐

Which problem are you MOST concerned about? Please choose ONE only:

Pelvic organ prolapse ☐

Urinary incontinence ☐

Which treatments have you previously had for these problems? Check ALL that apply:

None ☐

Lifestyle modification (decrease caffeine, increase fluid intake) ☐

Kegel exercises ☐

Pelvic floor physiotherapy ☐

Medication ☐

Pessary ☐

Surgery ☐

The Control Preferences Scale

Please circle the statement that most accurately reflects your preferences regarding your role in making a decision regarding the treatment of your pelvic floor problems:

1. **I prefer to make the final decision**
2. **I prefer to make the final decision after seriously considering my doctor's opinion**
3. **I prefer that my doctor and I share responsibility for the decision**
4. **I prefer that my doctor makes the decision after he/she seriously considers my opinion**
5. **I prefer my doctor to make the decision**

Decisional Conflict Scale

My difficulty in making this choice

A. Which [insert treatment/screening] option do you prefer? Please check ☑ one.

a. ☐ **[Option 1]**
b. ☐ **[Option 2]**
c. ☐ **[Option 3]**
d. ☐ Unsure

B. Considering the option you prefer, please answer the following questions:

	Yes [0]	Unsure [2]	No [4]
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

Decisional Conflict Scale © AM O'Connor, 1993, revised 2005

Post-Workshop Quesionnaire

Date of Workshop:

Please rate the following statements:

4 = strongly agree 3 = agree 2 = disagree 1 = strongly disagree

Information session				
The Nurse Continence Advisor was knowledgeable	4	3	2	1
The information provided was useful to me	4	3	2	1
I was satisfied with the length of the information session	4	3	2	1
Group Discussion				
I was comfortable with the size of the group	4	3	2	1
If you disagree, the group was:	Too big		Too small	
The psychologist created relevant group discussion	4	3	2	1
I felt comfortable discussing these topics in a group setting	4	3	2	1
The discussion brought out feelings I may not have discussed with my doctor	4	3	2	1
I was satisfied with the length of the group discussion	4	3	2	1
Overall Workshop				
I would recommend this workshop to a friend or family member	4	3	2	1
I would attend another session if given the opportunity	4	3	2	1
I would prefer to discuss these issues alone with my doctor	4	3	2	1
The nurse continence advisor was essential to the group experience	4	3	2	1
The psychologist was essential to the group experience				
Overall, this workshop was beneficial	4	3	2	1

(see next page)

What changes will you make in your decision for treatment as a result of this workshop?

Tell us about one thing you found most valuable in this workshop

What would you change about this workshop?

Other comments

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