Outcomes of a Longitudinal Multidisciplinary Program for the Treatment of Chronic Pelvic Pain, Incorporating Online and Mobile Applications to Promote Self Efficacy

The purpose of the study is to determine the impacts of a structured multidisciplinary longitudinal program for the management of chronic pelvic pain with an emphasis on adjunctive web based and mobile applications on patient satisfaction; secondary objectives are to measure the impacts of the treatment plan on quality-of-life measures and pain.

We hypothesize that those patients randomized to a structured chronic pelvic pain management program will demonstrate improved satisfaction with their care, and improved quality of life measures and pain scores as compared to those who receive standard care.

Background:

The diagnosis and treatment of conditions leading to chronic pelvic pain (CPP) is challenging for patients and providers alike. CPP is defined as pain perceived to originate from the pelvis, lasting greater than 6 months, often associated with negative cognitive, behavioral, sexual and emotional consequences. While CPP is estimated to affect 26% of the world's female population, and accounts for 10% of gynecologic office visits, there is a lack of high-quality evidence to support the use of many well accepted therapeutic interventions[1]. It has, however, been well established that treatments should be multimodal in order to address the overlapping non-gynecologic pain disorders and biopsychosocial factors impacting many patients with CPP [1-3]. A growing body of evidence has demonstrated improved pain severity and quality of life measures for patients receiving care in interdisciplinary centers, able to provide coordinated surgical, medical and/or pain management care in a centralized location[6-9]. Other studies have examined care delivered in tertiary care center clinics, relying on a multidisciplinary approach in which patients received care from a variety of providers both central to the clinic and in their referral networks[10]. Although effective, the aforementioned approach dictates a specialized allocation of resources not widely available for the treatment of CPP in this moment. While the later multidisciplinary model may be more feasible in this current environment, it demands that patients are able to navigate care delivered from a variety of providers. Patients in turn may face financial constraints, time constraints, or a perceived lack of utility of the prescribed treatments leading to poor adherence[4,5]. With widely available access to smart phones and the internet, we may consider how to incorporate mobile and web-based applications to supplement the multidisciplinary treatment of CPP in a way that alleviates barriers to care. There already exist a variety of resources dedicated to patient education and self-management which have been found to effectively help individuals with chronic pain conditions[11,12]. Improvements in self efficacy and depression, as well as decreased health service usage have also been established when these apps are supplemented with proactive calls encouraging app compliance[13,14]. Current practice at our tertiary care center relies upon a multidisciplinary model in which patients' surgical and medical management of chronic

pain is performed by clinic providers, and outside referrals are provided for complex pain management, pelvic floor therapy and psychotherapy services. We propose that formalizing the structure of our chronic pelvic pain management through the clear definition of available resources, supplemented with mobile and web-based applications supporting education and self-efficacy with the aim of reducing barriers to care, paired with a well-defined timeline for follow up, we will see improved patient satisfaction, improved quality of life and pain scores as opposed to patients enrolled in standard practice.

Study Endpoints:

The primary endpoint will be patient satisfaction scores related to their treatment for chronic pelvic pain. Secondary endpoints will be quality of life and pain scores.

Study Intervention:

Patients randomized to the intervention arm will receive standard care in addition to a Chronic Pelvic Pain Handbook which outlines their diagnoses and includes educational materials, an individualized treatment plan and follow up schedule.

Procedures Involved:

Patients meeting eligibility criteria will be approached regarding their interest in participating. Should they choose to participate they will be randomized using a random number generator- an odd number will designate randomization to the control group, while an even number will designate randomization to the intervention group. Those in the control arm will receive standard care which is individualized based on their specific needs and may include medical, procedural or surgical interventions. Those in the intervention arm will receive standard care in addition to our Chronic Pelvic Pain Handbook which includes educational resources pertinent to their specific diagnosis, defines available treatment resources, provides a clearly defined follow up schedule and points of contact. Resources included in the Chronic Pain Handbook were thoroughly reviewed by the study team and providers within the National Center for Advanced Pelvic Surgery team. They were screened to be sure that medically accurate information was being presented and that recommendations reflect best practices for the treatment of chronic pelvic pain based on expert consensus. The diagnoses designated on page 4 of the handbook will be filled out by the provider the patient is seeing in the office. Baseline demographics will be collected in addition to validated surveys measuring quality of life and pain scores for all participants. These surveys will be repeated at 3 months, 6 months and 12 months following initial enrollment. Patients' satisfaction with their treatment will also be measured at 3 months, 6 months and 12 months.

Data Collected:

Baseline demographic and pain related data including age, race/ethnicity, BMI, age when pain started, prior treatments, smoking status, history of anxiety/depression/sexual assault, current or prior engagement in psychotherapy, family history of chronic pain will be collected through chart review and patient interview at time of their scheduled visit.

Measurements of pain and quality of life will be collected through previously validated questionnaires regarding pelvic pain (Yosef et al, 2016), in addition to the PHQ-9, GAD-7, Pain Catastrophizing Scale, and Pain Self Efficacy Questionnaire.

Patient satisfaction data will be collected using the PSQ-18 with additional questions included regarding specific barriers they have experienced, what web based or mobile applications they have used and the degree to which they found them helpful.

The number of visits outside of scheduled follow ups, as well as number of patient portal messages sent between visits will be obtained through chart review.

Recruitment Methods:

Subjects will be screened for eligibility based on chart review conducted prior to their scheduled appointment. If eligible they will be contacted in advance of their appointment to determine their interest in participation. If they are interested in participating, they will be verbally consented and randomized prior to the appointment. This will be performed remotely by the study coordinator. A message will be sent to the provider they are seeing and a note placed in the medical record to designate their participation and treatment arm. The patient will then be seen by their National Center for Advanced Pelvic Surgery provider, whom are listed as sub-investigators on the project.

Consent Process:

The consents will be performed over the phone in advance of the patient's scheduled appointment. If they were not able to be contacted in advance of the appointment the consent may be performed in person.

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