RECOMMENDATIONS FOR BEST-PRACTICE INTERDISCIPLINARY MANAGEMENT OF WOMEN WITH VAGINISMUS

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ABSTRACT

Vaginismus is a female health condition characterised by a persistent difficulty in allowing vaginal penetration, in spite of an expressed desire to do so. It has been proposed that a comprehensive approach to this condition would address inherent elements of anxiety and fear, pain, increased pelvic floor muscle tone, and issues relating to sexual pleasure. Given that comprehensive management may best be accomplished by combining the expertise of various disciplines involved in patient care, a multi-modal, multidisciplinary approach is recommended. To date, there is little literature available to provide guidance in the operationalization of this type of approach for women with vaginismus, for example, to identify the disciplines that should be involved, to lay out the requirements for collaboration between disciplines and with the individual, and to outline a framework for optimum management. Furthermore, the term *multi*disciplinary is sometimes used interchangeably with the term *inter*disciplinary, yet they represent two distinct treatment models along a continuum of increasingly collaborative approaches. As the advantages of interdisciplinary management in primary healthcare are believed to outweigh those of multi-disciplinary management, one may propose that the ideal approach to the management of vaginismus be *inter*disciplinary. The global objective of the main study presented in this thesis was thus to establish recommendations for best-practice interdisciplinary management of women with vaginismus.

This thesis begins with a comprehensive literature review on treatment interventions for vaginismus and on current recommendations for the management of women with this condition, and is followed by the methodology and results from a study of health professionals who are considered expert on the topic of vaginismus. A two-fold approach was used in order to develop a set of recommendations for best-practice interdisciplinary management of women with vaginismus. First, a multi-disciplinary expert recommendations meeting was held during an international conference on women's sexual health to glean expert opinion on best-practice interdisciplinary management of this condition. Data obtained from this focus group was compiled and analysed to devise an initial list of recommendations, which was subsequently validated and further explored via a Two-Round Delphi electronic survey of additional experts on the topic of vaginismus. This consensus process also allowed for the identification of some of the areas requiring further discussion, investigation and research in this field.

While physiotherapists are involved in the study and treatment of a variety of disorders related to pelvic floor dysfunction, including urinary, ano-rectal and sexual pathologies, vaginismus is one disorder that has traditionally been studied and treated by disciplines other than physiotherapy. At the end of this thesis, a clinical commentary by the lead author is presented, to interpret the results of this study through the lens of a physiotherapist working clinically with women with vaginismus, in an attempt to help clarify the role of the physiotherapist in the interdisciplinary management of these women, within the context of daily practice.

RECOMMANDATIONS POUR LA GESTION INTER-DISCIPLINAIRE DES FEMMES SOUFFRANTES DE VAGINISME

ABRÉGÉ

Le vaginisme est une condition de santé féminine qui se caractérise par une difficulté persistante à permettre la pénétration vaginale, malgré l'expression d'un désir de le faire. Il est proposé qu'une approche compréhensive pour cette condition devrait se concentrer sur les éléments d'anxiété, de crainte/peur, de douleur, de l'hypertonicité musculaire du plancher pelvien, et des facteurs reliés au plaisir sexuel. Étant donné qu'une gestion compréhensive du vaginisme pourrait être accomplie plus efficacement en combinant les expertises de disciplines variées, une approche multi-modale et multi-disciplinaire est recommandée. À date, il existe peu de littérature expliquant comment exercer ce genre d'approche, par exemple, comment identifier les disciplines qui devraient être impliquées, comment énumérer la collaboration qui devrait prendre place entre les disciplines et avec le patient, et comment proposer un model pour la gestion optimale des femmes aux prises avec le vaginisme. De plus, le terme *multi*disciplinaire est souvent confondu avec le terme *inter*disciplinaire, même si ces deux termes représentent deux modèles distincts sur un continuum d'approches de plus en plus collaboratives. Comme les avantages de la gestion interdisciplinaire en soin de santé primaire ont été démontrées de surpasser ceux de la gestion multidisciplinaire, il est par conséquent proposé que l'approche idéale pour le vaginisme devrait être interdisciplinaire. L'objectif global de l'étude présentée dans cette thèse était donc d'établir des recommandations pour la gestion interdisciplinaire des femmes qui souffrent du vaginisme.

Cette thèse est présentée à l'aide de deux manuscrits, suivis d'un commentaire clinique. Le premier manuscrit concerne une révision compréhensive de la littérature sur les interventions pour le vaginisme et sur les recommandations pour la gestion des femmes aux prises avec cette condition. Le deuxième manuscrit décrit la méthodologie et les résultats d'une étude effectuée avec des professionnels de la santé considérés experts dans le domaine du vaginisme. Une approche de deux étapes a été employée pour développer un ensemble de recommandations pour la gestion interdisciplinaire des femmes avec le vaginisme. En premier lieu, une rencontre multidisciplinaire incluant divers experts a eu lieu pendant une conférence internationale en santé sexuelle de la femme pour obtenir l'opinion d'expertise sur la gestion interdisciplinaire de cette condition. Les données obtenues lors de cette rencontre ont été compilées et analysées pour créer une liste initiale des recommandations. Ces recommandations ont, par la suite, été validées et explorées d'avantage via un sondage électronique de Delphi avec deux ronds rempli par des experts additionnels sur le sujet du vaginisme. L'information obtenue a donné lieu à un ensemble de recommandations pour la gestion interdisciplinaire des femmes souffrantes de vaginisme. Ce processus de consensus a aussi permis l'identification des sujets qui requièrent plus de discussion, d'investigation et/ou de recherche dans ce domaine.

Même si les physiothérapeutes sont impliqués dans l'étude et le traitement d'une variété de problèmes reliés à la dysfonction du plancher pelvien, incluant des pathologies urinaires, ano-rectales et sexuelles, le vaginisme a dorénavant été étudiée et traitée par des disciplines autre que celle de la physiothérapie. À la fin de cette thèse, un commentaire clinique écrit par l'auteure principale est présenté dans le but d'interpréter les résultats de cette étude du point de vue d'une physiothérapeute qui

travaille cliniquement avec les femmes souffrantes du vaginisme et de clarifier le rôle de la physiothérapie dans la gestion interdisciplinaire de ces femmes.

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This thesis is dedicated to the memory of my younger sister

Mary Brown

who passed away in 2011.

CONTRIBUTION OF AUTHORS

I, Claudia Brown, certify that I am the primary author of the manuscripts, clinical commentary and bridging texts found within this thesis, and claim full responsibility for their content.

The first manuscript of this thesis entitled, *"Interventions for Vaginismus: A Literature Review"* was mainly written by myself with improvement, suggestions and guidance from Dr. Nicol Korner-Bitensky, and insightful suggestions from Dr. Yitzchak Binik and Dr. Marie-Andrée Lahaie. The electronic search of the literature for this manuscript was done with the help of Jill Boruff.

The second manuscript entitled, *"Recommendations for Best-Practice Interdisciplinary Management of Women with Vaginismus"* was mainly written by me with guidance, suggestions and improvements from Dr. Nicol Korner-Bitensky, and advice and suggestions from Dr. Yitzchak Binik, Dr. Marie-Andrée Lahaie and Talli Rosenbaum. Under Dr. Korner-Bitensky's guidance, I developed the consent forms, submitted the study for ethics approval, and created the socio-demographic questionnaires for the participants in both the expert group meeting and the Delphi electronic survey. Dr. Korner-Bitensky and I developed the content for the first round of the Delphi survey, which was formatted by an external consultant, Karen Korb. I developed the content and formatted the second round of the Delphi survey, under the guidance of Dr. Korner-Bitensky. I recruited the participants for both phases of the study with the help of Dr. Yitzchak Binik and Talli Rosenbaum, I collected all of the data, and analyzed the data under the supervision and guidance of Dr. Nicol Korner-Bitensky. This second manuscript is now being prepared for journal submission.

The clinical commentary was written by me, with thoughtful suggestions from Dr. Nicol Korner-Bitensky and Talli Rosenbaum.

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AND ABBREVIATIONS

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DIAGRAMS

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ABBREVIATIONS

ACOG:	American Congress of Obstetricians and Gynecologists
AGREE:	Appraisal for Guidelines Research and Evaluation
BASHH:	British Association of Sexual Health and HIV
CBT:	Cognitive behavioural therapy
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th ed.
FES:	Functional electrical stimulation
ICF:	International Classification of Function and Disability
ISSWSH:	International Society for the Study of Women's Sexual Health
PTSD:	Post-traumatic stress disorder
PVD:	Provoked vulvar vestibulodynia
TRIAGE:	Technique for Research of Information by Animation of a Group of Experts
VVS:	Vulvar vestibulitis syndrome

PREFACE

In accordance with the Guidelines for Thesis Preparation from the Faculty of Graduate Studies and Research at McGill University, a manuscript-based style of dissertation has been adopted for this thesis. Three manuscripts are thus presented, with the inclusion of introductory, connecting and summarizing texts intended to achieve an integrated presentation of the material. As this thesis has been prepared to document the steps taken within a single program of research, some overlap can be found within the texts.

Chapter 1 provides an introduction to the thesis, presenting a brief overview of the subject of vaginismus and the management of women with this condition, as well as a rationale for the literature review in Manuscript 1.

Chapter 2 is the first Manuscript, and entails a comprehensive literature review on treatment interventions for vaginismus and on current recommendations for the management of women with this condition**.** *Given that the literature review for this thesis is in the form of a manuscript, there is no literature review provided elsewhere within the thesis.*

Chapter 3 is a connecting text that serves to integrate Manuscript 1 and Manuscript 2.

Chapter 4 presents Manuscript 2, which is the main study of this thesis. It details a two-fold approach that was used to develop a set of recommendations for best-practice interdisciplinary management of women with vaginismus, through expert consensus.

Chapter 5 is an integrating text that serves as a preface to Manuscript 3.

Chapter 6 is the third Manuscript, a short clinical commentary that aims to interpret the results of the study through the lens of the physiotherapist.

Chapters 7 and 8 provide a summary and conclusions to this thesis.

An alphabetical reference list follows the conventional reference list at the end.

CHAPTER 1 - Introduction

Vaginismus is a female health condition characterised by a persistent difficulty in allowing vaginal penetration, in spite of an expressed desire to do so[1]. It has been proposed that a comprehensive approach to this condition would address inherent elements of anxiety and fear, pain, increased pelvic floor muscle tone, relationship issues and issues pertaining to sexuality[2]. In order for this to occur, various disciplines must be involved to provide the necessary expertise for appropriate multi-modal evaluation and treatment[3].

Although this multi-modal, multidisciplinary approach to the management of women with vaginismus is often postulated as the ideal, it does not appear to be supported by empirical research. Many intervention studies on vaginismus involve a uni-disciplinary approach with limited intervention modalities[3]. In addition, as is the case in other areas of health care, the benefits of *multi*disciplinary management may be surpassed by the benefits of the more collaborative *inter*disciplinary management, as active collaboration amongst the disciplines proposes to promote a better-integrated and more concerted approach to management[4].

This thesis begins with Manuscript 1, a comprehensive literature review on interventions for women with vaginismus. The Manuscript serves as an update to the most recent review found in the literature to 2009[3], prior to the beginning of this research, and includes a section on current recommendations that can be found on the management of women with vaginismus.

A connecting text follows Manuscript 1 that leads to the rationale for the study presented in Manuscript 2.

CHAPTER 2 - Manuscript 1 - Interventions For Women With Vaginismus: A Literature Review

1. INTRODUCTION

Vaginismus is characterised by the persistent or recurrent difficulty in allowing vaginal penetration, in spite of an expressed desire to do so[1]. It can be classified as total or partial, and primary or secondary. With total primary (lifelong) vaginismus the patient has never been able to have intercourse, while with partial primary vaginismus, intercourse is possible, but has always been difficult or painful. Secondary vaginismus represents the disability in the case of the patient who had previously been able to have pain-free penetration[5]. Vaginismus is often associated with marked distress and interpersonal problems, marital difficulties and issues related to the inability to conceive naturally [6,7].

While there are no epidemiological studies available to precisely determine the population prevalence of this condition[6] the *estimated* prevalence of vaginismus is from 0.5-1% in the general community and from 5-17% of referrals for female sexual dysfunction [6,8,9]. This may be a gross underestimation given that sexual dysfunction tends to be underreported in the community because of the fear of embarrassment and stigmatization[9], and because of an overlap in the definitions of vaginismus and dyspareunia (painful sexual intercourse). In fact, the precise definition of vaginismus has been under considerable debate. The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 2000), defines vaginismus as a 'recurrent or persistent involuntary spasm of the musculature of the outer third of the vagina that interferes with sexual intercourse' [10]. This definition does not take into consideration the

elements of fear (of penetration) and pain, which have been shown by recent evidence to be important components of this condition[11,12]. Also, the use of the term 'spasm' as a diagnostic criterion is disputable: it is a term for which dissimilar definitions may be found, and hence a term that is not interpreted in the same way by all professionals[13]. In fact, this term does not even appear in the publication of the Standardization of Terminology of Pelvic Floor Muscle Function and Dysfunction (2005)[14]. Moreover, a physical examination to determine the presence of spasm is not always possible, as many patients with vaginismus have issues with fear and avoidance, hence the diagnosis is often based purely on patient-reported difficulty with penetration[11,12,13]. As well, if the gynecological exam is possible but not the intercourse, the spasm may be situational and therefore difficult to objectify.

To explore the evidence on interventions for vaginismus and on recommendations for the management of women with this condition, MEDLINE, PsychINFO, CINAHL, AMED and Cochrane databases were searched to October 2012 for articles containing the key terms: *vaginismus, frigidity*, and *unconsummated marriage*, retrieving review articles on the subject, controlled intervention studies involving women with total primary vaginismus, and papers containing recommendations for the management of this condition. A structured review by Lahaie et al to December 2009 on the classification/diagnosis, etiology and treatment of vaginismus[3] and a Cochrane review to May 2005 on interventions for vaginismus[6] were found, both of which bring attention to the fact that a lack of well-designed research on treatments for vaginismus makes it difficult to draw firm conclusions about the efficacy of any of the interventions. An updated Cochrane review to August 2012 that has since been published provides a similar observation[15]. Only five studies met the inclusion criteria for the most recent Cochrane review, which searched for randomized or quasi-

randomised trials comparing treatments for vaginismus with another treatment, a placebo treatment, treatment as usual or a waiting list control.

Lahaie and colleagues categorize treatment interventions into four major categories: *general psychotherapy, sex/cognitive behavioral therapy (CBT)*, *pelvic floor physiotherapy, and pharmacological treatment,* and report that best management may involve a combination of these approaches[3]. A review of the findings from our search is the purpose of this first of two papers in this thesis. It begins with a report on the effectiveness of interventions in each of the four intervention categories stated above (along with any combination thereof), and is followed by a report on current recommendations for the management of women with vaginismus.

2. GENERAL PSYCHOTHERAPY

There are different orientations when it comes to psychotherapy, such as psychodynamic, systemic-interactional, existential-humanist, and cognitive-behavioural therapy (CBT). Psychotherapy may be provided in different formats including group, couple and individual, and may sometimes employ hypnosis[16]. While psychodynamic therapy explores the link between current difficulties and repressed experiences or conflicts in the past[3], this approach differs from the practical approach of sex/CBT, which seeks to define more concrete goals and uses specific techniques to address unhelpful cognitions, emotions and behaviours[17]. Depending upon the therapist's personality and orientation as well as the patient presentation, there may be considerable overlap in the use of the different forms of psychotherapy[18,19]. Numerous case reports show high success rates, usually measured in terms of penetration ability, with general psychotherapy[16,18,20], as do two uncontrolled trials[21,22]. However, no controlled studies exist on its effectiveness in the

treatment of vaginismus, making conclusions difficult to draw on its usefulness in treating women with this condition[3]. In this manuscript, CBT is considered in a separate category because of its prevalence, in combination with some form of sex therapy, in the treatment of women with vaginismus.

3. SEX/COGNITIVE BEHAVIORAL THERAPY

In the approach to vaginismus, sex/cognitive behavioral therapy (CBT), includes some form of sexual education, relaxation exercises, home exercise assignment for the insertion of graduated phallic insertion objects, cognitive therapy and/or sensate focus therapy[23,24]. It is aimed at educating the patient about sexuality and relaxation and systematically desensitizing her to vaginal penetration. Flooding, or exposure therapy, a more concentrated form of desensitization, is also used, which aims to reduce avoidance behaviour by providing prolonged exposure to the feared stimuli[25]. A number of uncontrolled series and case reports attest to the efficacy of sex/CBT in the treatment of women with vaginismus, most often with only a dichotomous outcome of self-reported penetration ability[26,27,28]. Four studies of more advanced design in this category were retrieved, including a high-quality RCT (van Lankveld et al, 2006), an uncontrolled randomised trial (Schnyder, 1998), a randomised-onset replicated single-subject series (Ter Kuile et al, 2009), and a descriptive and comparative case-series (Ben Zion et al, 2007), all described below.

Historically, methodologically less rigorous studies have consistently shown highly successful outcomes with CBT, which led to a general notion that CBT is a highly efficacious form of treatment for women with vaginismus[28,29,30,31]. This notion was challenged, however, when a high quality RCT (rating 6/8 on the Physiotherapy Evidence Database (PEDro) scale for internal validity and 2/2 for statistical

reporting)[32,33], investigated two forms of CBT in the treatment of women with total primary vaginismus (van Lankveld et al. 2006)[24]. One hundred and seventeen participants were randomised to a program of cognitive behavioural group therapy, cognitive behavioral bibliotherapy, or to a waiting list control group. The group therapy program involved ten two-hour sessions comprised of sexual education, relaxation exercises, gradual exposure, cognitive therapy and sensate focus exercises, while the bibliotherapy program used the same elements as those used in group therapy, but delivered in written format, with six bi-weekly fifteen-minute telephone support sessions. After 12 weeks, the primary outcome, self-reported successful intercourse, was attained by 14% of participants in both of the treatment groups compared to 0% in the control group, analyzed using intention to treat analysis: data from all of the 117 participants was analyzed, with the missing data from 21 drop-outs (10 from the group therapy cohort, 11 from bibliotherapy, and 3 from the waiting list control group) replaced by the individual participants' scores from the previous assessment point. Twelve-month follow-up revealed successful intercourse for 21% in the cognitive behavioral therapy group, 15% in the CBT bibliotherapy group and 0% in the non-treatment group. A critique of the study sample is that it included 69% with unsuccessful prior treatment for vaginismus instead of all first-time treatment seekers, such that the study sample may not have been truly representative of the population of women with vaginismus. This may in part explain the low success rate in comparison with the highly successful outcomes of less rigorous studies, as mentioned above. Also, while previous uncontrolled studies investigating the use of sex/CBT used an individual or couple therapy format[3,8], this study used group therapy and bibliotherapy, both of which would have been less personalized approaches, potentially reducing the intervention's effectiveness.

In a randomised trial, Schnyder et al (1998) compared two forms of systematic desensitization in the treatment of women with primary or secondary vaginismus[34]. This study was deemed by the Cochrane group to be equivalent to an uncontrolled trial as it compared two forms of the same treatment and did not have a non-treatment control group[6]. Forty-four participants were randomly allocated to an in-vitro desensitization group, whereby they received verbal instructions for self-insertion of progressively larger dilators, or to an in-vivo group, which involved the insertion of the dilators by a physician. The program for each group also included education, relaxation exercises, desensitization exercises, dilator insertion at home with four sizes of vaginal dilators and post-exercise journal entry. After an average of 6.3 treatments, 98% of the participants were able to have painless intercourse (the self-reported primary outcome measure), with no difference between the two groups. Sexual desire was a secondary measure obtained on 39 of the 44 participants: improvement was reported in 14, it remained the same in 20, and diminished in 5. At six-month follow-up, 50% of participants reported that the vaginismus had altogether subsided, while the other 48% reported that their condition remained improved. Participants had the choice to change treatment groups after the initial allocation process, which may have introduced a selection bias in this study, and while this study shows great improvements in penetration ability for patients undergoing either form of systematic desensitization, more detailed outcome measures, and the addition of a control group may have allowed for more firm conclusions to be made.

In a randomised-onset replicated single-subject series, Ter Kuile et al (2009) investigated the use of 'in-vivo exposure' in the treatment of women with total primary vaginismus[25]. For each of 10 participants, 'penetration behaviour' during the non-treatment first phase was compared with penetration behaviour during the second

phase. The second phase involved treatment with an explicit and systematic focus on exposure to feared stimuli during penetration, an approach hypothesized to enhance the effectiveness of treatment, considered after it was shown that a distinguishing feature of vaginismus is a high level of fear of vaginal pain or of vaginal penetration[12,23]. Secondary outcomes included penetration beliefs, coital fear and subjective sexual functioning, all measured using standardized tools pre- and post-treatment, and at 3-month and 12-month follow-up. The intervention consisted of self-performed vaginal penetration exercises with penetration objects of graduated diameter, in the presence of a female therapist (a psychologist or gynaecologist) who provided instruction, guidance and encouragement. As well, a home exposure program was provided consisting of graded penetration activities. Repeated measurement of the primary outcome (self-reported intercourse ability) was shown to be achieved by 0% of participants during the non-treatment phase, and achieved by 90% during treatment, which was comprised of a maximum of three 2-hour sessions during one week, and two follow-up sessions over the subsequent five weeks. One-year follow-up showed continued intercourse ability for 80% of participants. A significant decrease in fear and in negative penetration beliefs was demonstrated for 4 out of 10 participants at post-treatment, for 6/10 at three-month follow-up, and for 4/10 at one-year follow-up. There was no significant change in various aspects of sexual functioning, such as sexual desire, arousal, lubrication or orgasm, at post-treatment nor at follow-up. Further, it was demonstrated that although penetration became possible, dyspareunia constituted an important limiting factor to intercourse frequency[25], revealing the need to address sexual pain in the management of women with vaginismus, once penetration ability has been achieved. This well-designed pilot

study has generated much interest in the use of exposure therapy to address the component of fear in the treatment of women with vaginismus[3].

In a descriptive and comparative case series published in 2007, Ben Zion and colleagues compared the effectiveness of traditional couple therapy with therapy utilizing a surrogate partner[35]. As women without a cooperative partner are unable to complete the therapeutic process with penile penetration, trained male surrogates are used in some circumstances to participate in surrogate partner therapy, assisting with progressive sensate focus exercises, the use of dilators and eventually digital and penile penetration. Data for this study was obtained retrospectively, comparing results from the treatment of 16 patients in surrogate partner therapy and 16 in traditional couple therapy. One hundred percent of the surrogate group and 75% of the couple therapy group succeeded in having pain-free intercourse. The duration of therapy averaged 4.9 months for the surrogate group and 6.8 months for the couple therapy group. As the allocation to treatment group was not random, and indeed, participants in the surrogate therapy group differed significantly from those in the couple therapy group in that they did not have a cooperative partner, it is difficult to compare the results from these two intervention approaches. Although surrogate therapy appears an interesting alternative for women without a cooperative partner, studies with larger sample sizes and of more rigorous design must be done before any firm conclusions can be made about the effectiveness of this treatment approach. Also the implications of this type of therapy must be explored from an ethical, cultural, and social perspective.

4. PHYSIOTHERAPY

Physiotherapy for women with vaginismus aims at decreasing fear of vaginal penetration, improving body awareness (including genital observation and genital touch), improving the ability to relax the muscles of the pelvic floor, increasing comfort at the vaginal entrance and preparing the patient physically for intercourse[36,37]. Typical modalities of treatment include patient education, manual treatment techniques, pelvic floor exercises, relaxation techniques, biofeedback and/or electrical stimulation, and the insertion of graduated phallic objects[38]. As physiotherapy techniques involve in-vivo genital examination and treatment, it more closely addresses the component of anxiety in relation to vaginal penetration than the traditional sex/CBT approach described above[39]. While there are currently no studies available to attest to the effectiveness of physiotherapy in the treatment of women with vaginismus, its effectiveness in the treatment of vulvar pain has been investigated[40], whereby the approach is similar, with somewhat less emphasis on addressing anxiety.

For example, in an uncontrolled observational study, Bergeron et al (2002) evaluated the effectiveness of physiotherapy in relieving painful intercourse and improving sexual function in women with vulvar vestibulitis syndrome (VVS)[38]. VVS, which is now referred to as *provoked vulvar vestibulodynia (PVD),* is a form of dyspareunia characterized by burning pain at the vaginal entrance during attempts at penetration. Bergeron et al's study involved telephone interviews with 35 patients, at a mean of 15.8 months post physiotherapy treatment. The mean age of the participants was 35 years, and the mean number of physical therapy sessions was 6.6. Intervention included education on the importance of pelvic floor relaxation for pain control;

manual techniques to modify pain, normalise tone, mobilise the tissues and increase proprioception; biofeedback to enable the patient to visualise her muscle contraction and hence improve proprioception, contractility and voluntary muscle relaxation; electrical stimulation for proprioception and desensitization; insertion techniques with graduated phallic objects to prepare the patient physically and psychologically for intercourse; and an exercise program to improve body awareness and to increase the proprioception and control of the pelvic floor musculature. If the patient had a partner, she was encouraged to involve him in her home exercise program. (While 86% of participants were either married, co-habiting with their partner or intimately dating one partner, 14% did not have a sexual partner). The primary outcome, pain intensity during intercourse, measured subjectively on a scale of 0 – 10, was significantly decreased, and the secondary outcomes, sexual desire and intercourse frequency, were significantly increased. While a significant number of participants had used other methods, such as psychotherapy, vestibulectomy, homeopathic remedies, acupuncture, and other medical treatments to alleviate their pain following the physical therapy intervention, statistical analysis revealed no association between the use of these methods and the outcome. As mentioned, this study did not have a control group and was retrospective in nature.

In an uncontrolled clinical trial, Goldfinger and colleagues (2009) investigated the effectiveness of pelvic floor physiotherapy in the treatment of PVD[41]. Thirteen participants with provoked vulvar vestibulodynia completed eight 60-75 minute sessions of physiotherapy, which included education, exercises, manual treatment techniques, biofeedback, electrical stimulation and the insertion of progressive phallic objects, over the course of 10-19 weeks. Pre- and post-treatment assessment revealed significant reductions in pain intensity ratings for 77% of subjects during

gynecological examination and during intercourse, as well as a significant decrease in pain catastrophizing and pain-related anxiety, all maintained at 3-month follow-up. The absence of a control group and the small sample size make it difficult to draw firm conclusions from this study about the effectiveness of physiotherapy in decreasing coital pain for patients with VVS.

Studies of more rigorous design, with larger population samples and adequate control groups are seriously lacking in the relatively new field of physiotherapy and female sexual health[3,40].

5. PHARMALOGICAL TREATMENTS

Pharmacological treatments have also been used in the management of vaginismus and generally include some form of local anaesthetic to decrease sensation, muscle relaxant (including injections of botulinum toxin[42,43,44] to decrease spasm and hypertonicity, and/or anxiolytic medication to decrease anxiety and fear-induced pain. Numerous case reports have been published to suggest that pharmacological treatments may improve penetration ability for women with vaginismus[45,46,47], as have some uncontrolled and non-randomised studies. No studies involving pharmacological treatments have, however, met the inclusion criteria for the most recent Cochrane review on interventions for vaginismus.

In a non-randomised placebo-controlled study, Shafik and El-Sibai (2000) investigated the effectiveness of botulinum toxin injections on penetration ability in women with vaginismus, based on the premise that paralysis of the bulbospongiosus muscle would prevent closure of the vaginal introitus upon attempted vaginal penetration[42]. Thirteen patients were enrolled in the study after unsuccessful treatment with biofeedback. Eight patients were given botulinum toxin injections

bilaterally to each bulbospongiosus muscle, and five patients were given saline injections to the same sites. All of the patients who were given the botulinum toxin injections improved, improvement defined as becoming able to engage in 'satisfactory intromission' as compared to no improvement in the control group. Due to the small sample size, the un-randomised attribution to treatment group, and the lack of information on the participants' diagnostic criteria and on the precise measure of outcome, it is difficult at present to draw any firm conclusions about the efficacy of botulinum toxin injections.

6. SEX/CBT AND/OR PHYSICAL THERAPY

Two papers were found that studied the use of some component of physical therapy and sex/CBT combined in the treatment of women with vaginismus, one a case series (Seo, 2005) and the other a quasi-randomised trial (Zuckerman, 2005).

Seo et al (2005) examined the effectiveness of functional electrical stimulation (FES) and biofeedback combined with sexual CBT in a case series of twelve patients with total vaginismus[48]. Here, the primary outcome measure was defined as self-reported satisfactory intercourse, with positive outcome for 100% of the participants after a combination of 12 weekly FES-biofeedback and 8 weekly sexual CBT treatments, which was maintained at 8-week follow-up. Low subject numbers did not allow for statistical analysis of secondary outcomes. Moreover, the lack of a control group makes it difficult to draw conclusions from this study.

In 2005, Zukerman et al, published a quasi-randomised trial which compared two types of treatments for vaginismus, Paula Garburg exercises plus dilators vs. CBT plus dilators[49]. Paula Garburg exercises involve contraction and relaxation of 'circular' facial muscles, hand opposition muscles and sphincteric muscles of the

pelvic floor. Sixty patients were alternately allocated to one of the two groups, and stayed in treatment until successful intercourse was achieved. All participants had positive outcome, which was defined as the achievement of full intercourse (self-report) or the introduction of a #6 Young dilator. The mean number of treatment sessions required for positive outcome was 4.9 for the exercise plus dilators group and 7.4 for the CBT plus dilators group. Many elements included in therapy were similar in each group, as both used dilators and systematic desensitization, and both were instructed to contract and relax the pelvic floor musculature during insertion. The study presented several limitations, including lack of secondary outcome measures, lack of a non-treatment control group, and lack of follow-up measurements.

7. MULTI-MODAL, MULTIDISCIPLINARY APPROACH

The following quotations are among the recommendations found in the literature:

'Since the diagnosis of vaginismus is complex and, according to the literature, vaginismus, vestibulodynia and dyspareunia can overlap in clinical practice, a multidisciplinary team, including a gynaecologist, physical therapist and psychologist/sex therapist, should be involved in the assessment and treatment of vaginismus to address its different dimensions.'… *Cochrane review on interventions for vaginismus, Hawton et al, 2012* [6].

'..(for sexual dysfunction), after the initial evaluation, treatment can be initiated or a referral can be made to a marriage counselor or sex therapist, depending on the training and comfort level of the physician… The most effective treatment (for vaginismus) is a combination of cognitive and behavioral psychotherapy known as systematic desensitization. …If treatment is ineffective, the patient may benefit from

referral for pelvic floor physical therapy.' *ACOG Guideline on Sexual Dysfunction in Women, Armstrong, C, 2011*[50].

'Diagnosis of vaginismus should be made only after a clinical examination and full history. The use of vaginal trainers (phallic insertion objects) should be discussed with all patients... Information regarding sexual function and pelvic anatomy should be made available to all patients Ideally, a multidimensional multidisciplinary approach for sexual pain is recommended. ... Involvement of the partner in the treatment should be encouraged but remains the decision of the woman...' *Recommendations for the management of vaginismus: BASHH Special Interest Group for Sexual Dysfunction, Crowley et al, 2006* [51].

'A multidisciplinary diagnostic and adequate treatment approach for vaginismus addressing the fear, genital pain, pelvic floor muscle tension and sexual pleasure is recommended. This set of skills is not easily accomplished by individual practitioners and should probably be addressed by a multidisciplinary team.' ... *Vaginismus: a review of the literature on the classification/diagnosis, etiology and treatment. Lahaie, MA. et al, 2010* [3].

'Vaginismus should be treated with a multimodal approach, given its complex neurobiologic, muscular, and psychosexual etiology. Best outcomes are obtained by integrating several types of therapy'. *Dyspareunia and vaginismus: Review of the literature and treatment. Graziottin A., 2009*[2].

While there does appear to be consensus that the management of women with vaginismus should involve a multi-modal, multidisciplinary approach, no literature in this search has been found that details the modalities of such an approach.

8. CONCLUSIONS

In summary, while the majority of studies published on interventions for vaginismus report very high success rates on the outcome of penetration ability; the study of strongest design shows weaker results: the sole RCT with a large number of participants and a non-treatment control group (van Lankveld, 2006) shows only a modest improvement in penetration ability with sex/CBT. Published studies are varied in terms of the measurement and reporting of other outcomes such as pain, fear and sexual functioning, measures that may arguably be of equal importance to the overall success of the intervention. As it is not always possible to objectively assess the patient with vaginismus, and because the differential diagnosis between vaginismus and dyspareunia is not clear, the inclusion criteria for participants in many studies on vaginismus are not constant. Also, inconsistencies in treatment approaches and outcome measures make comparisons between studies difficult. While various treatment approaches do look promising, the level of evidence on interventions for vaginismus remains moderate, at Level 1b, for sex/CBT, and absent, at Level 5, for physiotherapy, psychotherapy, and pharmacotherapy. When we look at the evidence of effectiveness for combinations of treatments, the overall picture again suggests the need for more research before any firm conclusions can be made.

However, while this area of research is still very much in its infancy in terms of rigorously designed studies on specific interventions, there does appear to be consensus that the management of women with vaginismus should involve a multi-modal, multidisciplinary approach[1,3,6,10,43,50]. Further research is needed to identify the disciplines and modalities that should be involved, to lay out the requirements for

intervention and collaboration amongst disciplines and with the patient, and to outline a framework for the optimum management of women with vaginismus.

CHAPTER 3 - Integration Of Manuscript 1 And Manuscript 2

The literature review in Manuscript One underlines the fact that there is not enough evidence to attest to the effectiveness of any one intervention for the treatment of women with vaginismus, yet also points to a general consensus that, due to the multi-factorial nature of the disorder, the management of women with vaginismus should employ a multi-modal, multi-disciplinary approach. While the terms multidisciplinary and interdisciplinary are often used interchangeably, they actually represent two distinct treatment models along a continuum of increasingly collaborative approaches, and in the management of many health conditions the advantages of interdisciplinary management are believed to outweigh those of multidisciplinary management. There is sparse literature to describe the collaborative approach to vaginismus, and clinicians are left with little on which to base decisions regarding the key disciplines that should be involved, the requirements for collaboration between disciplines and with the patient, and, ultimately, an optimum framework for the management of women with vaginismus. Manuscript Two describes a study that responds to this gap by producing initial recommendations for best-practice interdisciplinary management of women with vaginismus, based on expert consensus. As this thesis has been prepared to document the steps taken within a single program of research, some overlap can be found in the presentation of the two Manuscripts.

CHAPTER 4 - Manuscript 2 - Establishing Recommendations for Best-Practice Interdisciplinary Management of Women with Vaginismus

1. INTRODUCTION

Vaginismus is characterised by the persistent or recurrent difficulty in allowing vaginal penetration, in spite of an expressed desire to do so[6]. It can be classified as total or partial, and primary or secondary. With total primary (lifelong) vaginismus the patient has never been able to have intercourse, while with partial primary vaginismus, intercourse is possible, but has always been difficult or painful. Secondary vaginismus represents the disability in the case of the patient who had previously been able to have pain-free penetration[5]. While the definition of vaginismus has recently been under significant debate (please see Manuscript 1) the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 2000)[10], currently defines vaginismus as a 'recurrent or persistent involuntary spasm of the musculature of the outer third of the vagina that interferes with sexual intercourse'[10]. Vaginismus is often associated with marked distress and interpersonal problems, marital difficulties and issues related to the inability to conceive naturally[6]. The estimated prevalence of vaginismus is from 0.5-1% in the general community and from 5-17% of referrals for female sexual dysfunction[6,8,9].

Treatment interventions for vaginismus can be classified into four major categories: *general psychotherapy, sex/cognitive behavioral therapy (Sex/CBT)*, *physiotherapy, and pharmacological treatments*; and management may involve a combination of

approaches[3]. General psychotherapy may include individual or couple 'talk' therapy, hypnosis, and/or psychodynamic therapy, to resolve psychological or relational problems deemed underlying to the disorder[3]. Sex/CBT includes sexual education, relaxation exercises, home exercise assignment for the insertion of graduated phallic insertion objects, cognitive therapy and/or sensate focus therapy[17,52] to educate and relax the patient and to desensitize her to vaginal penetration. Physiotherapy typically involves education, exercises, manual techniques, biofeedback, electrical stimulation, and/or the 'in-vivo' insertion of graduated phallic insertion objects to decrease fear of vaginal penetration, to increase body awareness, to improve muscle relaxation and comfort at the vaginal entrance and to prepare the patient for intercourse[36,37]. Pharmacological treatments may include local anaesthetics to decrease sensation, hormonotherapy and vaginal lubricants to improve the quality of the vaginal mucosa, muscle relaxants (including injections of botulinum toxin) to decrease spasm and hypertonicity, and/or anxiolytic medication to decrease anxiety and fear-induced pain[3].

While the majority of studies published on interventions for vaginismus report very high success rates in penetration ability[3,51,], the level of evidence on the effectiveness of interventions for vaginismus remains low (please see literature review in Manuscript 1). Various treatment approaches do look promising, and current recommendations for the management of vaginismus encourage the use of a multi-modal, multidisciplinary approach to treatment[3,6,50,51,53,54]. This is based on the premise that comprehensive management may best be accomplished by combining the expertise of various disciplines involved in patient care. While the terms multidisciplinary and interdisciplinary are often used interchangeably, and both adhere to the bio-psychosocial model to address the multi-factorial causes of

suffering, they actually represent two distinct treatment models along a continuum of increasingly collaborative approaches [4,55]. The multidisciplinary team approach utilises the skills and experience of individuals from different disciplines, with each discipline addressing the patient from its own perspective [55]. The interdisciplinary team model is an extension of this approach, and 'is characterized by team members working together for a common goal, making collective therapeutic decisions, and having face-to-face meetings and patient team conferences to facilitate communication and consultation'[4]. The Canadian Association of Occupational Therapists defines interdisciplinary collaboration as, "*the positive interaction of two or more health professionals, who bring their unique skills and knowledge, to assist patients/clients and families with their health decisions."* Interdisciplinarity facilitates multi-modal management through communication, coordination and collaboration of the disciplines, with the patient placed clearly at the centre of care[56]. The advantages of interdisciplinary management are believed to outweigh those of multidisciplinary management, for example in mental health and in the treatment of chronic pain[4], and collaborative practice has proven benefits in the management of many health conditions [4,56,57]. In keeping with this evidence, recommendations for the management of vaginismus should encourage the use of a multi-modal, *inter*disciplinary approach. Almost no literature is available to describe the collaborative approach to vaginismus nor how to operationalize such an approach. Clinicians are thus left with little on which to base decisions regarding the key disciplines that should be involved; the requirements for collaboration between disciplines and with the patient; and, ultimately, an optimum framework for the management of women with vaginismus. Recommendations for best-practice interdisciplinary management of women with vaginismus would provide needed

guidance for health care professionals, researchers and policy-makers involved in this field.

2. OBJECTIVES

The global objective of this study was to establish preliminary international recommendations for best-practice interdisciplinary management of women with vaginismus, where vaginismus was defined as a lifelong inability to have penetrative sexual intercourse. This objective was attained via a two-phase study:

1) *Phase One* - Establishing an initial set of recommendations for the interdisciplinary management of women with vaginismus, by conducting a multidisciplinary focus group meeting of health professionals who are deemed experts in this field

2) *Phase Two* - Validating the recommendations by conducting a Two-Round Delphi electronic survey of expert health professionals who had not been involved in the creation of the initial recommendations

3. OVERVIEW OF THE STUDY DESIGN

A two-fold methodological approach was used. First, a multidisciplinary group of health professionals, recognized by their peers as expert on the topic of vaginismus, was recruited for an international recommendations meeting. Prior to the meeting, each participant was provided with a brief definition of 'interdisciplinary collaboration'; was asked to read two review articles on vaginismus; and was asked to provide a written response to the following research question, *'In your opinion, what would be necessary for best-practice interdisciplinary management for women with total primary (lifelong) vaginismus?*' The experts' written responses were

collated by the research team to provide topics to be explored at the recommendations meeting, where facilitated group discussion provided data for an initial list of recommendations on the interdisciplinary management of women with vaginismus. In the second phase of the study, these recommendations were validated and the topics further explored via a structured questionnaire in the form of a Two-Round international Delphi electronic survey, involving a different set of participants who were also experts on vaginismus. This iterative process permitted the creation of a set of recommendations for best-practise interdisciplinary management of women with vaginismus. It also allowed for the identification of some of the areas requiring further discussion, investigation and research in this field. The Delphi technique can be applied to problems that do not lend themselves to precise analytical techniques but rather could benefit from the subjective judgments of individuals on a collective basis, and is often used with the goal of seeking consensus[58,59,60]. The focus group and Delphi techniques were chosen for this project because they are well-suited as research instruments when there is incomplete evidence-based research related to the subject to be explored[61,62,63]. Please see Diagram 1 for an overview of the study design.

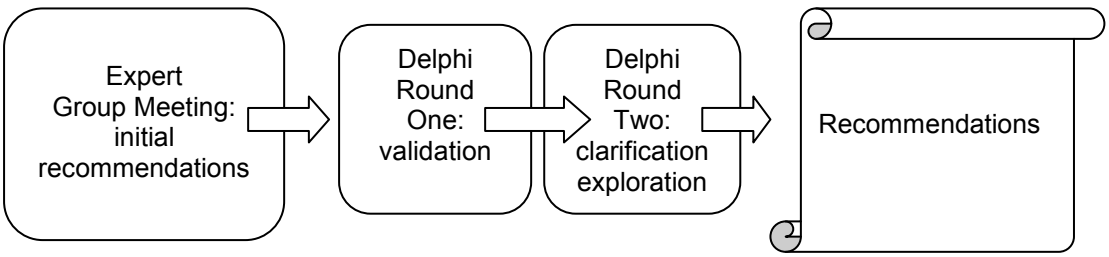

Diagram 1: Overview of study design

4. POPULATION AND SAMPLE SIZE

The goal in both Phase One and Phase Two was to accrue a representative sample of experts from the key disciplines that treat women with vaginismus. As such, the target population for both the expert recommendations meeting and the Delphi survey was expert health professionals involved in the management of this patient population, where an *expert was defined as someone who was recognized by their peers as a knowledgeable source on the topic.* More specifically, to be defined as an expert the individual also had to fulfill at least one of the following[58,60,64]:

- *had documented clinical experience in the treatment of at least 10 cases of vaginismus in the past two years*
- *had published professional papers on the topic area*
- *had initiated research on the topic area, with the expectation of publication in the near future*

4.1 Phase One: For the expert recommendations meeting, the goal was to recruit 12-15 expert health professionals, including a minimum of three gynecologists, three physiotherapists and three psychologists or sex therapists. This number of participants is deemed sufficiently large to encourage group interaction and to allow for a wide range and variability of responses[61,64]. The above choice of health disciplines was based on the literature review in Manuscript 1, as these are the primary disciplines currently involved in the management of women with vaginismus. The expert status and the multi-disciplinary nature of the target population would ensure for a rich exchange of ideas through collective experience and specific expertise. Acceptance to attend the expert meeting was partially dependant upon the participant's intended presence at the International Society for the Study of Women's

Sexual Health (ISSWSH), in Jerusalem in February 2012. This was the chosen arena for the expert group meeting, given the large number of expert health professionals who would be in attendance. In the months prior to the meeting, purposive sampling was used to identify potential participants. Experts identified by the research group through its knowledge of those in the field and through the literature review were contacted, as well as those identified on a preliminary list of registrants to the ISSWSH conference. Snowball sampling was also used, where some of those contacted provided names of others who might qualify as potential additions to the recruitment list. The expert health professionals who were interested in participating but who were not able to attend the in-person meeting were retained as potential participants for Phase Two.

4.2 Phase Two: For the Delphi electronic survey, the goal was to recruit 20-30 expert health professionals, again to include a minimum of three gynecologists, three physiotherapists and three psychologists or sex therapists. Purposive sampling was used in an effort to include a variety of professions from a variety of countries, to reflect the diversity of opinions and attitudes towards the management of vaginismus, and to include experts who had not been contacted in the initial recruitment process. As well, snowball sampling was used in an attempt to identify potential candidates who had not already been considered. The proposed number of the sample was deemed sufficient to provide validation, valuable opinion and insight into the results of the focus group, again partly due to the expert status of the participants and the multidisciplinarity of the sample population[59,60,64]

5. METHODOLOGY

5.1 Phase One: Expert Recommendations Meeting

Given the short time that would be available to elicit expert opinion on a variety of topics and, potentially, consensus on specific statements, it was important to structure the meeting in an organised format. For this reason, the Technique for Research of Information by Animation of a Group of Experts (TRIAGE) was used, combined with focus group methodology. The TRIAGE is a structured method for the collection of data[65], the first step of which is one of preparation. This began with the recruitment of participants, as detailed above, followed by the preparation and distribution of an information package, which included two recent review articles on treatment interventions for vaginismus[3,6], a brief definition of 'interdisciplinary collaboration' in general[51], and the open-ended question: *'In your opinion, what would be necessary for best-practice interdisciplinary management for women with total primary (lifelong) vaginismus?'*

Next was the 'individual production' step of the TRIAGE approach. Participants were to read the information package, reflect on the question, and respond to it with a maximum of five statements, by electronic mail, within three weeks. The investigators collated the responses to the research question to form a composite list, by classifying all items of a similar nature into major themes, or 'indicators', and items that had no similarity with other items as separate indicators. Seven indicators were identified for this list, which would inform the content of the recommendations meeting. To facilitate discussion, the indicators were placed in an order deemed to be amenable for an organised exploration of the topics at the expert group meeting, and were listed as follows: a) an accurate diagnosis; b) an appropriate intervention

program; c) a multidisciplinary team; d) multidisciplinary meetings with the whole team; e) robust international guidelines; f) robust local guidelines; and g) increased awareness about the problem of vaginismus.

A professional group facilitator was hired for the three-hour expert meeting, which was held in English. This was the final step in the TRIAGE: the 'interactive production' step. Upon arrival, participants were asked to complete a brief questionnaire eliciting some of their basic socio-demographic information and their experience in treating women with vaginismus. Each participant was also asked to provide written consent to be audio-taped and to have the information from the focus group used, with acknowledgement but without personal identifiers, in future presentations and publications (Please see Annex E). Participants were then provided with the indicators, or topics for discussion, which had been created from the collation of their responses to the aforementioned question, *'In your opinion, what would be necessary for best-practice interdisciplinary management for women with total primary (lifelong) vaginismus?*'

Facilitated group discussion ensued to gain insight and opinion on the indicators and to achieve, where possible, consensus on particular statements and recommendations. For example, during discussion of the first indicator, *accurate diagnosis*, important components were explored, including the details that should be incorporated in ascertaining the patient's medical and psychosexual history. Participants' comments were recorded in point-form on a flipchart viewable by all throughout the session, and summaries were re-read to the group for confirmation and clarification. Group consensus on certain statements was determined with a show of hands, and it was pre-determined that a vote over 70% would be sufficient to consider a statement important

and that a vote under 20% would be low enough to consider it unimportant[59,64,65]. The group was periodically reminded, as discussion became lively and sometimes went off-topic, that the goal was to create an initial list of recommendations for the interdisciplinary management of women with vaginismus, one that would be further validated in the second phase of the study.

The first half of the expert group meeting was led by a professional facilitator; the second half by the principal researcher. While in the first half a general understanding of the research goals, and expertise on group moderation was valuable for the establishment of ground rules, the presentation of the participants and the initial discussion of the key topics, by the second half it was deemed important that the meeting be moderated by an involved health care professional. This allowed for more in-depth, pertinent and directed questioning, based on a more substantial knowledge of the topic area. Due to the rich conversation and complicated subject matter, it quickly became evident that it would be necessary to proceed directly to items considered key to the goals of the study, if these items were to be sufficiently addressed in the time allotted.

Written notes from the facilitated discussion were transcribed immediately after the meeting and later validated against the tape-recording of the session. One month later, a brief summary of the findings from the meeting was sent to the participants by electronic mail. Each participant was asked whether s/he felt the summary accurately represented the content of the meeting. As well, each was asked a few additional questions for insight on how to present some of the findings in the next phase of the study, for example, whether to change the name of the indicator pertaining to team meetings from *multidisciplinary meetings with the whole team* to *Interdisciplinary*

Collaboration. Conclusions from this process served as the basis for an initial list of recommendations for best-practise interdisciplinary management of women with vaginismus, which was presented to the next group of experts for validation within a two-round Delphi questionnaire. This questionnaire was developed by the research team using rigorous question design methodology, and included questions for further opinion and insight into the topics as well as questions relating specifically to the initial list of recommendations.

5.2 Phase Two: Modified Delphi Technique

The modified Delphi technique used in this study differed from the traditional Delphi, which typically begins with a first round to determine important topics for investigation via an open-ended questionnaire, and then explores these topics in two or three more rounds[58,60,61]. In this study, important topics and information had already been gleaned from two sources: 1) the responses to the research question submitted by the expert group prior to the in-person meeting, and 2) the information resulting from the expert group meeting. It was therefore possible to use this information in lieu of the traditional Round One, and to obtain agreement and opinion on selected topics and statements in only two Delphi rounds. For Delphi Round One, a survey questionnaire was synthesized from the data from the expert group meeting to determine agreement with recommendations made and to gain further insight on several topics. Prior to distribution, the survey questionnaire was evaluated for its clarity in terms of both content and ease of response through a trial distribution, first within the research team and then to clinicians with expertise in vaginismus, including one medical practitioner, one physiotherapist and one psychologist. Adjustments were made (i.e. clarifying statements, reordering the questions to flow more easily)

based on their feedback, and the survey was formatted online and distributed electronically to a group comprised of international expert health professionals who had not been involved in the in-person expert meeting in Phase One of this study.

Before responding to the online survey, each Delphi participant was asked to complete an online consent form, and at the end to provide socio-demographic data and information on experience in treating women with vaginismus. Responses to questions from Round One were analyzed to provide data for Round Two: some questions were eliminated, some reformulated, and some repeated for inclusion in Round Two (please see DATA ANALYSIS and RESULTS below for further details). As such, participants were asked to rate some statements again in Delphi Round Two, and were instructed that they could change their answers in view of the group response in Round One, as revealed to them in this second questionnaire. Each participant was also provided with a reminder of their initial response. This not only allowed for participants' additional reflection: it also served to verify the stability of the responses, that is, the consistency of responses across Rounds One and Two. In addition, new questions were created as a result of the participants' commentary from Round One and the investigators' desire to elicit further feedback on specific topics. Information obtained from this process was used to validate the original recommendations for best-practise interdisciplinary management of women with vaginismus, and provided a bank of salient comments/written statements by participants, useful in clarifying the thinking process and reasoning behind the recommendations.

6. DATA ANALYSIS

Descriptive statistics were used to illustrate the personal and professional characteristics of participants from the expert group meeting in Phase One and from the Delphi survey in Phase Two. Most of the analysis of the results from Phase One was qualitative and content-based. Prior to the expert group meeting, the written responses to the research question were studied and analysed, employing constant comparison to identify and categorise themes as they emerged from the data (65a). This constituted a grounded approach, identifying categories from the ground upwards, without defining them a priori. An effort was made during classification so that these themes would be exhaustive, mutually exclusive and conceptually congruent (65b). The themes were termed 'indicators', and would subsequently form the framework for discussion at the expert group meeting. Hence, it was the participants themselves, through their previously-submitted written responses, who provided the data used to determine the themes, or indicators, for discussion at the expert group meeting.

Qualitative information from the expert group discussions in Phase One was used as connecting data to inform the questionnaire for Phase Two. Written transcripts from the expert group discussion of the list of indicators were studied along with the tape recordings of the session to reveal sub-themes and areas of common opinion. Salient comments were abstracted to illustrate these themes, and relevant statements that depicted them were categorized according to topic areas. Part of the data analysis was actually performed *during* the expert group meeting, as some of the statements made by the group in relation to the various themes were immediately validated with moderated group interactions. For example, five times during the in-person meeting,

a vote was taken to determine agreement with statements made by members of the group. Statements attaining over 70% agreement were considered important enough to be further assessed for consensus in the Delphi survey in Phase Two[59,64], in a questionnaire which would include other questions formulated as a result of the study of the total data set from Phase One, the expert group meeting. The questionnaire would delve into initial recommendations and concerns brought up at the group meeting, and would also explore topics that had not been fully covered. Specific questions reflecting the various topics discussed were formulated, some requiring open-ended responses, and many with ordinal or nominal response choices which would subsequently be summarised. The use of this connecting data from Phase One to develop the questionnaire for Phase Two resulted in a form of mixed-method analysis (65c). Statistical aggregation of group responses from the Delphi survey in Phase Two allowed for a quantitative analysis of the data. Since choice statements from the survey were to be retained for the final list of recommendations, a higher degree of agreement than that used during the in-person meeting was considered to qualify for consensus. Results from questions in the Delphi survey which demonstrated more than 80% agreement amongst respondents were considered to have attained expert consensus, and were retained for itemization[59,64]. Some questions from Delphi Round One were repeated in Round Two to allow participants to reconsider their responses in view of the group responses from Round One, and to allow the investigators to verify the stability of the responses. Some questions were reformulated to obtain a deeper level of understanding. For example, a Round One question: 'The interdisciplinary team should include at minimum a medical practitioner, physical therapist, and mental health professional' was rephrased for Round Two to elicit information pertaining to each of the individual disciplines: 'For

the treatment of women with vaginismus, do you think that the following are essential members of the interdisciplinary team?'. This allowed for a distillation and refinement of the group response[58]. Responses to questions that had been repeated or reformulated were assessed for consensus after Round Two. Qualitative methods were used to analyse unquantifiable results from both Round One and Round Two. Individual responses were compared and contrasted, feedback and insights from the respondents were examined for a deeper understanding of the phenomenon under study, and responses were summarised.

7. RESULTS

7.1 Phase One: Written responses and in-person meeting

Of the 33 professionals contacted in the initial recruitment process, 29 agreed to participate, two declined, one did not respond, and one did not meet the inclusion criteria. Of those who agreed, eighteen would be attending the ISSWSH meeting and hence were asked to participate in the in-person expert group meeting. The other eleven were retained for recruitment for Phase Two, the Delphi validation phase. Of the eighteen, ten returned their written responses to the research question prior to the meeting, and 15 attended the expert meeting. These participants included 7 medical practitioners (five of whom were gynecologists), 3 physiotherapists, and 5 mental health professionals (psychologists and/or sex therapists), from various nations including: England (1), Israel (9), Italy (1), the Netherlands (1), and the USA (3). There were two males and thirteen females. The range of years of experience treating women with vaginismus was from 6-41 years, with thirteen participants having over 10 years of experience. Please see Diagram 2 for the recruitment flowchart.

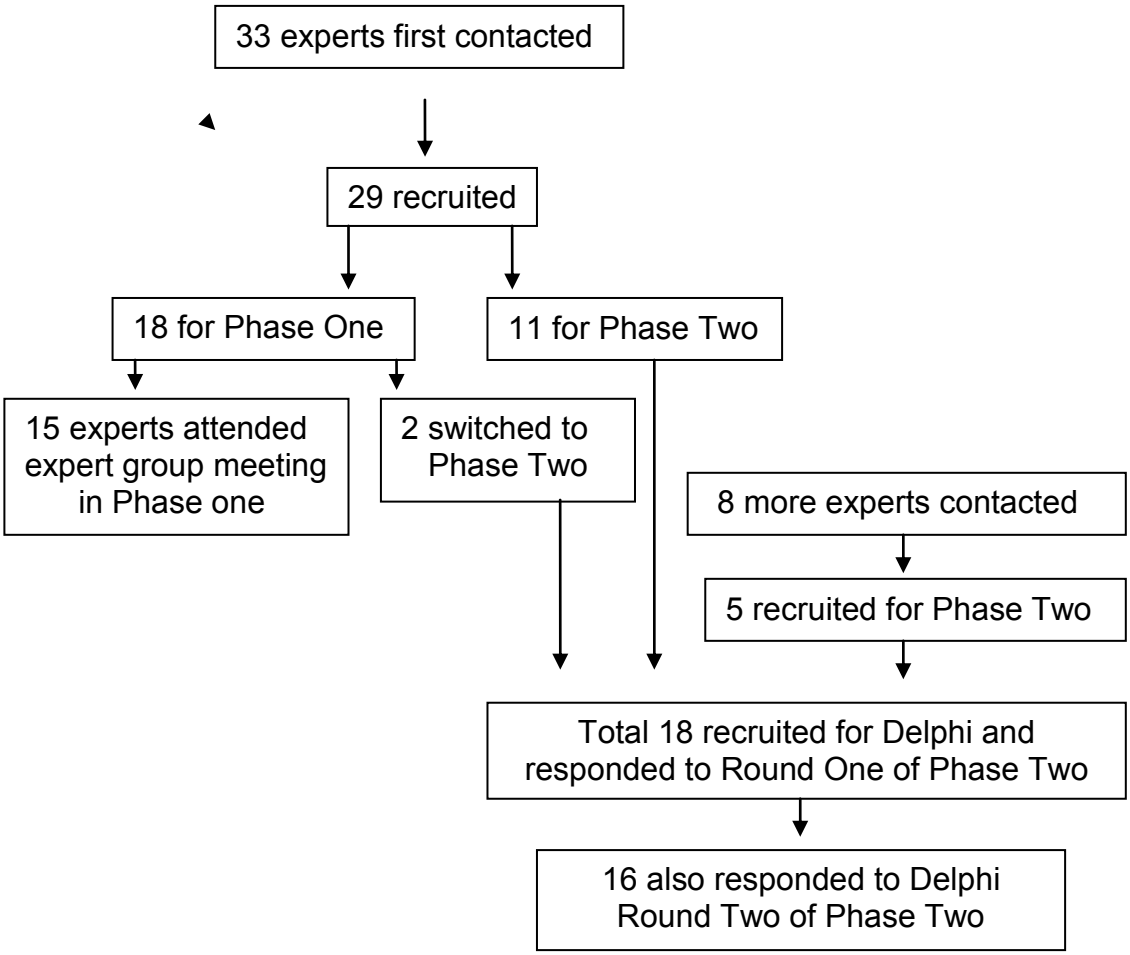

Diagram 2: Recruitment flowchart

Compilation of the data from the written responses to the question **'***In your opinion, what would be necessary for best-practice interdisciplinary management for women with total primary (lifelong) vaginismus?*' had inititally resulted in the formulation of a list of seven 'indicators', or major items for discussion at the in-person meeting. As mentioned, data fell into the following categories: a) an accurate diagnosis; b) an

appropriate intervention program; c) a multidisciplinary team; d) multidisciplinary meetings with the whole team; e) robust international guidelines; f) robust local guidelines; and g) increased awareness about the problem of vaginismus. This list was reduced to six items as the researchers reconsidered that two of the indicators, *Robust international guidelines* and *Robust local guidelines* were not actually mutually exclusive and therefore could be discussed together. The following is a synopsis of the results from the in-person discussion of each indicator, or item for discussion, including some of the sub-themes that emerged.

An accurate diagnosis: (an accurate and comprehensive clinical assessment)

When the expert group was asked to discuss 'an accurate diagnosis' it was agreed that, while this is may be important element in the interdisciplinary management of women with vaginismus, the definition of vaginismus is under debate. A recurrent and unanimous theme emerged: regardless of the actual diagnosis, a comprehensive clinical assessment was required for best-practice management of a woman with suspected vaginismus. This would include eliciting information from the patient about her medical, psychosocial and sexual history, performing a pelvic examination (not necessarily on the first visit) and possibly arranging for further investigation (such as blood testing to assess for hormonal levels). As well, the participants generated a list of what they considered to be essential elements of the medical, psychosocial and sexual history, which would be validated in Phase Two, the Delphi survey. The validated list will be presented with the results from Phase Two.

A multidisciplinary team

Within the written responses to the research question received prior to the in-person meeting, it had been proposed that best-practice management of women with

vaginismus would require the combined efforts of members of a multidisciplinary team. Participants all supported this idea at the expert group meeting, and they discussed at length the make-up of the ideal team, suggesting that three professional women's health care groups should be represented: a medical practitioner, a mental health professional and a physical therapist, and that one of these members should act as case manager-coordinator. The necessity of involving other disciplines in patient assessment and/or management on a consultant basis, according to individual patient profile, was also discussed, and a list was compiled, to be validated in the next phase of the study (Please see Table 1 for the alphabetic list of consultants generated in Phase One).

Table 1: (Expert group meeting)

List of potential consultants for women with vaginismus

a) Acupuncturist
b) Anesthesiologist
c) Dermatologist
d) Family doctor
e) Fertility expert
f) Gasteroenterologist
g) Gynecologist
h) Urologist
i) Neurologist
j) Nurse
k) Osteopath
l) Physiatrist
m) Physical therapist
n) Psychiatrist
o) Psychologist or psychotherapist
p) Religious or Spiritual consultant
q) Sex/Couple Therapist

r) Social Worker

The experts agreed that members from certain disciplines may play either an essential member role or a consultant role. For example, a gynecologist may be a member of the essential team, or may act as a consultant if there is another medical practitioner already on that team. Additionally, the gender of the professional was discussed as being an important consideration for some patients: *'I ask my patients if they care what is the gender (of the health care professional): most of my patients don't want to see men' – Psychologist at expert group meeting.*

Multidisciplinary meetings with the whole team: (interdisciplinary collaboration)

The major goal of holding a team meeting was discussed with the consensus being that primarily it is to facilitate interdisciplinary communication and collaboration in the interest of the patient. For example, one of the participants, a sex therapist, said:

'We (the gynecologist, physiotherapist and sex therapist) don't meet but we inform each other after every session. Every week I get (a) progress note, what she (the physiotherapist) recommends: she gives an assignment, I talk with the women and I (may) see that this assignment is too much for her, emotionally, so I would reduce it a little bit and then inform her (the physiotherapist) back, that she (the patient) may not (be able to) do this, so I would make it easier for her.'

Participants discussed various modes of communication including the traditional written note, telephone contact amongst team members or electronic mail. Mode of contact was also discussed with suggestions that mode may differ depending on the experience the team members have in working together. For example, it was suggested that a face-to-face meeting may be preferable initially, with subsequent communication by telephone. The group also identified the case coordinator's role in facilitating team collaboration. Cost was raised as an important barrier to the ideal of having team meetings, with variations in funding based on public/private health care

systems having a potential impact on interdisciplinary communication and collaboration. As one nurse practitioner said:

'Communication: there's a real world and a perfect world on this one!'

It was mentioned that while collaboration is important for patient management, it also provides an additional benefit in that it promotes team-building. Participants agreed that ethical considerations must be addressed, and that consent must be obtained from the patient in the sharing of patient information:

'The client also has to give (her) input about what kind of evaluation or treatment should be set up. A lot of these patients have problems with trust and borders, and, certainly, if you are going to involve a psychotherapist or a sex therapist, they need to sign confidentiality forms.'- Psychologist

During the expert group meeting, participants also discussed different means of interdisciplinary collaboration:

'We tried 2 models, one was ... physiotherapist, sexual therapist and gynecologist see (the) patient together, which was too embarrassing for many patients. They couldn't have 3 people in the room digging into their lives and vaginas at the same time so then we divided into two rooms, and (the psychologist) was doing the psycho- sexual intake, and gynecologist and physiotherapist were doing the (physical) exam together. Then the patient went out and we sat in the same room and we discussed the patient and we came out with... a program on how to treat her and we invited her back inside the room, and told her what we think her problems are and what we think the next steps are and, if I had a possibility to do it, (if money was not an object), I think this was the best way I ever practised.' - Gynecologist

'(Looking at it) from a decentralised lens , for multidisciplinary team communication, (we can use) either an in-person or virtual team communication portal, of some sort, that could be a written letter, a telephone call , or a one-on-one team meeting, because many people cannot have all those humans under one roof ...but at the very least, each clinician should be aware of the other clinicians' clinical impressions and input, preferably in writing but at the very least a telephone call and then once every one to four weeks, there is a convergence of the team to discuss many patients, in a team meeting, like a problem solving session.' - Nurse/sexologist

Three scenarios for interdisciplinary team collaboration are presented below, created to reflect potential formats discussed at the expert group meeting:

- Two or three of professionals in the room together with the patient for evaluation, and/or part of intervention process. Professionals share information with the patient and with each other at the same time. Communication may continue via meetings, by the internet or written communication.

- Patient seen sequentially by professionals, under one roof, for evaluation and/or part of the intervention process. There may be an interdisciplinary meeting with or without the patient after the consultations, or communication may be accomplished via meetings, telephone, internet or written communication

- Patient evaluated or treated by one professional, and subsequently seen by other professionals for evaluation or intervention during a subsequent visit, under the same roof or at another location. Ongoing interdisciplinary communication is accomplished via telephone, internet or written communication.

Intervention

The topic of interventions for vaginismus was only briefly discussed, with participants mentioning the use of the following: education, psychotherapy, individual therapy, couple therapy, cognitive behavioural therapy, surrogate therapy, systematic desensitization, sex therapy, psychiatry, physiotherapy, manual therapy, muscle relaxation therapy, use of dilators or trainers, mindfulness, medication and surgery. There was consensus that the intervention should be tailored to the individual, and that the patient should be involved in the process of setting goals for her management.

Also, participants agreed that the patient should be given the option of whether or not to involve her partner in the intervention process, and that couple therapy, and sometimes individual therapy for the patient's partner may also be indicated. A recurrent theme was that avoidance must be taken into consideration with this population:

'Sometimes (the) intervention doesn't work because the patient or the couple, they didn't follow through to the next step, and they come back to you worried they didn't reach their goal...(the one) who is responsible for the patient is the patient! *- Psychologist*

'If a part of the problem is avoidance, those people won't run to see consultants. They have terrible difficulty coming in the first place, coming for the second time....' *- Psychologist*

One physiotherapist expressed the importance of addressing the patient's anxiety throughout management, and especially during physiotherapy treatments, as it is in physiotherapy that the patient is exposed to physical contact and vaginal penetration:

'The physiotherapist deals with the patients' anxiety hands-on, (she is) the one who witnesses it and sees it...'

Access to services must be practical and equitable, and this topic was brought up on several occasions during the expert recommendations meeting:

'It tends to be 'healthy for the wealthy'... this is very idealistic, but many people that we see, part of their challenge (are) their absolute issues, financial issues, financial constraints ... I'd like to keep in mind how we can make this type of care open to the whole population, not just for those who can afford it.' - Psychologist

Robust international and local guidelines

Discussion pertaining to this topic revolved around the fact that recommendations from this study may be a first step to the establishment of guidelines for the

interdisciplinary management of women with vaginismus. This immediately led to discussion about the pertinence of these recommendations in the interdisciplinary management of other sexual health conditions. The following are statements made by two medical practitioners, with agreement from the entire group:

'*We only talked about vaginismus, but I think that everything that we discussed in terms of interdisciplinary management goes for other sexual problems as well.'*
- Gynecologist

'*I think that the teams that we have been talking about are entirely appropriate, if you have a cast-iron case of provoked vestibulodynia, I think the teams would be exactly the same.' - M.D.*

Increased awareness about the problem of vaginismus

While this topic was not discussed at length, group members expressed the need for education, of the individual and of society in general, in terms of body awareness and sexuality, and of health care professionals on the nature and existence of vaginismus. Written comments of group members specific to this topic were read to the group at the expert meeting:

'Increase awareness among gynaecologists and therapists regarding (these) issues to allow early referrals and better interventions.' - Psychologist

'Empower young girls, young adult women, and women throughout the adult life to know their bodies and to be able to read their emotional barometer, as well as be cognizant of their physical responses (for example, preparedness for penetration). This would require both health educators and primary health providers to take the initiative to include these issues in their health promotion and disease prevention efforts....Women and their partners need to take an active role in their own health advocacy as well.' - Psychologist

'The "silent suffering" (of both the woman and her partner) due to lack of knowledge/awareness, shame, and blame needs to be the focus of a multipronged approach.... A proactive campaign of including intake questions during (routine assessment) and/or pain assessment and intimacy questions concerning vaginismus symptoms in both community and hospital settings will give the topic the legitimacy and visibility it needs to be able to advance the process of diagnosis and treatment in an open and multidisciplinary point of view.' - Psychologist

7.2 Phase Two: Delphi electronic survey

A total of 22 expert health professionals were invited to participate in the Delphi survey, including 3 who had been absent from the meeting in Phase One, 11 who had been retained from the initial recruitment process, and 8 additional experts identified by snowball sampling (5) and purposive sampling (3). Eighteen agreed, and 4 did not respond. Participants included 5 medical practitioners (3 were gynecologists), 7 physiotherapists, and 6 mental health professionals (psychologists and/or sex therapists), from Canada (5), Israel (2), the Netherlands (5), Spain (1) and the USA (5). Six were male, and twelve were female. Each participant had over ten years of experience treating women with vaginismus.

As mentioned, a survey questionnaire was created for Phase Two; its contents based on the data from the written transcripts and tape-recordings from the expert group meeting in Phase One. The purpose of the questionnaire was to determine agreement with recommendations made at the meeting and to gain further insight on several topics of discussion. This was distributed in Delphi Round One (Please see Annex 1), to which all 18 participants responded. Responses to questions from Round One were analyzed to provide data for the survey questionnaire for Round Two (Please see Annex 2), to which 16 experts responded. A sample summary of multiple choice responses to the surveys can be found in Annexes 1 and 2. Consensus was reached for the majority of questions in Round One. Recommendations attaining 80% consensus, after the expert group meeting in Phase One and the two Delphi Rounds, fell into the areas of interdisciplinary team make-up, goals and functioning; elements required for a comprehensive patient assessment; and details pertaining to

intervention availability, patient involvement and consent. To elucidate, for example, participants indicated 4 key categories that fell into the category of *comprehensive patient assessment*: medical history, psychosocial history, sexual history and pelvic examination. Please see Table 2 for the list of Recommendations for Best-Practice Interdisciplinary Management of Women with Vaginismus.

Table 2: Recommendations for best-practice interdisciplinary management of women with vaginismus

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1) *For best-practice management of women with lifelong vaginismus, a team approach should be employed.*

2) *A medical practitioner, a mental health professional and a physiotherapist are essential members of the management team.*

3) *One member of the interdisciplinary team should be considered the case coordinator, whose most important duties would be to:*

    a. *maintain a global overview of patient progress*
    b. *recognize the need for team interaction*
    c. *organize team communication*

4) *Major goals of interdisciplinary collaboration, specific to patient management should be to:*

    a. *share clinical impressions*
    b. *agree upon intervention goals and proposed intervention plans*
    c. *report on success of intervention*
    d. *collectively address problems related to patient progress*

5) *Interdisciplinary team functioning should include:*

    a. *a mutual understanding of the scope of each member's practice*
    b. *the cultivation of professional relationships*
    c. *professional feedback between members*
    d. *interdisciplinary education*
    e. *guidelines about sharing information with each other and with the patient*

6) *It is important to include the following components in a comprehensive assessment of the patient with vaginismus, yet not necessarily on the first visit:*

Medical history:

a) *patient's motivation for consultation*
b) *current medication and medication history*
c) *accidents or major physical injuries*
d) *comorbidities*
e) *gynecological history*
f) *tampon usage*
g) *activity level (work, leisure, exercise)*
h) *vaginal, vulvar or pelvic pain (intensity, location, duration, incidence)*
i) *pain in other areas of body*
j) *urological problems*
k) *digestive problems*
l) *vulvar dermatological problems*

Psychosocial history:

a) *phobic disorders, general anxiety*
b) *fear of vaginal penetration*
c) *fear of other forms of bodily penetration*
d) *fear of pain during vaginal penetration*
e) *depression*

f) *cultural and/or religious customs and beliefs*
g) *fear of childbirth*
h) *anxiety related to gynaecological examination*
i) *guilt over inability to have intercourse*
j) *physical, sexual and/or emotional abuse (past and present)*
k) *current and past partner relationships (e.g. duration, commitment, support)*
l) *family psychosocial history (e.g. relationships, childbirth experience)*

Sexual history:

a) *sexual orientation*
b) *intimacy experience*
c) *genital experience (penetrative and non-penetrative)*
d) *sexual education (formal, family, informal)*
e) *sexual self-esteem*
f) *knowledge of physical anatomy of vulva and vagina*
g) *personal awareness of own vulvar/vaginal anatomy (i.e. has patient discovered own anatomy)*
h) *arousal disorders*
i) *anorgasmia*
j) *positive feelings related to intercourse attempt (e.g. desire, arousal)*
k) *negative feelings related to intercourse attempt (e.g. fear, anxiety, disgust)*
l) *pain during sexual activity*
m) *masturbation*
n) *partner's sexual experience*

Pelvic exam:

a) *ease of assuming the lithotomy position*
b) *vulvar appearance*
c) *ability to perform a pelvic floor contraction*
d) *post contractile relaxation of the pelvic floor musculature*
e) *ability to bulge or descend the perineum*
f) *protective reactions during attempted palpation*
g) *ability to allow penetration of one digit*
h) *degree of vaginal opening*
i) *pelvic floor muscle tone*
j) *verification of hymen or hymenal remnants*
k) *Q-tip test for vestibulodynia*
l) *Swab test to rule out infection or other pathology*

7) *It is very important:*

- *to have sex/cognitive behavioural therapy available to the patient with vaginismus.*
- *to have physiotherapy available to the patient with vaginismus.*
- *that interventions be tailored to the individual*
- *that the individual be involved in the goal-setting process of her management.*

8) *It is quite important:*

- *that the intervention be based on scientific evidence*
- *that the woman be offered an opportunity to involve her partner in the intervention process*
- *that the woman be counselled about issues surrounding sexual intimacy throughout the intervention process*

9) The patient should provide written consent to the sharing of pertinent personal information between professionals

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Agreement with the statement, '*The interdisciplinary team should include at minimum a medical practitioner, physical therapist, and mental health professional',* differed from Round One to Round Two, reaching 83% agreement in Round One and only 75% agreement in Round Two, and thereby disqualifying its inclusion in the list of recommendations. Posed differently, however, also in Round Two*, 'For the treatment of women with vaginismus, do you think that the following are essential members of the interdisciplinary team?':* 100% said *Yes* to a mental health professional, 94% to a physical therapist, and 88% to a medical practitioner, qualifying the inclusion of each of the three disciplines in the recommendations in a somewhat different format. Participants were also asked about the importance for a woman with vaginismus to have access to members of different disciplines, as listed in Table 1. Survey results showed this potential access to be in the following order of importance: 1) psychologist or psychotherapist, 2) physiotherapist, 3) gynecologist, sex and couple therapist, 4) family doctor, 5) psychiatrist, 6) dermatologist, 7) urologist, and 8) religious or spiritual consultant.

Elements to be included in a comprehensive assessment of the patient with vaginismus were agreed upon by more than 80% of the respondents. The pelvic exam proved to be one of these elements, yet comments from Delphi Round One led the researchers to provide different response options to the question '*Is it important to include a pelvic exam during patient assessment (NOTE: not necessarily on the first visit)?*' In Round One, 15/18 responded ***yes***, 2/18 responded ***no***, and 1/18 responded *don't know*. Response options were changed in Round Two, and 7/16 responded *'always'*, 8/16 responded *'usually'*, 0 responded *'sometimes'*, 1/16 responded *'rarely',* and 0 responded *'never'*. When asked for instances where the pelvic exam would not be indicated, the majority cited instances where the patient demonstrated high levels

of fear and anxiety; some cited presence of spasm, and one cited bleeding and infection. Please refer again to Table 2 for the list of the recommended items to include in the medical, psychosocial and sexual history, as well as in the pelvic exam. This list enumerates items of strong consensus (more than 80% agreement).

When participants in Delphi Round One were asked whether they agreed that effective interdisciplinary collaboration could take place in any or each of three scenarios formulated from the results of the expert group meeting, there was highest agreement (89%) for the following scenario: *Patient seen sequentially by professionals, under one roof, for evaluation and/or part of the intervention process. There may be an interdisciplinary meeting with or without the patient after the consultations, or communication may be accomplished via meetings, telephone, internet or written communication*. 67% of experts agreed that effective interdisciplinary collaboration could take place when: *Patient (is) evaluated or treated by one professional, and subsequently seen by other professionals for evaluation or intervention during a subsequent visit, under the same roof or at another location. Ongoing interdisciplinary communication is accomplished via telephone, internet or written communication.* Finally, 55% of experts had agreed that effective collaboration could take place in the following scenario: *Two or three of professionals in the room together with the patient for evaluation, and/or part of intervention process. Professionals share information with the patient and with each other at the same time. Communication may continue via meetings, by the internet or written communication.*

Round Two participants were asked, '*In 30 words or less, please let us know what you would consider an ideal scenario for effective interdisciplinary collaboration,'* and

while the responses confirmed that the first scenario as described above seemed ideal, some also mentioned that interdisciplinary collaboration may also be effective when all professionals do not work under the same roof.

In Round Two, participants were asked to provide an open-ended response to: *'Please describe the type of information (if any) that you think each professional could/should share with the team to improve patient management'*. Listed were the four professionals to whom access was considered most important from the responses in Round One. A summary of the Round Two responses follows:

Psychologist/psychotherapist: The psychologist/ psychotherapist could provide an assessment of the patient's psychological state, for example, the existence of psychopathology, levels of anxiety, depression, PTSD, and her response to psychometric testing. S/he could also provide information pertaining to the patient's self esteem, body image and body awareness, and whether there is a history of trauma and physical or sexual abuse. S/he could include details about the patient's sexual history, sexual attitudes, sexual function and satisfaction, and about fear and avoidance behaviour related to penetration and sexual contact in general, as well his/her impression of the nature of the patient's response to vaginal insertion (e.g. fear vs. pain). Information about the patient's psychosocial situation, about the dynamics of the relationship the patient has with her partner, and about partner factors that may be affecting the vaginismus positively or negatively could be included. Obstacles, educational or cultural barriers, as well as contributors to the pain and sexual and relationship difficulties could be explained. The psychologist/psychotherapist could also provide his/her recommendations pertaining to the treatment plan, such as the patient's emotional readiness for treatment, potential coping techniques, and skills and

resources the patient may use in preparation for treatment. As well, suggestions for managing situations that might arise in treatment could be shared to enable all members of the team, for example, to use a concerted approach. It was also mentioned that some information should not necessarily be shared with the other professionals.

Sex/couple therapist: Four of the participants responded that the information shared by the sex/couple sex therapist would be the same as that shared by the psychologist/psychotherapist, indicating that the team could include one or the other discipline. Other respondents indicated that the sex/couple therapist could include details pertaining to the patient's libido, arousal, desire and sexual self-image, her history and attitude about sexuality, her inhibitions and emotional limitations, and past trauma and sexual abuse. Details pertaining to the relationship of the couple, the attitude of the couple towards the problem, the partner's sexual function, and the partner's response to the dysfunction could also be included, as well as suggested methods to involve the partner in treatment, if indicated. Goals for optimum sexual function could be discussed, as well as the potential barriers to treatment. The therapist could provide information about the patient's reaction to education and discussion, the nature of her fears, and her compliance with the home program.

Physiotherapist: The discipline-specific contribution of the physiotherapist in interdisciplinary communication was seen to provide information pertaining to the extent of involvement of the pelvic floor musculature in the dysfunction, specifically the degree of muscle spasm and hypertonicity, and the ability of the patient to contract and relax her pelvic floor. As well, the physiotherapist could explain whether the hypertonicity, if present, is associated with penetration situations such as vaginal

palpation and insertion techniques, and thereby assist the psychologist, for example, in orienting his/her approach to therapy. The impact of the dysfunction on or from other systems (e.g. bowel and bladder, musculoskeletal, or neural) could be discussed with the other professionals, and the physiotherapist could share information about the patient's distress and response to treatment, in relation to the degree of muscle pathology. The patient's behavioural and verbal reactions, protective reactions, avoidance and the level of fear and anxiety during treatment and actual exposure to vaginal insertion could be described, and information on pain and sensitivity, and the patient's ability to tolerate manual stretching of the introitus and the insertion of dilators could be shared. The physiotherapist could also discuss the patient's participation in treatment and motivation for homework assignments and make recommendations pertaining to the overall treatment plan.

Gynecologist: Information that could be provided by the gynecologist included pertinent gynecological and obstetrical history, physical and gynecological findings, overall health, and medication or surgical needs. Also, the gynecologist could signal the existence of somatic/organic barriers (e.g. anatomical restrictions, vestibulodynia, skin problems and sensitivities, infection, fistula, fissures, or hormone deficiencies) and whether any of these should be treated prior to initiating other therapies. In addition, the status of the patient's vaginal skin, infections, skin sensitivities to topical (especially lubricant) ingredients, and results of the Q-tip test for vestibulodynia could be described to the other members of the team to help them to orient their objectives and management strategy. The gynecologist could also provide information on the patient's musculature, particularly pertaining to her ability to contract and relax the pelvic floor, whether hypertonicity or spasm were present, and whether these were evident at rest or only associated with penetration situations. S/he could also relate

how much of the gynecological exam the patient was able to complete, the patient's behavioural and verbal reactions to the gynecological examination and suggest potential strategies to facilitate treatment (e.g. Lidocaine, vaginal Valium). Incidentally, one participant mentioned that if the medical practitioner on the team were a gynecologist, it would be important for him/her to have minimal training in infectious diseases, dermatology and mental health.

8. DISCUSSION

In this multi-phase study, we identified key recommendations for best-practice interdisciplinary management of women with vaginismus. The collaborative nature of the in-person meeting, combined with the iterative process of the Delphi survey allowed us to obtain expert consensus on important practical aspects of management, immediately applicable in daily practise. Recommendations pertain to team make-up and coordination, team functioning, elements in a comprehensive patient assessment, intervention availability, and patient involvement, and include the following key constructs that are known to be important for interdisciplinary collaboration[56]: *i*) *Patient/client engagement* (Recommendations #7 and #8); *ii) Best possible care and services:* (Recommendations #1 through #9); and *iii) Trust and respect, and iv) effective communication:* (Recommendations #5, #7 and #8). Indeed, all six of the principles underpinning interdisciplinary collaboration according to the 'Enhancing Interdisciplinary Collaboration in Primary Health Care Initiative'[56] have proven important throughout this study. While the *population health approach (v)* is not provided for in the recommendations, related issues concerning the promotion of sexual health in general, through education, prevention, and the provision of services, were brought up in the written responses to the research question, touched upon in the

expert recommendations meeting, and mentioned in some of the survey responses, as was the undisputed importance of *practical and equitable access (vi) to services.* These are topics that should be explored further and provided for in future recommendations.

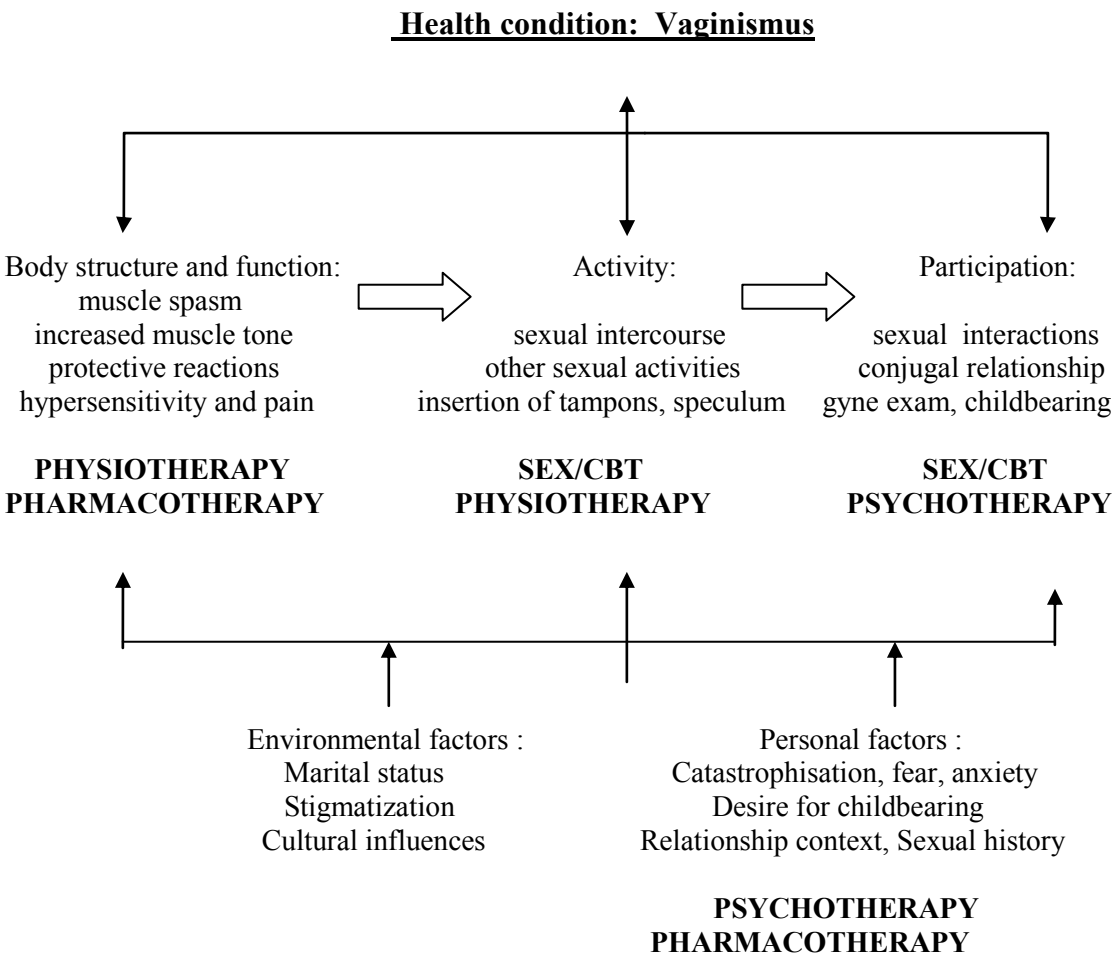

Diagram 3: ICF model in relation to vaginismus

Diagram 3, based on the biopsychosocial model of the International Classification of Function and Disability[66], illustrates the pertinence of various intervention approaches in the management of vaginismus. While the psychologist or sex therapist may use cognitive behavioural therapy (CBT) to address the behavioural and cognitive aspects of fear and of pain, and use other approaches to target different aspects of sexual

functioning, the physical therapist may use various treatment techniques to address the physical aspects of pain, spasm and hypertonicity, and address the behavioural aspects of the fear of vaginal penetration with the in-vivo exposure to phallic objects of insertion. The patient's physician may or may not include the use of pharmacotherapy to control the afore-mentioned elements of fear, pain and spasm, and other aspects relating to sexual function. Results from this study show that vaginismus is a female sexual health condition that most positively requires interdisciplinary collaboration across this biopsychosocial model:

'When we attribute the mental part to the psychologist, and the medical part to the doctor and the muscles to the physical therapist, we are compartmentalising the human being.' -expert group participant, physiotherapist

In spite of an important lack of evidence in the literature, particularly within the medical domain and the domain of the physical therapist, experts considered the medical practitioner, the mental health practitioner, and the physical therapist to be essential members of the interdisciplinary management team for women with vaginismus, and that any one of these professionals should act as case coordinator. Because of the extent of the anxiety and the degree of the muscle dysfunction apparently inherent in this condition, health professionals involved in the management of women with vaginismus need to communicate with one another to align their respective treatment goals and to ensure that their respective interventions complement one another, all of this in keeping with the patient's own goals and particular personal, societal and cultural reality. This collaboration would also aim at helping the patient with vaginismus to deal with issues of avoidance and at allowing her to more easily withstand and participate in the treatment procedures, hopefully leading to more successful outcomes.

It must be considered that significant overlap in approach can and should occur across disciplines, and would largely depend upon the experience and specific training of each of the professionals involved, as well as the particular management situation. As interprofessional education becomes more popular in the health sciences[67], its potential to discourage the 'compartmentalisation' of care often encountered with the multidisciplinary model can be explored in the management of women with vaginismus, for example, as the physiotherapist learns more about anxiety management, mindfulness[68], medication and sex therapy, as the psychologist learns more about pelvic floor exercises, muscle relaxation and insertion techniques, and as the doctor learns more about pelvic floor muscle evaluation, sex therapy and fear cognitions.

According to the Donebedian Model[68a], information pertaining to the structure, process and outcome of health care delivery should be considered in the assessment of quality of care. This research presents recommendations that deal with structure and process in the approach to vaginismus, and may serve as a template to help improve outcomes for women with this condition.

Experts at the in-person recommendations meeting agreed that the proposed recommendations could very easily apply to the interdisciplinary management of other sexual health conditions, and in particular, provoked vulvar vestibulodynia, incidentally believed by some to be the underlying cause and by others to be a consequence of vaginismus[53,54]. This proves to be relevant, as confirmed by the very recent decision of the DSM-5 committee to collapse dyspareunia and vaginismus into the one category of genito-pelvic pain/penetration disorders[69]. A potential consequence of this decision may be an increase in research that reports on outcomes

such as pain, fear and sexual functioning, measures that may arguably be of equal importance to those of penetration ability in the overall success of the management of women with vaginismus.

9. LIMITATIONS

While the International Society for the Study of Women's Sexual Health attracts more sex therapists and psychologists than physiotherapists, it also has more of a medical emphasis than would, for example, a sex therapy conference. This may have introduced a potential bias by limiting the community of experts willing and able to attend the expert group meeting. Also, the fact that the meeting was held in Jerusalem enabled the attendance of more professionals from Israel than from the Americas. The fact that the subsequent survey was undertaken over the Internet served to off-set potential bias, allowing for the input of professionals from disciplines and nations not equally represented during the expert group meeting.

The fact that the principal researcher is a physiotherapist provided potential for selection bias, and bias in the reporting of the data related to this discipline. And, while a professional moderator was hired to moderate the expert recommendations meeting, the second half of the meeting was also moderated by the principal researcher. Every attempt was made to maintain impartiality and to employ reflexivity throughout the research process.

During the expert group meeting there was insufficient time to cover all of the major topics/ indicators in detail; only three of six were deemed to be covered to saturation, in that new concepts or ideas on the topic were no longer forthcoming. However, the three topics covered were considered key to the goals of this study.

Discussion and diversity of opinion regarding the definition and differential diagnosis of vaginismus led to the need for clarification about the patient population addressed in this study. However, as was discussed at the expert meeting, the recommendations might prove useful to the management of women with other sexual health conditions requiring the intervention of more than one health care discipline.

The quality of any set of recommendations or practice guidelines is open to critique and may often be controversial[59,70,71]. The methodology for this study was partially inspired by the 'Appraisal for Guidelines Research and Evaluation' (AGREE II) instrument, particularly in the domains of Scope and Rigor, to ensure that the rationale and methodology for the establishment of these recommendations were sound[70,71]. In accordance with the AGREE II, it would also be desirable for measures to be taken to test the applicability of these recommendations in the clinical setting, to seek feedback from key stakeholders (psychologists, physiotherapists, medical practitioners, sex therapists and women with vaginismus), to identify and manage barriers and facilitators to the application of these recommendations, and, eventually, to ensure for their promotion in clinical practice. Women with vaginismus were not involved in the planning, execution or analysis in this study.

10. ETHICAL CONSIDERATIONS

The proposal for this project was submitted to the Institutional Review Board (IRB), Faculty of Medicine, McGill University. All participants completed a written consent form, were assured of confidentiality and told that they could withdraw from the project at any time without any negative consequences (Please see Annexes E and F). The contact information of the researchers was provided as well as the name of a

contact at the IRB. Individual participant data is confidential and kept in a password secured database. First names only were used and recorded during the focus group session, and Delphi participants remained incognizant of the names of their co-participants during the study process. Those who agreed to be recognised for their contribution are named/acknowledged in this thesis, with their consent

11. CONCLUSIONS

This is the first study to be conducted on interdisciplinary management of women with vaginismus, and it brings important information to members of a field where the treatment approach is varied and is lacking in empirical evidence. In the field of sexual health, the multidisciplinary model illustrates the physical aspect of the patient's condition being managed by the medical practitioners (doctors and physiotherapists) and the psychological aspect managed by the mental health professionals (psychologists and sex therapists). Should there be little communication or collaboration between the multiple disciplines, this approach may prove to be incohesive and lack in integration and effectiveness[72]. An interdisciplinary approach to the management of women with vaginismus will allow for the integration of the efforts of professionals who may otherwise have worked in isolation, and lead to an improvement in patient satisfaction and treatment outcome[73]. Results from this study should encourage those with advanced expertise in the field of sexual health to actively explore and improve their collaboration with other disciplines; and serve as a template for those who are less-experienced as well as for those who are in a position to make policy decisions in health care. Ultimately, this should serve to improve the quality and the delivery of care to the patient with vaginismus.

The recommendations produced from this study can be used in the clinical setting and in future research on this condition, and may serve as an example for interdisciplinary practice in the management of related conditions, in particular, provoked vulvar vestibulodynia, and also in other areas of expertise. In addition to allowing for the promotion of interdisciplinary learning and collaboration, leading to common measures and complimentary philosophies, this study should underline the importance of shared responsibility and respect across disciplines, of the development of a holistic understanding of the client, of creating opportunities for informal education across disciplines and promotion of reflection on practice. These results should help inform health professionals on collaborative practise so that members from each discipline can share knowledge and develop, report, and modify intervention strategies to the benefit of each patient with vaginismus. These recommendations should be made available to medical practitioners, mental health practitioners and physiotherapists involved in the field of women's sexual health, and should be revised and updated as necessary.

12. FUTURE CONSIDERATIONS

The current study employed the perspective of the expert health professional to produce recommendations for the interdisciplinary management of women with vaginismus. It will be important to consider the patient's point of view pertaining to the pertinence of these recommendations, for example, through formal consultation with women with vaginismus via interviews or focus groups and via their external review of this document. In a future research agenda, measures may be taken to evaluate and test the applicability of these recommendations in clinical practice, and provisions for the improvement, implementation and update of these

recommendations should be established. Processes and structures that could potentially facilitate or hinder the implementation of these recommendations should be identified and explored. Future studies of an interdisciplinary nature should be conducted on interventions for vaginismus. And finally, interdisciplinary education amongst the various disciplines involved in the management of women with vaginismus should be encouraged and explored.

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CHAPTER 5 - Preface To Manuscript 3

In spite of the fact that the physiotherapist's contribution to empirical research is seriously lacking in the field of women's sexual health[40], experts from the study presented in Manuscript 2 concurred that the physiotherapist is an essential member of the management team for women with vaginismus. As the principal author of this thesis is a physiotherapist who works clinically with women with vaginismus, she presents Manuscript 3 in an attempt to interpret the results of this study through the lens of the physiotherapist, to help clarify this professional's role in the interdisciplinary management of women with vaginismus, within the context of daily practice.

CHAPTER 6 – Manuscript 3 – The Role of the Physiotherapist in Best-Practice Interdisciplinary Management of Women with Vaginismus: A Clinical Commentary

A perfect illustration of the expanding scope of physiotherapy lies in the field of pelvi-perineal re-education. For example, while physiotherapy for female urinary incontinence was virtually unexplored just twenty years ago, research now underlines the importance of physiotherapy in the first-line management of this condition[36]. In addition, pelvi-perineal re-education plays an increasingly important role in the management of other health conditions related to pelvic floor dysfunction, most notably in pelvic pain and in conditions related to sexual health[40]. One such health condition is vaginismus, characterised by the persistent and recurrent difficulty for a woman to allow vaginal penetration. The physiotherapist's involvement in the management of women with vaginismus requires effective interaction and collaboration with other medical and mental health professionals participating in the care of the same patient.

The multi-factorial nature of sexual dysfunction is gradually becoming recognized, in particular in the area of women's sexual health[2,3,19,]. A comprehensive intervention for vaginismus would ideally address the three elements inherent in its presentation: fear, pain and spasm[3,11,12], as well as issues of a sexual nature, for example a lack of sexual knowledge, avoidance of non-intercourse related sexual functioning, decreased libido, and issues related to couple dynamics. It is here that the advantages of interdisciplinarity may become truly evident. The needs of most patients with vaginismus are beyond the expertise of any single profession, and inter-professional collaborative care is required for genuine patient-centered service[4]. Inter-professional

Patient-Centered Practice involves 'the active participation of different professional groups in decision making and delivery of patient/client care. It is responsive to patient and family goals, opens mechanisms for continuous communication and fosters mutual respect among professionals' (*Health Canada, 2004*)[74] facilitating collaborative practice and improving patient care.

Albeit the fact that members of each intervening discipline must work within their individual scope of practice, in the management of women with vaginismus, too rigorous an application of this dictum may prove to be deterrent to best-practice. Attributing the psychological aspects of treatment to the psychologist only, the medical aspects to the doctor only and the pelvic floor muscle dysfunction to the physical therapist only may lead to a compartmental treatment approach[76]. While psychologists may be best-trained to execute anxiety interventions, it is often in physiotherapy that the patient with vaginismus is most closely confronted with her fear. The physiotherapist is able to witness the full extent of her patient's anxiety 'in-vivo', and must therefore be adequately equipped for its management[39]. This can be accomplished through the application of psychological techniques such as CBT and mindfulness (please see Rosenbaum, 2013[68]) during the physiotherapy sessions and can be facilitated through interdisciplinary collaboration. Communication with the psychologist will allow the physiotherapist to know, for example, about the coping strategies that are effective for a particular patient, about the basis of the patient's fear, and her level of anxiety and/or depression, whether the patient responds more effectively to physical or psychological explanations of the treatment process, or about the couple's level of readiness to work together. It will also allow the psychologist, to know, for example, about the patient's reaction to physical therapy, the success of her coping strategies, her level of fear or of pain during treatment, the

extent of catastrophization she exhibits, and her ability to control her pelvic floor musculature. Equipped with additional and complementary knowledge, professionals may adapt their interventions accordingly, and continuing interdisciplinary communication will allow for truly integrated management.

In spite of the fact that physiotherapists' involvement in the management of vaginismus is relatively recent in comparison to that of medical and mental health professionals, and the fact that their involvement in scientific research on the subject has been minimal, international experts on the subject agree that the physiotherapist is an essential member of the best-practice management team for women with vaginismus. The importance of having a physiotherapist as one of the three essential members of the team was first agreed upon at the expert group meeting, where only three of the fifteen professionals were physiotherapists, and later confirmed through the Delphi survey, with only seven of the eighteen experts practising physiotherapy. Still, the referral of a patient with vaginismus for physiotherapy is currently not standard. For example, the ACOG guidelines[50] for the management of sexual dysfunction suggest the referral of patients with vaginismus for pelvic floor physical therapy only after treatment with systematic desensitization has been deemed ineffective. And, in the most recent Cochrane review[15] on interventions for vaginismus, pelvi-perineal re-education, 'deep muscle relaxation' and 'strategies to reduce the hypertonicity' are listed under psychological therapies, even though these interventions are clearly within the domain of the physiotherapist. There is an urgent need for physiotherapists to disseminate information to health professionals and to the lay public pertaining to the nature and pertinence of physiotherapy in the management of women with vaginismus as well as in the management of women with other forms of sexual pain and dysfunction. Equally, there is a need to strengthen the evidence

base relating to the physiotherapeutic intervention in the care of women with vaginismus. Physiotherapists should become more actively involved in research on the subject of vaginismus, using rigorously designed studies to evaluate outcomes secondary to penetration ability. Changes in fear, pain and muscle spasm could be studied during actual attempts at penetration with graduated insertion devices. Correlations between the successful penetration of an insertion device during physiotherapy treatment and successful self-reported sexual penetration could be determined. Collaborative pluri-disciplinary research which tests the efficacy of interventions for women with vaginismus within the multi-disciplinary model could be compared to those employing the more integrative interdisciplinary model. Additional outcome measures such as avoidance, subjective sexual functioning and intercourse frequency could be incorporated in addition to the more commonly used dichotomous measure of penetration ability.

The recommendations for best-practise interdisciplinary management of women with vaginismus from Manuscript Two map out a framework in which the role of the physiotherapist is clear. As vaginismus and dyspareunia are soon to be classified together under 'genito-pelvic pain/penetration disorders'[69], these recommendations should easily lend themselves to the management of other female sexual health conditions that require the intervention of professionals from more than one health-care discipline.

CHAPTER 7 – Thesis Summary

Vaginismus is a female sexual health condition characterized by a persistent difficulty in allowing vaginal penetration, in spite of an expressed desire to do so. It is often associated with marked distress and interpersonal problems, marital difficulties and issues related to the inability to conceive naturally. Because vaginismus involves significant *physical* and *psychological* components, current recommendations for the management of vaginismus encourage the use of a multi-modal, multidisciplinary approach to treatment. This thesis presented a comprehensive literature review on interventions for vaginismus and on current recommendations for the management of women with this condition, which was followed by details and discussion of a two-phase study, via expert consensus, aimed at establishing a list of recommendations for best-practice interdisciplinary management of women with vaginismus.

Results from an expert group meeting using TRIAGE and focus group methodology was combined with those from a two-round structured Delphi questionnaire to attain expert consensus. Qualitative and quantitative analysis led to a list of nine recommendations for best-practice interdisciplinary management of women with vaginismus, to include team make-up and coordination, goals of interdisciplinary collaboration and team functioning, elements in a comprehensive patient assessment, intervention availability, and patient involvement. This list can be found in Table 2 of Manuscript 2. Study results also allowed for the presentation and discussion of other elements related to interdisciplinary management, such as the specific contributions that each of three disciplines may provide for interdisciplinary collaboration, and different means by which to encourage collaborative practice.

A clinical commentary by the principal author was also presented in this thesis, in an attempt to interpret the results of the main study in this thesis through the lens of the physiotherapist.

This thesis also allowed for the identification of some of the areas requiring further discussion, investigation and research in this field.

CHAPTER 8 – Thesis Conclusions

A review of the literature shows that there is a lack of empirical evidence on the effectiveness of interventions for women with vaginismus, yet points to perceived advantages of a multi-modal, multidisciplinary approach.

The main study presented in this thesis allowed for the establishment of a set of nine recommendations for best-practice interdisciplinary management of women with vaginismus. This is the first study to be conducted on the interdisciplinary management of women with vaginismus, and it brings to light important information to members of a field where the treatment approach is varied and is lacking in empirical evidence. These recommendations provide a framework that can be used in the clinical setting and in future research on this condition. They may also serve to exemplify interdisciplinary practice in the management of related conditions, in particular, dyspareunia, and in other areas of expertise.

While this study has underlined the importance of the role of the physiotherapist in the interdisciplinary management of women with vaginismus, it also calls for increased participation on the part of the physiotherapist, in research on the subject and in the promotion of the value of pelvic floor physiotherapy in the management of women with problems related to female sexual health.

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APPENDICES

APPENDIX A

McGill Faculty of Medicine

V1 DELPHI SURVEY ON BEST-PRACTICE INTERDISCIPLINARY MANAGEMENT OF VAGINISMUS

We are interested in your opinion on the management of women with lifelong vaginismus. We realise that the definition of vaginismus may be subject to interpretation, and for the purpose of this questionnaire we would like you to consider the patient with total primary vaginismus, that is, the patient who has attempted, but has never been able to have penetrative sexual intercourse, despite her expressed desire to do so. For the purpose of this survey, please differentiate this patient from the patient who has painful sexual intercourse.
This survey is a preliminary follow-up to a focus group, which was convened to discuss best-practice interdisciplinary management of women with total primary (lifelong) vaginismus.

A1 - For best-practice management of women with lifelong vaginismus an interdisciplinary team approach should be employed.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
○	○	○	○	○

A2 - The interdisciplinary team should include at minimum a medical practitioner, physical therapist, and mental health professional.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
○	○	○	○	○

A3 - One member of the interdisciplinary team should be considered the case coordinator.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
○	○	○	○	○

A4 - How important is it to have access to the following professionals when treating a woman with lifelong vaginismus?

	Not important	Of little importance	Somewhat important	Quite important	Very important
a) Acupuncturist	○	○	○	○	○
b) Anesthesiologist	○	○	○	○	○
c) Dermatologist	○	○	○	○	○
d) Family doctor	○	○	○	○	○
e) Fertility expert	○	○	○	○	○

	Not important	Of little importance	Somewhat important	Quite important	Very important
f) Gasteroenterologist					
g) Gynaecologist					
h) Urologist					
i) Neurologist					
j) Nurse					
k) Osteopath					
l) Physiatrist					
m) Physical therapist					
n) Psychiatrist					
o) Psychologist or psychotherapist					
p) Religious or Spiritual consultant					
q) Sex/Couple Therapist					
r) Social Worker					
s) Other.					

(Please Specify)

Please provide us with any comments or insights you may have regarding interdisciplinary teams.

B1 - MEDICAL HISTORY – Is it important to include the following medical history components during patient assessment? (NOTE: not necessarily in the first interview)

	YES	NO	DON'T KNOW
a) current medication and medication history			
b) accidents or major physical injuries			
c) comorbidities			
d) gynecological history			
e) vaginal, vulvar or pelvic pain, (intensity, location, duration, incidence)			
f) pain in other areas of body			
g) urological problems			

	YES	NO	DON'T KNOW
h) digestive problems			
i) vulvar dermatological problems			
j) auto-immune disorders			
k) family medical history (autoimmune disorders, vaginismus, related problems)			

B2 - PSYCHOSOCIAL HISTORY– Is it important to include the following psychosocial history components during patient assessment? (NOTE: not necessarily in the first interview)

	YES	NO	DON'T KNOW
a) phobic disorders, general anxiety			
b) fear of vaginal penetration			
c) fear of pain during vaginal penetration			
d) depression			
e) cultural and/or religious customs and beliefs			
f) fear of childbirth			
g) anxiety related to gynaecological examination			
h) guilt over inability to have intercourse			
i) physical, sexual and/or emotional abuse (past and present)			
j) current and past partner relationships (e.g. duration, commitment, support)			
k) family psychosocial history (e.g. relationships, childbirth experience)			

B3 - SEXUAL HISTORY– Is it important to include the following sexual history components during patient assessment? (NOTE: not necessarily in the first interview)

	YES	NO	DON'T KNOW
a) intimacy experience			
b) genital experience (penetrative and non-penetrative)			
c) sexual education (formal, family, informal)			
d) sexual self-esteem			
e) knowledge of physical anatomy of vulva and vagina			

	YES	NO	DON'T KNOW
f) personal awareness of own vulvar/vaginal anatomy (i.e. has patient discovered own anatomy)	○	○	○
g) arousal disorders	○	○	○
h) anorgasmia	○	○	○
i) positive feelings related to intercourse attempt (e.g. desire, arousal)	○	○	○
j) negative feelings related to intercourse attempt (e.g. fear, anxiety, disgust)	○	○	○
k) pain during sexual activity	○	○	○
l) masturbation	○	○	○
m) partner's sexual experience	○	○	○

B4 - Would you consider it important to include anything else in the (medical, psychosocial, sexual) patient history ? Please specify:

B5 - PELVIC EXAM- Is it important to include a pelvic exam during patient assessment? (NOTE: not necessarily on the first visit)

YES	NO	DON'T KNOW
○	○	○

B6 - If yes to B5, do you think it is important to include the following components in the pelvic exam?

	YES	NO	DON'T KNOW
a) Ease of assuming the lithotomy position	○	○	○
b) Vulvar appearance	○	○	○
c) Ability to perform a pelvic floor contraction	○	○	○
d) Post contractile relaxation of the pelvic floor musculature	○	○	○
e) Protective reactions during attempted palpation	○	○	○
f) Ability to allow penetration of one digit	○	○	○
g) Degree of vaginal opening	○	○	○
h) Pelvic floor muscle strength	○	○	○
i) Pelvic floor muscle tone	○	○	○
j) Speculum examination of vagina and cervix	○	○	○

	YES	NO	DON'T KNOW
k) Verification of hymen or hymenal remnants			
l) Swab test to rule out infection or other pathology			
m) Blood tests to rule out hormonal imbalance or other pathology			

Would you consider it important to include anything else in the pelvic exam? Please specify:

SECTION C Please answer the following questions that deal with interventions.

C1 - In your opinion, how important is it to have the following intervention(s) available for a woman with vaginismus?

	Not important	Of little importance	Somewhat important	Quite important	Very important
a) Pharmacological treatments					
b) General psychotherapy					
c) Sex/Cognitive behavioural therapy					
d) Pelvic floor physiotherapy					

Other interventions. Please specify:

C2 - For a woman with vaginismus, how important do you think it is that:

	Not important	Of little importance	Somewhat important	Quite important	Very important
a) the intervention be based on scientific evidence?					
b) the intervention be tailored to the individual?					
c) the woman be involved in the goal-setting process?					
d) the woman be offered an opportunity to involve her partner in the intervention process?					
e) the woman be counselled about issues surrounding sexual intimacy throughout the intervention process?					
f) the woman provide written consent to the sharing of pertinent personal information between professionals?					

Please provide us with any comments or insights you may regarding interventions.

SECTION D This section deals with interdisciplinary collaboration in the management of lifelong vaginismus. Please indicate the extent to which you agree or disagree with the following statements.

D1 - Major goals of interdisciplinary collaboration, specific to patient management should be to:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
a) share clinical impressions					
b) agree upon intervention goals and proposed intervention plans					

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
c) report on success of intervention					
d) collectively address problems related to patient progress					

D2 - The patient should provide consent to the sharing of pertinent personal information between professionals

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

D2 - B - Patient consent should be in written format.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree

D3 - Interdisciplinary team functioning should include:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
a) a mutual understanding of the scope of each member's practice					
b) the cultivation of professional relationships					
c) professional feedback between members					
d) interdisciplinary education					
e) guidelines about sharing information with each other and with the patient					

D4 - Interdisciplinary collaboration may occur in different ways. Do you agree that effective interdisciplinary collaboration may take place in each of the following scenarios?

	Strongly disagree	Disagree	Neutral	Agree	Strong agree
a) Two or three of professionals in the room together with the patient for evaluation, and/or part of intervention process. Professionals share information with the patient and with each other at the same time. Communication may continue via meetings, by the internet or written communication.					
b) Patient seen sequentially by professionals, under one roof, for evaluation and/or part of the intervention process. There may be an interdisciplinary meeting with or without the patient after the consultations, or communication may be accomplished via meetings, telephone, internet or written communication.					
c) Patient evaluated or treated by one professional, and subsequently seen by other professionals for evaluation or intervention during a subsequent visit, under the same roof or at another location. Ongoing interdisciplinary communication is accomplished via telephone, internet or written communication.					

D5 - In your opinion, should the patient with lifelong vaginismus be assigned a case coordinator, how important would the following duties of that coordinator be?

	Not important	Of little importance	Somewhat important	Quite important	Very important
a) To organize and co-ordinate patient care	○	○	○	○	○
b) To motivate the patient in her intervention process	○	○	○	○	○
c) To recognize need for team interaction	○	○	○	○	○
d) To organize team communication	○	○	○	○	○
e) To help the patient to communicate with other members of the team	○	○	○	○	○
f) To maintain a global overview of patient progress	○	○	○	○	○

D6 - Please provide us with any comments or insights you may have regarding interdisciplinary collaboration.

If you wish, please provide us with any additional comments, insights and feedback on this subject and/or on this survey:

APPENDIX B

McGill Faculty of Medicine

Round Two DELPHI SURVEY ON BEST-PRACTICE INTERDISCIPLINARY MANAGEMENT OF VAGINISMUS

Welcome to the second and final round of this Delphi survey. These first three questions are identical to questions from Round One, and you may answer these questions by re-entering your original response or by modifying your response if you wish to do so. For a reminder of your original responses, please refer to the email you received with this link.

A1 - Please state your level of agreement with the following statement: The interdisciplinary team should include at minimum a medical practitioner, physical therapist, and mental health professional. (In Round One of this survey, 72% of you 'strongly agreed', 11% 'agreed', 6% were 'neutral', and 11% 'disagreed'.)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
○	○	○	○	○

A2 - Please state your level of agreement with the following statement: One member of the interdisciplinary team should be considered the case coordinator. (In Round One, 72% of you 'strongly agreed', 17% 'agreed', and 11% were 'neutral'.)

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
○	○	○	○	○

A3 - For a woman with vaginismus, how important do you think it is that the intervention be based on scientific evidence? (In Round One, 33% of you responded 'very important', 33% responded 'quite important', 28% responded 'important', and 6% 'of little importance'.)

Not important	Of little importance	Somewhat important	Quite important	Very important
○	○	○	○	○

The rest of the questions are new, designed to gain further insight on the interdisciplinary management of women with (lifelong) vaginismus.

B1 - For the treatment of women with vaginismus, do you think that the following are essential members of the interdisciplinary team?

	YES	NO	DON'T KNOW
a) a medical practitioner	○	○	○
b) a physical therapist	○	○	○
c) a mental health professional	○	○	○

Your responses from Round One imply that it is most important for the patient with vaginismus to have access to the following professionals: psychologist/psychotherapist, physical therapist, gynaecologist and sex/couple therapist. There may be overlap in the roles of the respective disciplines, and some professionals may cover more than one discipline. In 30 words or less, please describe the type of information (if any) that you think each professional could/should share with the team to improve patient management.

B2 - Psychologist/psychotherapist
B3 - Physical therapist
B4 – Gynaecologist
B5 - Sex/couple therapist

B6 - How important do you think it is for the patient to have a case coordinator?

Not important	Of little importance	Somewhat important	Quite important	Very important
○	○	○	○	○

B7 - When taking the patient history, is it important to include the following components? (These items were suggested in comments from Round One and are in addition to those presented in that survey.)

	YES	NO	DON'T KNOW
a) Patient's motivation for consultation	○	○	○
b) Sexual orientation	○	○	○
c) Activity level (work, leisure, exercise)	○	○	○
d) Tampon usage	○	○	○
e) Fear of other forms of bodily penetration	○	○	○

B8 - In Round One, 83% responded YES, it is important to include a pelvic exam during patient assessment. In light of some of your comments, we are providing different response options to this question: Is it important to include a pelvic exam during patient assessment (not necessarily on the first visit)?

Never	Rarely	Sometimes	Usually	Always
○	○	○	○	○

In which instance would the pelvic exam be indicated?

In which instance would the pelvic exam not be indicated?

Do you think it is important to include the following components in the pelvic exam? (These are in addition to the components from the same question in the first round, which were only presented to those respondents who had considered the pelvic exam necessary.)

	YES	NO	DON'T KNOW
a) Q-tip test for vestibulodynia	○	○	○
b) Ability to bulge or descend the perineum	○	○	○
c) Pelvic floor EMG	○	○	○

Please review the following possible reasons why a clinician might choose to use a specific intervention. In deciding on a specific intervention for your patient, please rank the following reasons with (1) indicating your most common reason for choosing an intervention to (5) indicating your least common reason.

	1 (most common reason)	2	3	4	5 (least common reason)
a) Expert opinion/consensus that the intervention is effective	○	○	○	○	○
b) Previous clinical experience and success using the intervention	○	●	○	○	○
c) It is a conventional intervention that is typically used by colleagues	○	○	○	○	○
d) Decision is logical given the patient's presenting history and medical/psycho-social issues	○	○	○	○	○
e) Scientific evidence indicates that the intervention is effective	○	○	○	○	○
Other (please specify)					

B10 - In the first round of this survey, you were presented with three potential scenarios for interdisciplinary collaboration. There was highest agreement (89%) that effective interdisciplinary collaboration may take place 'when the patient is seen sequentially by professionals, under one roof, for evaluation and/or part of the intervention process; and where there may be an interdisciplinary meeting with or without the patient after the consultations, or communication may be accomplished via meetings, telephone, internet or written communication'.

In 30 words or less, please let us know what you would consider an ideal scenario for effective interdisciplinary collaboration.

APPENDIX C

Perceived level of importance pertaining to management	% Very Important	% Quite important or very important
In your opinion, should the patient with lifelong vaginismus be assigned a case coordinator, how important would the following duties of that coordinator be?		
To organize and co-ordinate patient care	44	66
To motivate the patient in her intervention process	33	66
To recognize need for team interaction	44	83
To organize team communication	39	83
To help the patient to communicate with other members of the team	44	77
To maintain a global overview of patient progress	44	88
In your opinion, how important is it to have the following intervention(s) available for a woman with vaginismus?		
Pharmacological treatments	11	27
General psychotherapy	39	45
Sex/Cognitive behavioural therapy	94	94
Pelvic floor physiotherapy	83	89
For a woman with vaginismus, how important do you think it is that:		
the intervention be based on scientific evidence?	33 (Round 1) 31 (Round 2)	66 (Round 1) 80 (Round 2)
the intervention be tailored to the individual?	83	94
the woman be involved in the goal-setting process?	89	100
the woman be offered an opportunity to involve her partner in the intervention process?	72	100
the woman be counselled about issues surrounding sexual intimacy throughout the intervention process?	72	100
the woman provide written consent to the sharing of pertinent personal information between professionals?	56	89

APPENDIX D

Statements requesting validation	% Strongly agree	% Agree or strongly agree
For best-practice management of women with lifelong vaginismus an interdisciplinary team approach should be employed.	83	94
The interdisciplinary team should include at minimum a medical practitioner, physical therapist, and mental health professional.	72 (Round 1) 44 (Round 2)	83 (Round 1) 75 (Round 2)
Major goals of interdisciplinary collaboration, specific to patient management should be to:		
-share clinical impressions	61	100
-agree upon intervention goals and proposed intervention plans	72	94
-report on success of intervention	39	96
-collectively address problems related to patient progress	67	95
Interdisciplinary team functioning should include:		
-a mutual understanding of the scope of each member's practice	61	100
-the cultivation of professional relationships	44	83
- professional feedback between members	61	100
- interdisciplinary education	33	94
-guidelines about sharing information with each other and with the patient	44	88
One member of the interdisciplinary team should be considered the case coordinator.	72 (Round 1) 69 (Round 2)	89 (Round 1) 82 (Round 2)
The patient should provide consent to the sharing of pertinent personal information between professionals	56	84
Patient consent should be in written format.	47	87

APPENDIX E

McGill Faculty of Medicine

Consent to Participate in an International Recommendations Meeting

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Study Title: Mapping Out an Interdisciplinary Framework for the Management of Vaginismus
Principal Investigators: Claudia Brown, B.Sc. P.T., Irv Binik, PhD and Nicol Korner-Bitensky, PhD
Department: School of Physical and Occupational Therapy, Faculty of Medicine

Study Site: Jerusalem, Israel

Study Contact telephone number: 001 (514) 398-5457
Study Contact email address: claudia.brown@mail.mcgill.ca

You are being asked to take part in an International Recommendations Meeting and your participation is voluntary. You may refuse to join, or you may withdraw your consent to be in the study for any reason and at any time.

What is the purpose of this meeting?

The goal is to explore the interdisciplinary approach to the management of vaginismus and to create specific recommendations to advance interdisciplinary management. Recommendations will be further validated in a second step to this phase of the total research project.

How many people will take part in this meeting?

If you decide to participate in this Expert Recommendations Meeting, you will be one of approximately 12-18 expert health professionals who have agreed to attend. The meeting will be conducted towards the end of the meeting of the International Society for the Study of Women's Sexual Health (ISSWSH), on February 21st, 2012.

How long will my part in this meeting last?

The meeting will last approximately 2.5 to 3 hours, and will begin at 6 PM. A dinner will be served.

What will happen if I take part in the meeting?

You will be expected to read a package of materials sent to you which will include the latest Cochrane report on vaginismus, a recent review article and the sole RCT

published on interventions. You are also being asked to provide a written response to a question concerning interdisciplinary management of patients with vaginismus. Your responses will be used to assist in building the recommendations during the Meeting.
You may choose to answer or not answer any of the questions posed during the Meeting, at any point. The meeting will be audio-taped, and the tapes will be used only for scientific purposes and shall remain confidential; this means that identifying information will never be abstracted from the tapes and any publication or presentation resulting from this study will not include personal identifiers.

What are the possible benefits from being in this meeting?
While you may or may not benefit personally from participating in this group, the information obtained from this meeting will be used scientifically in the hope of helping patients, clinicians and policy-makers make informaed decisions regarding the interdisciplinary management of vaginismus.

What are the possible risks or discomforts involved in being in this meeting?
We do not anticipate any risks or discomfort to you from participating in this meeting. We will emphasize to all participants that everyone is considered equal in this meeting and that all discussions and interactions must remain confidential and be conducted with respect.

Will I be able to withdraw from the meeting?
You may withdraw from the meeting for any reason, at any time.

Will it cost me anything to be in this study?
There will be no costs charged for your participation.

Will I receive any compensation for being in this study?
There is no monetary compensation for participation in this study. A complimentary dinner will be served.

What if I have questions about this study?
You have the right to ask, and have answered any questions you may have about this research. If you would like additional information or have any questions or concerns regarding this expert group meeting, please contact Dr. Nicol Korner-Bitensky: School of Physical and Occupational Therapy, McGill University, telephone 001 (514) 398-5457, or nicol.korner-bitensky@mcgill.ca.

What if I have questions about my rights as a research participant?
At McGill University, all research involving volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, Ms. Ilde Lepore of the Faculty of Medicine's Institutional Review Board at (514) 398-8302 or by email to ilde.lepore@mcgill.ca.

Participant's Agreement

I,_____, agree to participate in the International Recommendations Meeting described above. I give permission to the research team including, Dr. Nicol Korner-Bitensky, Claudia Brown, Dr. Irv Binik, Talli Rosenbaum, Marie-Andrée Lahaie, and Dr. Samir Khalifé to use the information that I provide in the group discussion to explore the interdisciplinary approach to the management of vaginismus and to create specific recommendations to advance interdisciplinary management. All questions that I had regarding the meeting have been answered to my satisfaction. I have read and I understand the procedures of the meeting and willingly give my consent to participate.

_____ _____
Signature of Participant Date

_____ _____
Witness Date

I _____ hereby certify that I have explained to

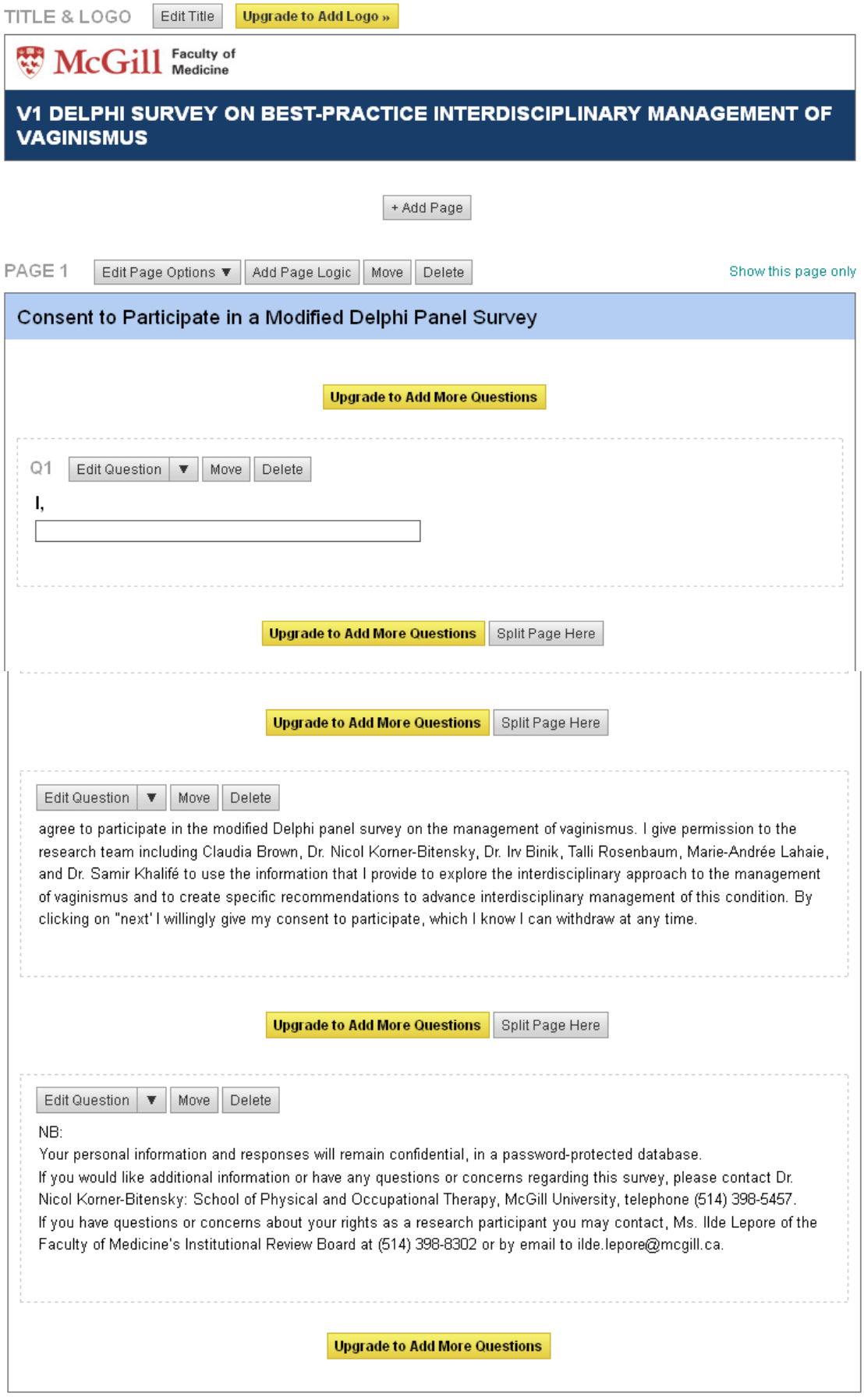
_____ the nature of the research project and the known risks of participating in the International Recommendations Meeting, as well as that the option of withdrawing from the meeting at any time.

Should any publication(s) ensue from this Meeting, I agree to have my name on its list of expert health professionals acknowledged for their collective contribution.

Yes _____ No _____

_____ _____
Signature of Researcher Date

APPENDIX F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McGill Faculty of Medicine
V1 DELPHI SURVEY ON BEST-PRACTICE INTERDISCIPLINARY MANAGEMENT OF VAGINISMUS
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agree to participate in the modified Delphi panel survey on the management of vaginismus. I give permission to the research team including Claudia Brown, Dr. Nicol Korner-Bitensky, Dr. Irv Binik, Talli Rosenbaum, Marie-Andrée Lahaie, and Dr. Samir Khalifé to use the information that I provide to explore the interdisciplinary approach to the management of vaginismus and to create specific recommendations to advance interdisciplinary management of this condition. By clicking on "next' I willingly give my consent to participate, which I know I can withdraw at any time.
Upgrade to Add More Questions
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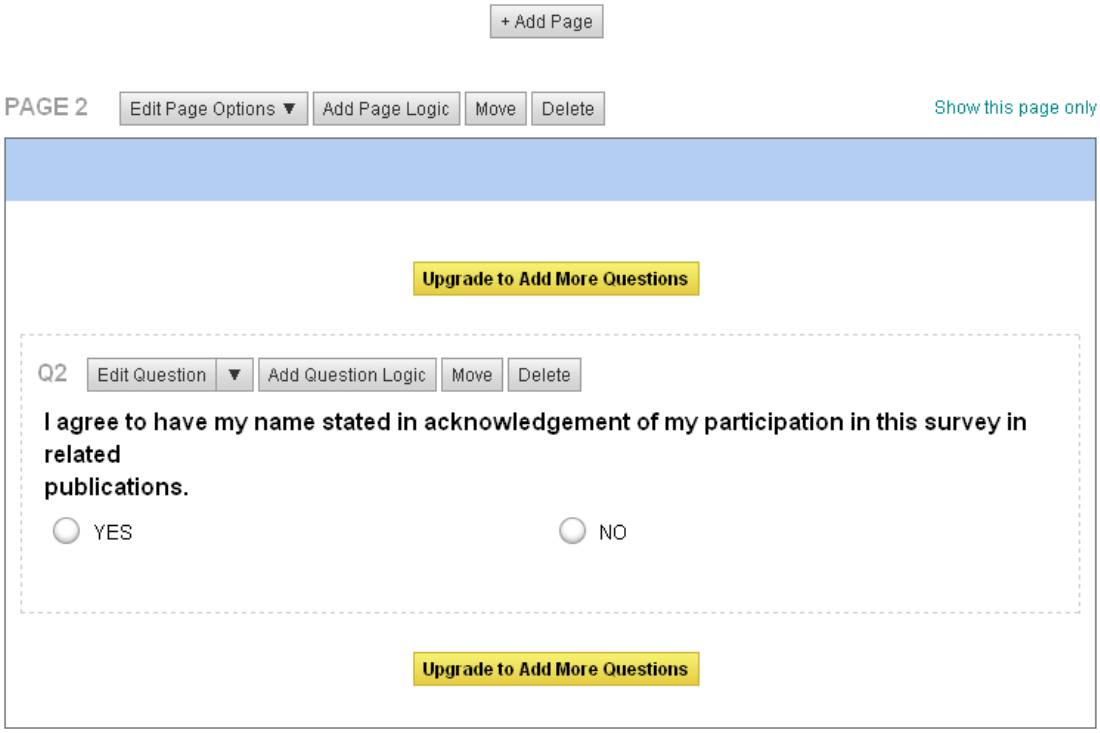
NB:
Your personal information and responses will remain confidential, in a password-protected database.
If you would like additional information or have any questions or concerns regarding this survey, please contact Dr. Nicol Korner-Bitensky: School of Physical and Occupational Therapy, McGill University, telephone (514) 398-5457.
If you have questions or concerns about your rights as a research participant you may contact, Ms. Ilde Lepore of the Faculty of Medicine's Institutional Review Board at (514) 398-8302 or by email to ilde.lepore@mcgill.ca.
Upgrade to Add More Questions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I agree to have my name stated in acknowledgement of my participation in this survey in related
publications.
YES
NO
Upgrade to Add More Questions