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Feasibility, acceptability and effects of multimodal pelvic floor physical therapy for gynecological cancer survivors suffering from painful sexual intercourse: A multicenter prospective interventional study

Marie-Pierre Cyr [a,b], Chantale Dumoulin [c,d], Paul Bessette [b,e], Annick Pina [f,g], Walter Henry Gotlieb [h,i], Korine Lapointe-Milot [b,e], Marie-Hélène Mayrand [g,j], Mélanie Morin [a,b,*]

[a] School of Rehabilitation, Faculty of Medicine and Health Sciences, University of Sherbrooke, 3001 12e Avenue N, Sherbrooke, Quebec J1H 5N4, Canada
[b] Research Center of the Centre Hospitalier Universitaire de Sherbrooke, 3001 12e Avenue N, Sherbrooke, Quebec J1H 5N4, Canada
[c] School of Rehabilitation, Faculty of Medicine, University of Montreal, 7077 Park Avenue, Montreal, Quebec H3N 1X7, Canada
[d] Research Center of the Institut Universitaire de Gériatrie de Montréal, 4545 Queen Mary, Montreal, Quebec H3W 1W6, Canada
[e] Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Faculty of Medicine and Health Sciences, University of Sherbrooke, 3001 12e Avenue N, Sherbrooke, Quebec J1H 5N4, Canada
[f] Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Faculty of Medicine, University of Montreal, PO Box 6128 Centre-ville Station, Montreal, Quebec H3C 3J7, Canada
[g] Research Center of the Centre Hospitalier de l'Université de Montréal, 900 Saint-Denis, Montreal, Quebec H2X 0A9, Canada
[h] Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Faculty of Medicine, McGill University, 1001 Decarie Blvd, Montreal, Quebec H4A 3J1, Canada
[i] Lady Davis Institute, Jewish General Hospital, 3755 Chemin de la Côte-Sainte-Catherine, Montreal, Quebec H3T 1E2, Canada
[j] Departments of Obstetrics and Gynecology and Social and Preventive Medicine, Faculty of Medicine, University of Montreal, PO Box 6128 Centre-ville Station, Montreal, Quebec H3C 3J7, Canada

HIGHLIGHTS

- Dyspareunia is highly prevalent among gynecological cancer survivors and treatments remain limited and poorly studied.
- Multimodal pelvic floor physical therapy is a feasible and acceptable intervention for cancer survivors with dyspareunia.
- This treatment resulted in significant improvements in pain, sexual function, pelvic floor dysfunction symptoms and quality of life.
- These findings support the practice and implementation of multimodal pelvic floor physical therapy in follow-up cancer care in women.

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ABSTRACT

Objectives. Painful sexual intercourse (dyspareunia) is a distressing condition affecting a large proportion of gynecological cancer survivors, yet treatments remain limited and poorly studied. This multicenter prospective interventional study examined the feasibility, acceptability and effects of multimodal pelvic floor physical therapy in gynecological cancer survivors with dyspareunia.

Methods. Thirty-one endometrial and cervical cancer survivors with dyspareunia participated in 12 weekly 60-min physical therapy sessions combining education, manual therapy, pelvic floor muscle exercises using biofeedback and home exercises, which included the use of a dilator. The adherence rate to home exercises (≥80%), the attendance rate at physical therapy sessions (≥80% of participants attending ≥10 sessions) and the dropout rate (˂15%) served as feasibility and acceptability outcomes and benchmarks. Pain intensity, pain quality, sexual function, pelvic floor dysfunction symptoms and quality of life were measured at baseline and post-treatment. Treatment satisfaction and participants' perceived improvement were also assessed.

Results. The adherence rate was 88% (SD 10), 29/31 (94%) women attended ≥10 treatment sessions, and the dropout rate was 3%. Moreover, women experienced significant improvements in all outcomes after the intervention ($p \leq 0.044$). They also reported being highly satisfied with the treatment (9.3/10 (SD 1.2)), and 90% of them were very much or much improved.

* Corresponding author at: University of Sherbrooke, 3001, 12e Avenue N, Sherbrooke (Quebec) J1H 5N4, Canada.
E-mail address: melanie.m.morin@usherbrooke.ca (M. Morin).

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Conclusions. Our findings support the feasibility and acceptability of multimodal pelvic floor physical therapy for gynecological cancer survivors with dyspareunia. The intervention also led to significant improvements in pain, sexual function, pelvic floor dysfunction symptoms and quality of life. A randomized controlled trial is needed to confirm these results.

1. Introduction

The number of female cancer diagnoses is rising worldwide. Fortunately, continually improving cancer awareness, detection and treatment have increased survival rates [1]. These advances contribute to the growing number of women living with the deleterious effects of cancer, which accentuate the need for adequate follow-up care, particularly in gynecological cancer survivors. Among the several negative effects affecting survivors following their treatment, pain and sexual morbidities are important concerns [2] as, unlike other side effects, they persist, worsen or may arise over time [3]. Painful sexual intercourse, also named dyspareunia, afflicts up to 67% of women with a history of gynecological cancer [4]. Consequently, gynecological cancer survivors experience sexual dysfunction, relationship difficulties and psychological distress disrupting their quality of life [5].

Despite the high prevalence of dyspareunia among gynecological cancer survivors, the available evidence-based treatment options remain limited and poorly studied [6]. Several clinical guidelines suggest pelvic floor physical therapy among first-line treatments to address dyspareunia in cancer survivors [6,7]. Nevertheless, as highlighted in a recent systematic review [8], no studies so far have evaluated the effectiveness of this conservative non-invasive and nonpharmacological intervention to reduce painful intercourse after gynecological cancer treatment. The available literature in gynecological cancer survivors is limited to a few small prospective studies and pilot randomized controlled trials non-specific to dyspareunia investigating pelvic floor muscle training to improve urinary incontinence [9], cognitive behavioral therapy to address various sexual issues [10,11], and vaginal dilator use to prevent vaginal stenosis [12,13]. Multimodal pelvic floor physical therapy could be efficacious to treat dyspareunia as the intervention targets its biological and psychosexual pathophysiological mechanisms [14,15]. A recent case-control study confirmed the involvement of pelvic floor muscle alterations in dyspareunia in gynecological cancer survivors [15]. More specifically, patients with dyspareunia present with heightened pelvic floor muscle tone and lower control and endurance [15]. Through education, manual therapy, pelvic floor muscle exercises using biofeedback and home exercises, physical therapy is intended to address the deleterious effects of cancer treatment on the pelvic floor muscles while providing support and counsel to women to reduce their pain. As dyspareunia is an understudied condition and affects a large proportion of gynecological cancer survivors, investigating physical therapy could help to fill the void in knowledge to improve the management and care of women in oncology. Therefore, this study aimed to develop a multimodal pelvic floor physical therapy intervention and to examine its feasibility and acceptability in gynecological cancer survivors with dyspareunia as well as its effects on pain, sexual function, pelvic floor dysfunction symptoms and related impact on quality of life.

2. Materials and methods

2.1. Study design

A multicenter prospective interventional study was conducted in Sherbrooke and Montreal (Canada) in three University Hospitals. In this single-arm study, feasibility and acceptability of multimodal pelvic floor physical therapy were examined in gynecological cancer survivors with dyspareunia. The effects of this intervention were also assessed from baseline to post-treatment. The study was approved by the institutional ethics committee and was registered on ClinicalTrials.gov (NCT03935698) before the start of the study. Participants provided written informed consent.

2.2. Recruitment

Gynecological cancer survivors with dyspareunia were recruited from September 2016 to September 2019 using non-probability/convenience sampling. Patient recruitment letters for this study were sent to women according to a primary pre-screening based on the medical records, following the opt-out recruitment strategy [16]. Women were invited to contact our research team for participation or a third party to indicate their refusal to be contacted within three weeks of the mailing date. After the deadline, the research coordinator called those who had not opted out to give further information about the study. An opt-in recruitment strategy was also used and involved referrals by health care providers, newspaper advertising, posters/brochures in public health care facilities, word of mouth and online advertising. Women willing to participate initiated contact with our team [16]. All potential participants identified through these recruitment strategies underwent a standardized screening telephone interview which served as a secondary pre-screening to verify eligibility.

2.3. Participants

Women were eligible if they had been treated for endometrial or cervical cancer (stages I–IV) and were considered cured given the absence of disease for at least three months. They had to report vulvovaginal pain at a minimal intensity of five on an 11-point Numerical Rating Scale (NRS) ranging from zero (no pain) to 10 (worst pain), in more than 80% of sexual intercourse, for at least three months. Also, those included needed to have a stable sexual partner and be willing to attempt vaginal penetration to evaluate pain. The exclusion criteria were: a) painful intercourse prior to cancer; b) pelvic pain unrelated to intercourse; c) other pelvic conditions including urinary tract or vaginal infection, deep pelvic pain, chronic constipation, pelvic organ descent of ≥stage III based on the Pelvic Organ Prolapse – Quantification system, d) other primary pelvic cancer or breast cancer, e) other vulvar, vaginal or pelvic surgery unrelated to cancer; f) pelvic floor physical therapy in the last year; g) changes in the use or dosage of menopausal hormone therapy in the last six months; h) major medical or psychological condition likely to interfere with study procedures; and i) refusal to abstain from using other treatments for dyspareunia during participation in the study. To further confirm eligibility in a final screening, a gynecologic oncologist of our team performed a standardized gynecological examination to rule out other conditions that may explain dyspareunia (e.g., vaginitis, cystitis or dermatitis). Excluded women were referred to treatment resources if interested.

2.4. Intervention

The multimodal pelvic floor physical therapy intervention consisted of 12 weekly individual 60-min sessions delivered by an experienced and certified physical therapist in women's health. All physical therapists received standardized training for the treatment protocol. To portray clinical practice, the standardized intervention combined multiple

modalities including education, manual therapy, pelvic floor muscle exercises using biofeedback and home exercises, which included the use of a dilator (see treatment protocol details in Appendix 1). The educational component comprised various topics such as the pathophysiology and management of dyspareunia including the use of an organic vaginal lubricant (YES®, The Yes Yes Company Ltd., United Kingdom) and vaginal moisturizer (Gynatrof®, Tyros Biopharma Inc., Canada), which were provided. Moreover, the women were guided towards resuming non-painful sexual activities. At the start of treatment, they were advised to abstain from intercourse as it caused them pain. The physical therapist later encouraged them to resume intercourse, depending on their progress. Sexual partners were also invited to attend one session to discuss the main educational topics and learn how they could assist their partner during the treatment. At each treatment session, 20–25 min were dedicated to manual therapy techniques (i.e., stretching, myofascial release, pressure and massage) that were applied externally and intravaginally to the pelvic floor muscles. In addition, 20 min focused on pelvic floor muscle exercises with biofeedback (Evadri, Hollister®, Biomation, Canada) using a small intravaginal probe to promote mainly pelvic floor muscle relaxation and coordination, as well as strength and endurance. The home exercises incorporated deep breathing and similar pelvic floor muscle exercises to those during the treatment sessions five times per week. Furthermore, participants were instructed to perform insertion techniques using a finger or graded vaginal dilators and vestibule tissue mobilization three times per week.

2.5. Outcomes

An experienced physical therapist not involved in the participant's care conducted the baseline and post-treatment (two weeks after the end of the intervention) assessments. At baseline, a structured interview gathered sociodemographic characteristics and clinical information. Details pertaining to cancer history or treatment were retrieved from the participants' medical records.

2.5.1. Feasibility and acceptability

Examining feasibility provides the basis for determining whether a large-scale randomized controlled trial could be successfully conducted [17]. Acceptability is an area of focus of feasibility [18] that reflects the extent to which the participants consider the intervention to be appropriate and meeting their needs based on their behavioral, emotional and cognitive responses [19]. Feasibility and acceptability outcomes and benchmarks were selected based on the literature [20–22]. They included: 1) the adherence rate to home exercises of ≥80% for both pelvic floor muscle and insertion exercises according to a diary completed by participants, 2) the attendance rate at physical therapy sessions of ≥80% as the proportion of participants attending ≥10 sessions, and 3) the dropout rate of ˂15%. Treatment dropout was defined as a participant that, for any reason, fails to continue in the study until the post-treatment assessment. Data regarding recruitment procedures were recorded including the participant accrual rate. Adverse events were monitored throughout the study.

2.5.2. Treatment effects

In line with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus, women were asked to evaluate the average intensity of pain during sexual intercourse using the 11-point NRS (minimal clinically important difference (MCID) = −2.0) [23] and to complete questionnaires with strong psychometric properties to thoroughly assess pain and its impact on function. The McGill Pain Questionnaire (MPQ) allowed the pain to be qualified with reference to its sensory, affective and evaluative components [24]. A higher score indicates greater pain (MCID = -30%) [25]. The Female Sexual Function Index (FSFI), which evaluates desire, arousal, lubrication, orgasm, satisfaction and pain, was used to assess sexual functioning [26,27]. A higher score means a better sexual function (MCID = +2.1) [28]. Women were also questioned about the average number of sexual activities with vaginal penetration they engaged in per month. Pelvic floor dysfunction symptoms and related impact on quality of life were assessed with the International Consultation on Incontinence Questionnaire (ICIQ) modules. The ICIQ-Urinary Incontinence Short Form (ICIQ-UI SF) was used for urinary symptoms (MCID = −3.4–4.4) [29], the ICIQ-Vaginal Symptoms (ICIQ-VS) for vaginal symptoms [30], and the ICIQ-Bowel (ICIQ-BS) for bowel symptoms [31]. Higher scores correspond to higher symptoms or related impact on quality of life. Women rated their level of satisfaction with the treatment from zero (completely dissatisfied) to 10 (completely satisfied). The Patient Global Impression of Change (PGIC) 7-point scale allowed the participants to self-report their perceived improvement (categories ranging from very much improved to very much worse) [32]. Additional secondary variables pertaining to treatment effects on pelvic floor muscle function and morphometry and psychosexual outcomes will be presented in further publications.

2.6. Sample size

A priori sample size was calculated based on the proportion of completed home exercises, as adherence is key to significant effects in physical therapy. Consequently, a proportion of completed home exercises of 80% [20] with a confidence level of 95% and an interval width of 30% following the formula $n = (z_{1-\infty}/\delta)^2 p(1-p)$ [33] resulted in a sample size of 27 participants. A total of 31 women were recruited to account for potential dropouts (15%).

2.7. Statistical analyses

Statistical analysis was performed using IBM SPSS Statistics, version 25.0 (IBM Corp., Armonk, N.Y., USA). Descriptive statistics were used to summarize participants' sociodemographic characteristics and clinical information. The normality of data distribution was checked using visual inspection and the Shapiro-Wilk test. Feasibility and acceptability outcomes, treatment satisfaction and participants' perceived improvement were evaluated using descriptive statistics. Paired *t*-tests or Wilcoxon signed-rank tests were conducted to examine the effects of treatment. Effect sizes for paired *t*-tests were calculated as $Cohen's\ d = \frac{mean\ of\ the\ differences}{standard\ deviation\ of\ the\ differences}$ (0.2 = small effect, 0.5 = medium effect, 0.8 = large effect. All tests were two-sided, and a *P*-value of <0.05 was considered statistically significant.

3. Results

3.1. Recruitment and study participation

Fig. 1 presents the flow diagram of the current study. After verifying the eligibility criteria from the data available in every medical record, letters were sent to 3422 potentially eligible women (opt-out recruitment strategy). Eighteen additional women contacted our team to get more information (opt-in recruitment strategy). After combined recruitment strategies, 140 (4%) women were screened by telephone for participation. According to this screening, 45 (32%) were eligible and agreed to attend the standardized gynecological examination to confirm eligibility. Of these, 38 women were found to be eligible and 31 consented to participate (participant accrual rate of 69%).

3.2. Participant characteristics

Table 1 shows the baseline characteristics of the 31 women who participated in the study.

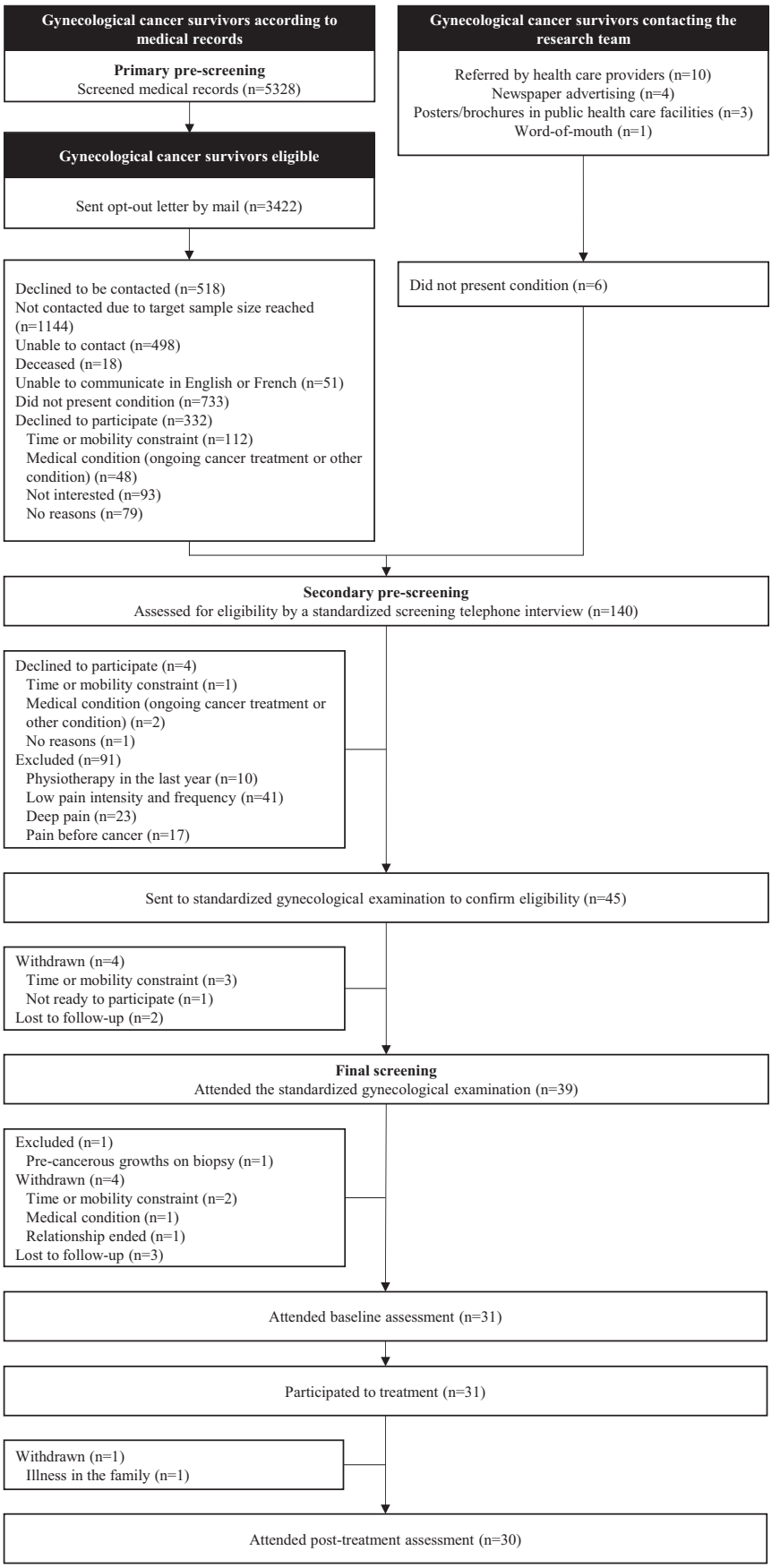

Fig. 1. Flow diagram of the study.

Table 1
Sociodemographic and clinical characteristics of the participants ($n = 31$).

Participant characteristics	Value
Age (years), mean ± SD	55.9 ± 10.8
Body mass index (kg/m^2), mean ± SD	28.5 ± 5.3
Race/ethnicity, n (%)	
Caucasian	30 (97)
Hispanic or Latino	1 (3)
Level of education, n (%)	
High school	6 (19)
Vocational	4 (13)
College	9 (29)
Bachelor	5 (16)
Master	5 (16)
Doctorate	2 (7)
Approximate annual income, n (%)	
$ 0–39.999	12 (39)
$ 40.000–79.999	13 (42)
$ 80.000 and more	6 (19)
Civil status, n (%)	
Single (engaged in a relationship)	6 (19)
Common law	7 (23)
Married	18 (58)
Vaginal delivery, n (%)	
0	13 (42)
1	6 (19)
2	9 (29)
3	3 (10)
Cancer diagnosis, n (%)	
Endometrial	20 (64.5)
Cervical	11 (35.5)
Cancer stage, n (%)	
I	19 (61)
II	6 (19)
III	5 (16)
IV	1 (3)
Time since last treatment for cancer (months), median (Q1; Q3)	38 (9; 70)
Cancer treatments, n (%)	
Surgery	24 (77)
Hysterectomy without salpingo-oophorectomy	1 (4)
Hysterectomy and bilateral salpingo-oophorectomy	18 (75)
Radical hysterectomy and bilateral salpingo-oophorectomy	5 (21)
Brachytherapy	19 (61)
External beam radiation therapy	15 (48)
Chemotherapy	16 (52)
Current use of menopausal hormone therapy, n (%)	4 (13)

SD, standard deviation; n, number of participants; Q1, first quartile; Q3, third quartile.

3.3. Outcomes

3.3.1. Feasibility and acceptability

The mean adherence to home pelvic floor muscle and insertion exercises was respectively 93% (SD 8) and 83% (SD 16) for an average adherence rate of 88% (SD 10). The mean attendance rate at treatment sessions was 93% (SD 21), and 29/31 (94%) women attended ≥10 sessions. Of the 31 women assessed at baseline, one withdrew from the study because of illness in the family, representing a dropout rate of only 3%. Apart from one woman experiencing difficulties with insertion exercises due to mild shoulder pain and one woman reporting irritation related to a vaginal product, no adverse events were reported.

3.3.2. Treatment effects

Significant changes from baseline to post-treatment were found for all outcomes ($p \leq 0.044$) (Tables 2 and 3). A reduction in pain intensity and pain quality was reported. Sexual functioning improved in women engaging in sexual activities after multimodal pelvic floor physical therapy. An increase in frequency of sexual activities with vaginal penetration was also observed (Table 2). Women experienced fewer urinary, vaginal and bowel symptoms with lower related impact on quality of life following treatment (Table 3). Participants reported high treatment satisfaction with an average of 9.3/10 (SD 1.2), and 90% (27/30) of them were very much or much improved.

4. Discussion

This is the first study examining the feasibility, acceptability and effects of multimodal pelvic floor physical therapy to address painful intercourse in gynecological cancer survivors. The high adherence and attendance rates as well as the very low dropout rate obtained surpassed all the pre-established benchmarks, which supports the feasibility and acceptability of this intervention for gynecological cancer survivors with dyspareunia. Moreover, significant reductions in pain intensity, pain quality, pelvic floor dysfunction symptoms and related impact on quality of life were found after treatment. Participants also experienced better sexual functioning following the intervention. Their high satisfaction, combined with their substantial impression of change, underscores the clinical significance of the effects of physical therapy.

Our study demonstrated that multimodal pelvic floor physical therapy is a feasible and acceptable intervention for gynecological cancer survivors. These results demonstrate that women were committed to the intervention despite their severe vulvovaginal pain at baseline and the fact that the treatment required them to attend 12 sessions and perform home exercises regularly. These high rates are similar to or higher than those of interventional studies involving sexual education and pelvic floor muscle training without intravaginal manual therapy in gynecological cancer survivors [9,10,12,34]. The high adherence to the treatment protocol in the current study could be explained by the sustained, close and in-person supervision offered, enhancing women's motivation and compliance. As for participants' screening and enrollment, our data showed that recruiting women affected by dyspareunia after cancer treatment is feasible but challenging. Even though a routine screening of sexual health concerns in survivors is strongly recommended [35], unfortunately this information was not systematically collected in the medical chart nor coded as to enable an automated search. After massive mailings and phone calls to overcome barriers to participation such as shame and stigma associated with pain and sexual dysfunction, enough women agreed to be screened. Most of them (69%) did consent to participate and proceeded with the study, representing a screen failure rate of 31%. This rate is better than those in contemporary trials in gynecologic oncology that are approximately 38% to 62% [36]. A decrease in the perception of harm with physical therapy compared to cancer treatment probably contributed to minimizing screening failure. In this regard, no vulvovaginal adverse events related to the physical therapy modalities were reported in the present study. Nonetheless, our study highlights the need to implement several adapted strategies to ensure participant recruitment in any future large-scale trial.

The changes following the intervention were all statistically significant. Gynecological cancer survivors presented reductions in pain intensity, pain quality, pelvic floor dysfunction symptoms and related impact on quality of life. They also had an improvement in all aspects of sexual function. In addition to the large effect sizes obtained, our results also confirmed clinically important changes in pain and overall sexual functioning as they largely exceeded the known MCID. Given that it is the first interventional study focusing on physical therapy for pain in gynecological cancer survivors, the comparison of our results is limited to the literature investigating other interventions for survivors presenting a wide range of sexual issues. Larger treatment effects in sexual functioning were observed in our study as compared with the previous studies investigating vaginal dilator [10,12] and pelvic floor muscle training [34] in gynecological cancer survivors. The pain reduction in our study could have contributed to these superior effects since their treatment protocol was not designed to address dyspareunia, which is highly prevalent in survivors. Moreover, our intervention comprised more

Table 2
Effects on pain intensity, pain quality and sexual function.

	Baseline (n = 31)	Post-treatment (n = 30)	Changes from baseline	P[a]	d
Pain intensity (NRS)	7.3 ± 1.7	1.7 ± 1.6	−5.6 ± 2.2	<0.001	2.52
Pain quality (MPQ)	21.1 ± 13.2	7.2 ± 8.4	−12.9 ± 14.7	<0.001	0.87
Sexual functioning (FSFI)	18.2 ± 5.6 (*n* = 20)[b]	26.2 ± 5.7 (*n* = 26)[b]	6.9 ± 6.4	<0.001	1.08
Desire	2.6 ± 1.2	3.5 ± 1.3	0.9 ± 1.3	<0.001	0.73
Arousal	3.8 ± 1.3 (*n* = 24)[c]	4.5 ± 1.2 (*n* = 28)[c]	0.5 ± 1.1	0.040	0.46
Lubrication	3.6 ± 1.6 (n = 24)[c]	4.5 ± 1.1 (*n* = 28)[c]	0.7 ± 1.4	0.017	0.54
Orgasm	3.7 ± 1.8 (n = 24)[c]	4.6 ± 1.5 (n = 28)[c]	0.8 ± 1.8	0.044	0.45
Satisfaction	2.9 ± 1.3	4.5 ± 1.2	1.6 ± 1.5	<0.001	1.08
Pain	2.2 ± 0.8 (n = 20)[b]	4.7 ± 1.1 (*n* = 26)[b]	2.3 ± 1.2	<0.001	1.86
Frequency of sexual activities with vaginal penetration (per month)	1.4 ± 1.5	3.0 ± 1.8	1.6 ± 1.9	<0.001	0.85

Data are expressed as mean ±standard deviation (SD).
[a] Paired *t*-tests.
[b] Eleven participants at baseline and four at post-treatment did not engage in sexual activities including vaginal penetration in the last month (time frame of FSFI). Among the four women who did not engage in such activities at post-treatment, two reported not being able to as their partner had erectile problems or a medical condition preventing intercourse, one did not have enough sexual desire, and one did not engage even though she experienced a pain reduction from 8 to 6/10.
[c] Seven participants at baseline and two at post-treatment did not engage in any sexual activities in the last month (time frame of FSFI).

sessions with frequent contact with the therapist that ensured a close follow-up to target all the aspects of sexual function. Our sample also presented a reduction in pelvic floor dysfunction symptoms with lower related impact on quality of life. The pelvic floor muscle exercises included in the treatment could explain these extended effects.

The development of a multimodal treatment to address the complexity of gynecological cancer survivors with pain constitutes a strength of our study. The intervention was designed by consulting experts in gynecologic oncology, sexual therapy and physical therapy to treat the multidimensional aspect of pain in cancer survivors. The combination of multiple modalities prevents us from discussing the isolated contribution of each modality. Nevertheless, this reflects the practice of physical therapy in a clinical setting [37] and is probably the key to the effects obtained given that a single modality would unlikely address the multifaceted pathophysiological mechanisms underlying dyspareunia [37]. Another strength is the eligibility criteria that included a standardized gynecological examination to rule out the potential effects of confounding variables on the outcomes. Despite all these efforts to minimize bias, our study still had some limitations. Although positive results were found in our study, the absence of a control group limits drawing definitive conclusions about treatment efficacy and inference for causal effects. It should, however, be underlined that the women were severely affected at the beginning of the study and the median time since the last cancer treatment was more than 3 years and, hence, it is improbable that dyspareunia would have spontaneously improved without treatment. Moreover, the women were highly adherent to the treatment protocol and did not undertake any other treatment during their participation, which strengthens the possibility that the intervention engendered the observed effects. The non-probability/convenience sampling that is largely used in interventional studies could have introduced a selection bias. However, our sample appears representative of gynecological cancer survivors, as shown in other studies of this population [10,11,34]. Our study can be generalized to women suffering from dyspareunia after gynecological cancer who have similar characteristics and are interested in undertaking treatment for their condition. Even if not all the women agreed to be screened or to participate in the study, the high accrual rate obtained stresses the importance of sexual health for these women, as reported in other studies [38,39]. A randomized controlled trial is still needed to confirm the results of our research. A future study should also include a follow-up assessment to determine whether the changes could be maintained over time.

Finally, our findings support the hypothesis that multimodal pelvic floor physical therapy is a feasible and acceptable intervention to treat women experiencing painful sexual intercourse after gynecological cancer. This multicenter prospective interventional study also demonstrated statistically and clinically significant improvements in pain, sexual function, pelvic floor dysfunction symptoms and related impact on quality of life following this intervention. This provides new level II evidence supporting the practice of physical therapy in oncology to address dyspareunia, a treatment which could be implemented in multidisciplinary follow-up cancer care in women. Data may be used to plan a definitive randomized controlled trial to ascertain treatment efficacy.

Prior presentation

The preliminary results of the current study were presented at the 2020 International Society for the Study of Women's Sexual Health Annual Meeting. Orlando, USA. March 5–8, 2020. Reference: Cyr M.P., Dumoulin C., Bessette P., Pina A., Gotlieb W.H., Lapointe-Milot K., Mayrand M.H., Morin M. Feasibility, Acceptability and Effects of Physical

Table 3
Effects on pelvic floor dysfunction symptoms and related impact on quality of life.

	Baseline (*n* = 31)	Post-treatment (*n* = 30)	Changes from baseline	P[a]
Urinary symptoms (ICIQ-UI SF Form)	2.0 (0; 8.0)	0 (0; 3.3)	0 (−3.0; 0)	0.001
Vaginal symptoms (ICIQ-VS)	15.0 (8.0; 20.0)	8.0 (4.0; 12.0)	-−5.0 (−9.0; −2.0)	<0.001
Sexual matters (ICIQ-VS)	42.0 (37.8; 49.8) (n = 24)[b]	19.0 (0; 31.0) (n = 28)[b]	-−24.0 (−35.3; −12.5)	<0.001
Overall impact on quality of life (ICIQ-VS)	4.0 (1.0; 8.0)	0 (0; 3.0)	-−1.5 (−5.3; 0)	<0.001
Bowel pattern (ICIQ-BS)	4.0 (3.0; 5.0)	3.5 (2.0; 4.3)	-−1.0 (−1.5; 0)	0.005
Bowel control (ICIQ-BS)	6.5 (2.8; 8.3)	4.0 (1.8; 8.0)	−1.0 (−3.0; 0)	0.010
Impact on quality of life (ICIQ-BS)	2.0 (1.0; 8.0)	2.0 (0; 4.3)	−1.0 (−4.0; 0.5)	0.018

Data are expressed as median (Q1, first quartile; Q3, third quartile).
[a] Wilcoxon signed-rank tests.
[b] Seven participants at baseline and two at post-treatment did not engage in any sexual activities in the last month (time frame of ICIQ-VS for sexual matters).

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Declaration of Competing Interest

The authors declare that there are no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ygyno.2020.09.001.

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