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ORIGINAL ARTICLE

Pre-rehabilitation of the pelvic floor before radiation therapy for cervical cancer: a pilot study

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Abstract

Introduction and hypothesis The objective was to evaluate pelvic floor muscle (PFM) function regarding strength, activation and incontinence, approximately 1 month before and after radiation therapy in women with cervical cancer.

Methods This was a pilot study of 49 women with cervical cancer at stages I to III. These women attended an educational session with a physical therapist who taught them to perform preventive pelvic floor muscle exercises (PFMEs; slow and fast contractions and the "knack") at home before, during and after radiation therapy. The women received instructions for performing PFME prior to radiation therapy. The modified Oxford scale, electromyography (EMG), the International Consultation on Incontinence Questionnaire Short Form to assess urinary incontinence and two questions for faecal and gas incontinence were used.

Results Twenty-eight women (57%; mean age = 44 years, range 27–66) completed the study, 21 (43%) were lost to follow-up. There was no significant change from baseline to post-radiation therapy in muscle strength, EMG records and incontinence ($p > 0.05$). The median of PFM strength was equal at baseline and after intervention (median = 2; IQR = 1).

Conclusions The results of this study suggest that pre-rehabilitation teaching PFMEs might be a protective factor for preserving PFM strength and preventing incontinence 1 month after radiation therapy. It is a feasible intervention.

Keywords Cervical cancer · Radiotherapy · Brachytherapy · Pelvic floor · Muscle strength · Pre-rehabilitation

Introduction

Cervical cancer treatment, e.g. radiotherapy, is considered a risk factor for pelvic floor dysfunction (PFD) because it produces functional, anatomical, neurological, vascular, or myofascial alterations [1]. Studies suggest that radiotherapy (external beam radiation and intracavitary radiation, known as brachytherapy) has a greater effect on the pelvic floor (PF) than other treatments because it causes actinic injuries [2, 3].

Adverse effects from radiation can be divided into acute, subacute, and chronic (or late) effects. Acute effects are more common, affecting organs that depend on rapid self-renewal, primarily the skin or mucosal surfaces of the rectum and bladder. These side effects typically resolve after 1–2 weeks of treatment. However, in some cases they are severe and remain for more than 6 months after radiation. Late effects include fibrosis, fistula formation, or long-term organ damage [4]. Late toxicities usually represent a continuation and evolution of the same pathological process and tissue damage that occurs in the short term after radiation therapy [5].

In the short term, pelvic radiation leads to fibrosis in muscle tissues, especially in the smooth-layer muscle cells, which compromises the ability of the levator ani muscles to support organs and to resist increased abdominal pressure, leading to PFD such as urinary incontinence (UI), faecal incontinence (FI) [6] and vaginal dryness [7]. In the long term, radiation therapy may generate vaginal stenosis (a decrease in vaginal length resulting from the reduced elasticity of the muscles) [8] and impair PF function, as women treated for cervical cancer

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have more bothersome PF symptoms—UI and obstructive voiding—compared with the reference community group from a case–control study [3]. Vaginal dryness and stenosis are associated with dyspareunia [8].

A recent systematic review showed that PFD is common in gynaecological cancer survivors. PFD includes UI (4–76%), FI (2–34%), urinary retention (UR; 0.4–39%), faecal urge (3–49%), dyspareunia (12–58%) and vaginal dryness (15–47%) [9]. However, PFD is not consistently reported by patients and is frequently overlooked by many clinicians [1]. Further studies are encouraged as there are few studies detailing muscle function outcomes after cervical cancer [6].

The available rehabilitation treatments to mitigate the side effects of pelvic radiation are aimed at enhancing the function of the anatomical elements of the pelvis that were harmed and to minimise the sexual disorders that could be triggered by the physical disorders [10]. Techniques such as vaginal desensitization and PF re-education through exercises, vaginal cones and electrostimulation have been found to play a role in preventing the onset of these complications [11]. However, there is a lack of strong evidence to support the recommendation of these therapies as pre-rehabilitation, i.e. preventative measures against the complications from PF radiation. However, there is evidence of benefits in using pelvic floor muscle exercises (PFMEs) to prevent UI as an international recommendation [12].

As exposed above, the aim of this study was to evaluate the influence of an educational intervention teaching PFMEs prior to pelvic radiation, either external or intracavitary, for cervical cancer on pelvic floor muscle (PFM) function (strength, activation and incontinence) in the short term after approximately 1 month of pelvic radiation. The women received instructions on how to perform home-based PFMEs before, during and after radiotherapy.

Materials and methods

This is a pilot study with a 1-month follow-up after radiation therapy. The study included an educational intervention to teach women PFMEs prior to pelvic radiation therapy. The women were re-evaluated approximately 1 month after radiotherapy.

Participants

To determine eligibility, 648 women with gynaecological cancer were screened at The Chilean National Cancer Institute, Santiago de Chile. They were recruited at Gynaecological Cancer Committee sessions from August 2017 to July 2018. For inclusion in this study they should be referred for pelvic radiation treatment, external beam and/or brachytherapy, for cervical cancer. The women, aged 18–70, were first-time referrals for curative radiotherapy with or without previous or concomitant treatments, such as surgery and chemotherapy. The exclusion criteria included cancer stage IV, illiteracy, cognitive deficits and observed vaginal prolapse that exceeded the hymenal area. Non-acceptance of the invitation to participate was also a reason for exclusion. The sample size comprised all of the eligible women who chose to participate in the study. Only 15 women did not accept the invitation.

This project was approved by the Ethical Committee of the North Metropolitan Health Service (letter number 007/2017, approval date 5 April 2017). Informed consent was provided by all participants.

Instruments

The primary outcome was PF strength, which was assessed through vaginal bidigital evaluation grading with the modified Oxford scale [13] by a physical therapist with expertise on PF rehabilitation. This scale classifies muscle strength in six categories on a scale of: (0) no contraction, (1) sign of an unsustained contraction, (2) presence of a weak but sustained contraction, (3) moderate contraction felt as an increase in intravaginal pressure with palpable upward and forward movement, (4) satisfactory contraction squeezing the examiner's fingers with elevation of the vaginal wall in the direction of the pubic symphysis, and (5) strong contraction with firm compression of the examiner's fingers with positive movement in the direction of the pubic symphysis, the examining finger is squeezed and drawn into the vagina. The patients were evaluated in lithotomy position.

Secondary outcomes included PFM activation, the presence of UI symptoms and adherence to the PFME regimen. All the questionnaire assessments were performed by four well-trained researchers, but PFM strength and activation were assessed by only one researcher with expertise.

Activation of the PFMs was assessed with an electromyographic measurement by the Myomed 632X® using an intravaginal probe. A reference electrode was placed on the right anterior superior iliac spine to eliminate external interference. The minimum, maximal and mean electromyography (EMG) measurements in microvolts (μV) were obtained during the patient's maximum voluntary contractions.

The presence of UI was evaluated using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) [14], which has been validated in Chile [15]. The frequency and amount of urine loss were measured in relation to the last 4 weeks. The scores (0–21) indicated the effects of UI on quality of life [14]. In addition, the first question of this questionnaire was adapted to the context of frequency of gas and FI with two additional questions (0 = never, 1 = once or less per week or less, 2 = twice or three times per week, 3 = once per day, 4 = several times per day and 5 = continually).

Adherence to non-supervised home-based PFMEs was assessed through an exercise diary in which women registered their completion of the recommended exercises. Sociodemographic and clinical variables were also obtained. The sociodemographic variables included age, marital status, education level, perceived health status and sexual activity. The clinical variables were cancer stage, previous cancer treatments, menopause, body mass index, and comorbidities (diabetes, hypertension and constipation).

Interventions

The interventions took place at the Rehabilitation Service of the National Cancer Institute. They were conducted by a physical therapist specialist in oncology and PF rehabilitation. The intervention included one approximately 30-min physical therapy session to teach PFMEs. The patients were instructed to practice at least twice per day at home. The following were recommended:

a) Low contractions: eight maximal voluntary contractions of 6 s each with a rest of 10 s
b) One-second contractions: eight maximal voluntary contractions followed by relaxation
c) The “knack”: a voluntary precontraction of the PF before activities that increased intra-abdominal pressure [16]

This protocol for increasing PFM strength was similar to those of previous studies [17, 18].

Steps were taken to promote home-based PFME adherence. An educational flyer and an audio recording with the instructions for the exercises were given to the patients. Information on PF anatomy and function and the importance of PFMEs in preventing dysfunctions was also provided. The patients’ external beam radiotherapy and brachytherapy treatment was in accordance with international standards following the Chilean Guideline for Cervical Cancer [19].

Data analysis

The data were analysed using SPSS 23.0. Descriptive statistics were used. The data were tested for normality and did not meet the criteria in accordance with the Shapiro–Wilk test. The Wilcoxon signed-rank test ($p < 0.05$) was used for comparing pre- and post-radiotherapy PFM function, including the instruction of PFMEs. To compare women with and without symptoms of UI at baseline we used the Mann–Whitney U test. Because of the high rate of women who were lost to follow-up, the intention-to-treat analysis was not used. Some studies have suggested that the use of imputation techniques for replacing missing data do not yield good representations of the original data when both the number of respondents with missing data and the number of missing items were more than 20% [20].

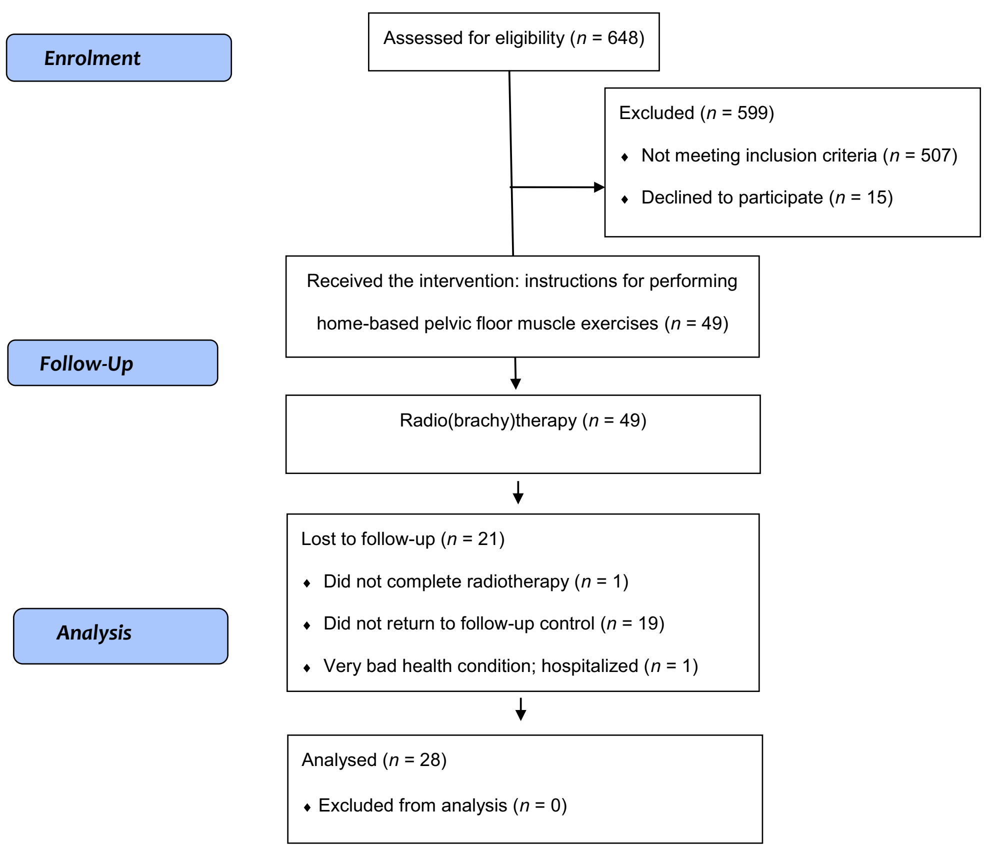

Fig. 1 Flow diagram of participants from enrolment to analysis

Results

In this study, 49 women received the intervention; however, only 28 returned to the follow-up control (42.8% had been lost to follow-up). Figure 1 displays the flow of participants from enrolment to analysis. At baseline, there was no significant difference ($p < 0.05$) between women lost to follow-up and women who finished the study regarding age, parity, incontinence and PFM strength and activation.

Table 1 presents the sociodemographic and clinical characteristics of the participants. The mean age was 44.0 (standard deviation [SD] = 11.1). There was heterogeneity regarding their education levels. Most of the women were married or living with partners (42.8%). Only 17.9% were nulliparous. Only 35.7% were sexually active at baseline. Constipation was highly prevalent (60.7%). Nine women (32.1%) had undergone a surgery previously for gynaecological cancer, only 1 (3.6%) did not receive brachytherapy, and 16 (57.1%) also received chemotherapy concomitantly with radiotherapy.

Among the women who returned for re-evaluation, adherence to home-based PFMEs was high. All reported doing the exercises; however, 6 women (21.4%) did not return their diaries. With the exclusion of the women who did not return their diaries, the average number of days per week for performing the exercises was 4.9 (SD = 1.5). None of the women reported adverse events related to the practice of home-based PFMEs.

Table 2 shows that there was no significant change in PFM strength and activation from baseline (before radiation therapy and the instruction to perform non-supervised home-based PFMEs) to approximately 1 month after radiation. The median of PFM strength was 2 at baseline and 1 month after radiation therapy, which means the presence of a weak but sustained contraction. The median ICIQ-SF score, representing the impact of incontinence on daily life, was low both at baseline (four points) and 1 month after RT (three points).

Table 3 shows specific lower urinary tract symptoms. At baseline, 53.6% had symptoms of UI, which was more common during stressful situations such as coughing and exercise. One month after pelvic radiation therapy combined with home-based PFMEs, 46.4% of the women had UI symptoms. The frequency and amount of UI slightly reduced from baseline to post-radiation therapy. Symptoms of gas incontinence were reported by 75.0% of the participants at baseline and by only 28.6% after the intervention. Symptoms of FI were reported by 39.3% of the participants at baseline and by 25.0% after the intervention.

We compared PF function in women with UI symptoms at baseline ($n = 15$, 53.6%) and women who did not report UI at baseline ($n = 13$, 46.4%). Only the mean EMG measurement 1 month after radiation therapy was different in these groups, with higher scores for women without UI than for women with UI symptoms (median 7 and 5 respectively, $p = 0.022$). PFM strength was similar in these groups ($p < 0.05$).

Table 1 Sociodemographic and cancer-related clinical characteristics ($n = 28$)

Variable	*n*	%
Education level		
Basic incomplete	3	10.7
Basic complete	2	7.1
Medium incomplete	3	10.7
Medium complete	10	35.7
Technical education	7	25.1
University	3	10.7
Marital status		
Single	9	32.1
Married	9	32.1
Cohabiting with a partner	3	10.7
Divorced/separated	7	25.0
Parity		
Nulliparous	5	17.9
Primiparous	6	21.4
Multiparous	17	60.7
Perimenopausal	11	39.3
Constipation	17	60.7
Diabetes	4	14.3
Arterial hypertension	4	14.3
Smokers	5	17.9
Former smokers	3	10.7
Cancer stage (TNM system)		
I B	15	53.6
II A	3	10.7
II B	7	25.0
III B	3	10.7
Oncological treatments		
Radiotherapy and surgery	9	32.1
Radiotherapy and brachytherapy	27	96.4
Radiotherapy and chemotherapy	16	57.1
Sexually active	10	35.7
Self-reported health status[a]		
Very good	4	14.8
Good	12	44.4
Regular	9	33.3
Bad	2	7.4

[a] Data from one patient were missing; thus, we used the valid percentage

Discussion

This quasi-experimental study was aimed at investigating the influence of an educational intervention with a physiotherapist's instructions to women with gynaecological cancer to perform PFMEs before, during and after pelvic radiotherapy with brachytherapy treatment. The pre-rehabilitation was found to have a protective effect on PFM function, mainly concerning muscle strength and activation, which did not

Table 2 Comparison of pelvic floor muscle function at baseline and post-radiotherapy combined with non-supervised home-based pelvic floor muscle exercises (n = 31)

Variables	Baseline		After radiotherapy combined with home-based PFMEs		Wilcoxon test
	Mean (SD)	Median (IQR)	X (SD)	Median (IR)	*p*
Mean PFM strength[a]	1.7 (0.8)	2.0 (1.0)	2.6 (0.7)	2.0 (1.0)	0.052
Right PFM strength[a]	1.7 (0.8)	2.0 (1.0)	2.6 (0.7)	2.0 (1.0)	0.083
Left PFM strength[a]	1.8 (0.9)	2.0 (2.0)	2.5 (0.8)	2.0 (1.0)	0.095
Minimum EMG (μV)	1.4 (1.0)	1.0 (1.0)	1.4 (1.0)	1.0 (1.0)	1.0
Maximal EMG (μV)	39.7 (22.0)	29.0 (31.0)	47.4 (28.1)	37.5 (38.0)	0.196
Mean EMG (μV)	5.7 (1.7)	6.0 (3.0)	6.5 (4.0)	6.0 (5.0)	0.586
Effect of incontinence on daily life (ICIQ-SF score)	5.9 (5.5)	4.0 (9.5)	5.3 (5.3)	3.0 (9.0)	0.794

[a] Assessed using the modified Oxford scale: 0 = no contraction and 5 = very strong

PFMEs pelvic floor muscle exercises, *EMG* electromyography, *ICIQ-SF* International Consultation on Incontinence Questionnaire Short Form, *SD* standard deviation, IQR interquartile range

change 1 month after pelvic radiation therapy. A review of the literature suggests that this might be a novel result. No studies were found to include the teaching of PFMEs to women prior to pelvic radiation therapy. These positive findings support the importance and feasibility of the implementation of preventive programmes that include teaching PFMEs to women who will undergo pelvic radiation therapy.

In addition, few studies tested PFMEs in cervical cancer survivors after radiation treatment, including only women with PFD [21, 22]. They showed that PFMEs are useful to improve PFD and quality of life [21, 22].

The median PFM strength was still low 1 month after (median = 2, IQR = 1); the presence of a weak but sustained contraction suggests the need for more intensive supervised PF rehabilitation for these women. PFM strength can be improved by PFMEs that include fast contractions, sustained contractions, proprioceptive and "the knack" exercises. PFM strength is a single aspect of PFM function and represents the ability to prevent urinary or anorectal leakage during activities that increase intraabdominal pressure. PFM strength is measured during a voluntary maximal contraction. Meanwhile, EMG results suggest a pattern of activity or behaviour of the muscle, but have limited value as a tool for diagnosis of the functioning of the PF [23]. For this reason, most of the therapists use EMG records as biofeedback to help patients improve their PF contraction abilities. However, there is a need to establish minimal clinically important differences for PFM strength and activation (EMG) in order to improve the clinical interpretation of results.

The results of a qualitative study indicated that women with gynaecological cancer with UI or FI after radiation and/or surgery had a positive attitude towards PFM training [24] and that this may have contributed to their well-being. In a study of the effects of gynaecological cancer treatments on PFM strength, a previous study [25] found no significant difference between the surgical group and the radiation groups regarding maximum PF strength, as measured by the modified Oxford scale in the present study. They found that the radiation therapy group appeared to have a greater proportion of extremely low maximum strength scores (such as 0 and 1) on the scale [25]. A randomized controlled trial demonstrated that a supervised programme of PFM training improved PF dysfunction and quality of life in women who had undergone radical hysterectomies for gynaecological cancer [21]. In another study of gynaecological cancer survivors with UI, 18% of the women who had received radiation exhibited symptom improvement after a PFME programme [22]. Most studies have indicated that PFMEs would benefit women with gynaecological cancer.

The rationale for the effectiveness of PFMEs in the prevention of PF dysfunction after pelvic radiation therapy is related to its effect on muscle strength and the increased blood flow to the pelvic structures [26]. This may have contributed to the improved functioning of these structures, as measured during the short period after radiotherapy.

In this study, PFM activation and UI symptoms remained unchanged after the combination of pelvic radiation therapy and home-based PFMEs. Another study found the pretreatment prevalence of stress UI and urgency UI to be 24–29% and 8–18% respectively, and the post-treatment prevalence to be 4–76% and 4–59% respectively [9]. Considering the high prevalence of UI after gynaecological cancer treatment, the proposed intervention of providing PFMEs could be interpreted as having a preventive effect by protecting the PF structures, which are typically impaired as a result of pelvic radiation therapy. The recommended minimal important differences for ICIQ-UI SF are minus 5 at 12 months and minus

Table 3 Lower urinary tract symptoms at baseline and after radiotherapy treatment combined with non-supervised home-based pelvic floor muscle exercises (n = 28)

Variable	Baseline, *n* (%)	After radiotherapy combined with home-based PFME, *n* (%)
Frequency of urinary incontinence		
Never	13 (46.4)	15 (53.6)
Once or less than once per week	8 (28.6)	2 (7.1)
Twice or three times per week	2 (7.1)	2 (7.1)
Once per day	2 (7.1)	4 (14.3)
Several times per day	3 (10.7)	3 (10.7)
Amount of urinary incontinence		
Nothing	13 (46.4)	15 (53.6)
Very small	10 (35.7)	7 (25.0)
Moderate	4 (14.3)	4 (14.3)
Very much	1 (3.6)	0 (0)
Situations during urine loss		
Before arriving at the toilet	4 (14.3)	8 (28.6)
While coughing	12 (42.9)	6 (21.4)
While sleeping	0 (0.0)	1 (3.6)
While exercising	5 (17.9)	4 (14.3)
While dressing after urinating	3 (10.7)	3 (10.7)
Without an evident motive	0 (0.0)	1 (3.6)
Continually	0 (0.0)	0 (0.0)
Frequency of gas incontinence[a]		
Never	7 (25.0)	20 (71.4)
Once or less than once per week	7 (25.0)	1 (3.6)
Twice or three times per week	2 (7.1)	1 (3.6)
Once per day	1 (3.6)	2 (7.1)
Several times per day	2 (7.1)	1 (3.6)
Continually	1 (3.6)	0 (0)
Frequency of faecal incontinence[a]		
Never	17 (60.7)	21 (75.0)
Once or less per week	2 (7.1)	1 (3.6)
Twice or three times per week	0 (0)	2 (7.1)
Once per day	1 (3.6)	0 (0)
Several times per day	0 (0)	1 (3.6)

PFMEs pelvic floor muscle exercises

[a] The valid percentage was used because there were 9 missing cases at baseline and 4 after treatment

4 at 24 months [27]; meaning that in this study there was no clinically relevant worsening of the UI condition.

In this study, women with UI symptoms at baseline had a significantly lower mean EMG score 1 month after radiation therapy than those without UI. EMG was sensitive in detecting differences between these groups, as demonstrated in an EMG reliability study that compared healthy women and women with PFD [28].

Faecal and gas incontinence decreased from pre- to post-intervention. FI symptoms were reported by 39.3% of the participants at baseline and by 25.0% after the intervention. Meanwhile, gas incontinence symptoms decreased from 75% to 28.6%. However, these results should be interpreted with caution because, as a result of operational issues, eight data points were missing data for this variable at baseline and three after radiation therapy. According to a previous systematic review, the prevalence of FI in women with cervical cancer was 6% before treatment and 2–34% after treatment [9]. The associated symptoms, such as urinary leakage, FI and pelvic organ prolapse, are considered disabilities [26].

The barriers to the implementation of this intervention were related to the difficulty of patient follow-up, as there was a high attrition rate (42.8%). Many women missed their appointments, and the researchers had to call many times to reinforce the importance of continuing the exercises and attending the follow-up visit. It was hypothesised that this could be a result of the study population characteristics. First, cancer treatment probably affected many of the women's daily routines and financial stability. Second, they were receiving treatment from a public hospital; thus, attendance may have been affected by the exposure to greater socioeconomic risk and also less social support. Third, cultural issues related to sexual taboos may have influenced adherence to the intervention. Other studies that included only cervical cancer patients who presented symptoms of PFD showed a slightly lower attrition rate: 29.4% [21] and 10% [22]. It is probable that people tend to more frequently adhere to treatments than to preventive approaches.

A systematic review with women with gynaecological cancer suggested that adherence rates to interventions, such as the use of vaginal dilators, might low: 25 to 89.2%. The study also found a large variation in the definitions and methods of assessing therapy adherence [29].

Future studies should explore the long-term (ideally more than 6 months) effects of home-based PFMEs during pelvic radiation therapy. In addition, qualitative studies could provide an in-depth understanding of non-adherence. Finally, it would be interesting to evaluate the feasibility of conducting a similar project in a private health-care setting with women of higher socioeconomic status.

Contributions C. Sacomori: protocol/project development, data collection or management, data analysis, manuscript writing/editing; P. Araya-Castro: protocol/project development, data collection or management, manuscript writing/editing; P. Diaz-Guerrero: protocol/project development, delivered the intervention, manuscript editing; I.A. Ferrada: recruited participants, data collection or management, manuscript editing; A.C. Martínez-Varas: recruited participants, tabulated data, data collection or management, manuscript editing; K. Zomkowski: manuscript writing and editing.

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Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflicts of interest.

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