

# Group-based multimodal physical therapy in women with chronic pelvic pain: A randomized controlled trial

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## Abstract

**Introduction:** Chronic pelvic pain in women is a complex condition, and physical therapy is recommended as part of a broader treatment approach. The objective of this study was to compare structured group-based multimodal physical therapy in a hospital setting (intervention group) with primary-care physical therapy (comparator group) for women with chronic pelvic pain.

**Material and methods:** Women aged 20–65 years with pelvic pain  $\geq 6$  months and referred for physical therapy were eligible. The primary outcome measure was change in the mean pelvic pain intensity from baseline to 12 months, measured using the numeric rating scale (0–10). Secondary outcomes were changes in scores of “worst” and “least” pain intensity, health-related quality of life, movement patterns, pain-related fear of movements, anxiety and depression, subjective health complaints, sexual function, incontinence, and obstructed defecation. The differences between the groups regarding change in scores were analyzed using the independent t test and Mann-Whitney U test. Sensitivity analysis of the primary outcome was performed with a linear regression model adjusted for the baseline value. A *P* value  $< .05$  was considered statistically significant.

**Results:** Of the 62 women included, 26 in the intervention group and 25 in the comparator group were available after 12 months for data collection and analysis. The difference between the groups for change in the mean pain intensity score was  $-1.2$  (95% CI  $-2.3$  to  $-0.2$ ; *P* = .027), favoring the intervention group. The intervention group showed greater improvements in respiratory patterns (mean difference 0.9; 95% CI 0.2–1.6; *P* = .015) and pain-related fear of movements (mean difference 2.9; 95% CI  $-5.5$  to  $-0.3$ ; *P* = .032), and no significant differences were observed between the groups for the other secondary outcomes.

**Conclusions:** Although the reduction in the mean pelvic pain intensity with group-based multimodal physical therapy was significantly more than with primary-care

**Abbreviations:** CPP, chronic pelvic pain; NRS, numeric rating scale; RCT, randomized controlled trial.

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physical therapy, the difference in the change between the groups was less than expected and the clinical relevance is uncertain.

### KEYWORDS

body awareness, chronic pelvic pain, group-based, patient education, physical therapy, randomized trial, women

## 1 | INTRODUCTION

Chronic pelvic pain (CPP) in women is a complex condition, with a suggested worldwide prevalence of 6%-27%.<sup>1</sup> CPP is defined as “chronic or persistent pain for at least 6 months, perceived in structures related to the pelvis, and often associated with negative cognitive, behavioral, sexual and emotional consequences and symptoms of lower urinary tract, sexual, bowel, pelvic floor or gynecological dysfunction.”<sup>2</sup> CPP is further subdivided into pain syndromes according to the location of the pain; however, in this study, we did not differentiate between these syndromes.<sup>2</sup>

Compared with the general female population, women with CPP report poorer total health, higher number of surgeries in the pelvic area, and more incidences of physical, sexual, and psychological abuse.<sup>1-3</sup> Altered movement and respiratory patterns are observed,<sup>4</sup> and pain-related fear of movements are reportedly present.<sup>5</sup> Long symptom duration and extensive investigations and treatments in different specialties are reported, often without satisfactory results.<sup>1</sup>

Clinical guidelines recommend a biopsychosocial approach including physical therapy, pain education, and active patient participation.<sup>2</sup> A systematic review of physical therapy treatment for CPP summarized that positive results can be achieved with single modalities such as manual techniques and exercises, but the evidence is limited.<sup>6</sup> Physical therapy focusing on body awareness and cognitive techniques has been highlighted as a promising therapy, and a future avenue for research in CPP.<sup>6</sup>

Group-based physical therapy is considered time saving and cost efficient; it can be as effective in reducing pain as individual treatment and can provide social affinity for the participants.<sup>7</sup> Despite this, no randomized controlled trials (RCTs) on group-based physical therapy for CPP have been identified.

A group-based multimodal physical therapy program that combines body awareness therapy and patient education has been developed at the Pelvic Floor Center at the University Hospital of North Norway.<sup>8-10</sup> Traditionally, women with CPP are referred for primary-care physical therapy after assessment by specialist doctors at hospitals.

The objective of this RCT was to compare group-based multimodal physical therapy (intervention group) with primary-care physical therapy (comparator group) in women with CPP. The primary hypothesis was that the intervention group will show greater reduction in the mean pain intensity than the comparator group after 12 months.

### Key Message

The reduction in the mean pain intensity with group-based multimodal physical therapy in a hospital setting was significantly more than that with primary-care physical therapy, but the difference in the change between the groups was less than expected and the clinical relevance is unclear.

## 2 | MATERIAL AND METHODS

This was a parallel group RCT with an allocation ratio of 1:1. Participants were recruited from the outpatient clinic at the Pelvic Floor Center at the University Hospital of North Norway, after assessment by medical specialists. Eligibility and exclusion criteria are listed in Table 1.

The study intervention was based on the biopsychosocial model,<sup>11</sup> combined body awareness therapy,<sup>8,12</sup> patient education,<sup>9,13</sup> and cognitive approach of “acceptance and commitment therapy”<sup>10</sup> in a group setting. There was a pre-planned schedule, with an initial 10-day session followed by 2-day sessions after 3, 6, and 12 months. The aim was to reduce pain and improve daily function by challenging avoidance habits and providing new positive body experiences.<sup>8,12</sup> Detailed information about the intervention is shown in Supporting material, Table S1 (schedule) and Table S2 (TidIER checklist).

Women in the comparator group were referred to a physical therapist in primary health care with competence in women's health. The therapists received an information letter (Supporting material, Appendix S1), and they were asked to provide treatment according to their academic competence and in consultation with the woman. The deductibles of the physical therapy treatment were refunded.

The randomization database was administered by the Clinical Research Department at the hospital, and was available only for the primary researcher and the project leader. Randomization with alternating block sizes of four and six was applied. A nurse at the Pelvic Floor Center provided the referrals to the treatment groups.

Baseline data were collected at the outpatient clinic at the time of inclusion before randomization, and all outcomes were collected again after 12 months. Information about pain intensities was also collected by mail at 3 and 6 months. Women who did not manage to travel to the hospital for the post-test for practical reasons were contacted by phone and mail. Two physical therapists (ASN and MFE) performed the baseline and follow-up tests.

**TABLE 1** Eligibility criteria

Inclusion criteria	Exclusion criteria
Norwegian-speaking women	Malignancy and conditions requiring special medical attention
Age 20-65 years	Pregnancy at the time of inclusion or childbirth during the previous 12 months
Chronic pelvic pain diagnosis <sup>a</sup>	Drug addiction
Motivated to participate in a group intervention	Serious psychiatric diagnosis
	Previous treatment by the physical therapists involved in the intervention
	Intra-abdominal or pelvic surgery within the last 6 months
	Botulinum toxin injections in the pelvic area in the last 4 months

<sup>a</sup>Engeler et al, European Association of Urology Guidelines on Chronic Pelvic Pain 2017. <https://uroweb.org/guideline/chronic-pelvic-pain/>.

A semi-structured interview was used to collect demographic information (age, body mass index, smoking, children, civil status, education, and work status) and medical history (pain duration, previous surgeries, other diagnosis, and abuse exposure). At 12 months, the number of consultations and type of treatment were also registered. Supporting material, Appendices S2 and S3 show the interview guides.

The primary outcome measure was change in mean pain intensity from baseline to 12 months of follow up. The mean pelvic pain intensity during the previous 7 days was recorded on the validated 11-point numeric rating scale (NRS, 0 = no pain, 10 = worst pain imaginable).<sup>14</sup>

The "worst" and "least" pain intensities during the last 7 days were registered as secondary outcome measures using the NRS.<sup>14</sup>

Movement patterns were assessed using the Standardized Mensendieck test, which evaluates performance of standing and sitting posture, active movements, gait, and respiration patterns according to criteria based on functional anatomy.<sup>15</sup> The test was video recorded before a blinded physical therapist scored the five domains on a scale of zero to seven (0 = least optimal, 7 = optimal) (Supporting material, Appendix S4). The Standardized Mensendieck test was validated in a sample of Norwegian women with CPP.<sup>15</sup>

Pain-related fear of physical movement and activity was registered with the validated Tampa scale for Kinesiophobia.<sup>16</sup> The women reported to what extent they agreed with the 13 different statements regarding associations between movement and possible injury or pain on a four-point Likert scale (1 = strongly disagree, 4 = strongly agree), and the total was calculated in the score range of 13-52.

Health-related quality of life was measured using the EQ5D-5L questionnaire. An EQ5D-index and an EQ visual analogue scale (VAS) score were reported.<sup>17</sup> The EQ5D-index ranges from -0.624 to 1.000, with higher scores indicating better health, whereas the

EQ VAS records total health on a VAS (0-100), where 100 is the best health you can imagine.<sup>17</sup>

Symptoms of anxiety and depression were recorded using the Hopkins Symptom checklist-25 (0-4, higher scores indicating more severe symptoms).<sup>18</sup> Common somatic and psychological health complaints during the last 30 days were recorded using the Subjective Health Complaints questionnaire (0-87, higher scores indicating more complaints).<sup>19</sup> The presence and extent of urinary incontinence (yes/no, scores 0-21),<sup>20</sup> anal incontinence (yes/no, scores 0-24),<sup>21</sup> and obstructed defecation (yes/no, scores 0-25)<sup>22</sup> were recorded using validated questionnaires. Sexual function was mapped with questions regarding whether the women were sexually active (yes/no), had reduced/lack of sexual desire (yes/no), and/or had presence of pain during intercourse (yes/no). Pain intensity during intercourse was registered using an NRS (score 0-10).<sup>23,24</sup>

## 2.1 | Statistical analyses

The sample size was calculated based on the results from an RCT conducted on women with CPP that applied an intervention similar to the one in this study, though it was individually delivered. The aforementioned study showed a change of 2.2 on the NRS for mean pain intensity between the groups after 3 months,<sup>25</sup> which indicated a difference of one standard deviation in the change. Based on these assumptions, the effect size was estimated as "1". With a significance level of 0.05, a power of 90%, and an estimated dropout rate of 30%, 33 women should be included in each group.

Descriptive statistics were presented as mean and standard deviation or median and interquartile range for the continuous variables, and frequencies and percentages for the categorical variables. In case of missing data on sub-items of the secondary outcome measures, averages of the available responses were used.<sup>26</sup>

Statistical analyses followed the intention-to-treat approach. For continuous data, independent samples *t* test or Mann-Whitney *U* test was used for primary analyses of group differences in the change in the groups from baseline to 12 months. The assumptions for parametric tests of normal distribution of residuals and equality of variances were checked before analyzing the data. For the categorical variables, changes in the number of women reporting problems were described. Sensitivity analysis of the primary outcome was performed with a linear regression model adjusted for the baseline value. The significance level was set at  $P = .05$ . Statistical analyses were conducted using the Statistical Package for the Social Sciences, version 25 for Macintosh (IBM SPSS Statistics).<sup>27</sup>

## 2.2 | Ethical approval

This study was conducted in accordance with the principles of the Declaration of Helsinki. Written and oral study information was provided to the participants, and the informed consent forms were signed. The study was approved by the Regional Committee for

Medical and Health Research Ethics North (18.09.2014 2014/1398) and by the Institutional Review Board at the University Hospital of North Norway (0444/24.02.2015). The trial was registered at clinicaltrials.gov (NCT02356796, 5 February 2015) and reported in accordance with the CONSORT statement (Supporting material, Table S3).<sup>28</sup>

### 2.3 | Deviations from registered trial protocol

Regrettably, the registration of the primary outcome at clinicaltrials.gov was misleading, including mean, least, and worst recorded pain intensities at three different time-points. Some secondary outcomes were also registered as measured at different time-points. However, the objective of the trial was to analyze changes from baseline to 12 months. Additionally, the sample size calculation was 46 and not 50, as registered at clinicaltrials.gov.

## 3 | RESULTS

Sixty-two women were randomly assigned to the intervention group (n = 30) and the comparator group (n = 32) between March 2015 and November 2016. Data collection was completed in January 2017, with the data of 26 and 25 women available for the 12-month analyses from the intervention and comparator groups, respectively. Participant selection flow, including reasons for dropout, is shown in Figure 1. Table 2 provides the baseline characteristics of the

participants in both groups. A detailed description of the sample was provided in a previously published paper.<sup>24</sup>

The majority of women in the intervention group attended all the sessions. One woman attended only for the first 10-day session, and seven attended 12-14 days of the total 16 treatment days (median 16, interquartile range 2). In the comparator group the median number of physical therapy consultations was 14 (interquartile range 29). One-third of the comparator group women reported that they had received pelvic floor muscle training combined with general exercises and/or relaxation exercises, 50% had received soft-tissue treatment alone or in combination with exercises, and 50% reported that dialogue with the therapist was a part of the treatment.

For the primary outcome the group-difference in change was -1.2 (95% CI -2.3 to -0.2, P = .027) (Table 3). In the intervention group, 19 women reported improvement, whereas four women reported no change and three reported worsening in mean pain intensity as compared with the 17, 3, and 5 women, respectively, in the comparator group. Except for a lack of reduction in pain, no adverse effects were registered.

Regarding the secondary outcomes, statistically significant differences were detected only in the respiratory patterns and pain-related fear of movements (Tables 4 and 5). Sixteen women (62% and 64% in the intervention and comparator groups, respectively) from both groups reported being sexually active both at baseline and 12 months. Among those, 12 (86%, two missing) in the intervention group and 12 (75%) in the comparator group reported reduced sexual desire at baseline. After 12 months, eight

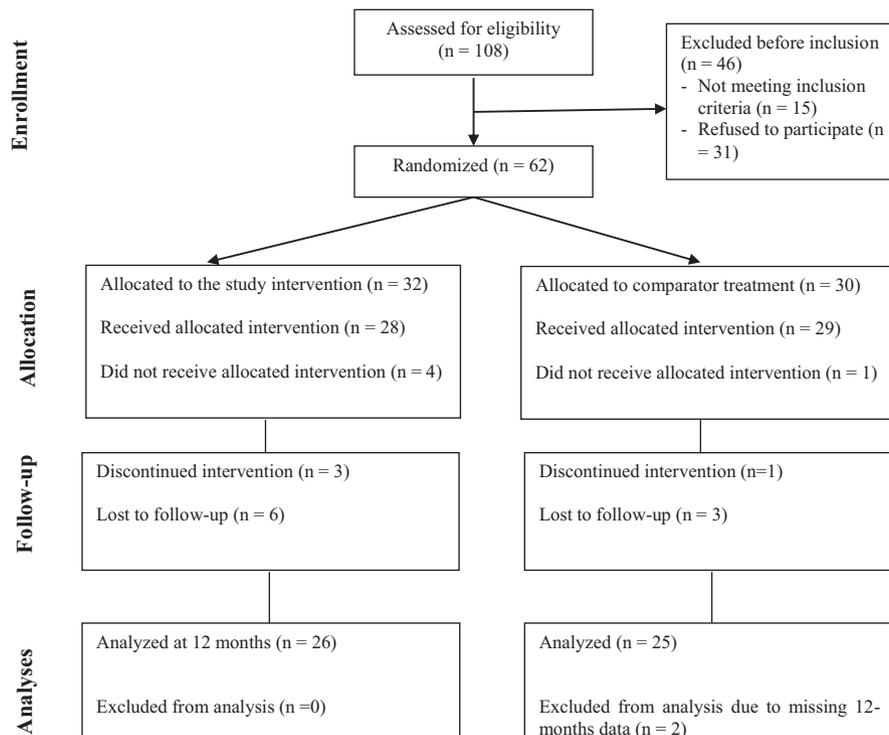


FIGURE 1 Participant flow including reasons for dropout

	Intervention group (n = 32)		Comparator group (n = 30)	
	Mean, n or median	SD, % or IQR	Mean, n or median	SD, % or IQR
Age, years	39.7	10.9	36.2	13.8
BMI, kg/m <sup>2</sup>	26.7	5.8	26.9	5.6
Smoking, yes	8	25	6	20
Premenopausal, yes	23	77	22	76
Children, number	2.0	1.5	1.3	1.2
Married or cohabiting, yes	27	84	21	70
Education, higher <sup>a</sup> , yes	13	41	15	50
Working or student, yes	16	50	18	60
Currently on sick leave, yes	5	16	7	23
Sick leave >12 weeks last year, yes	11	34	7	23
Receiving social benefits, yes	12	38	11	37
Previous surgery (lower abdomen or pelvis), yes	22	71	20	67
Previous surgeries, number	1.5	0-3	1.0	0-2
Previous diagnosis in the pelvic area, yes				
Ovarian cysts	13	41	9	30
Urinary tract infections, repeated	9	28	7	23
OASIS	4	13	4	13
Endometriosis	3	9	6	20
Exposed to abuse (physical, psychological or sexual), yes	13	41	18	60
Duration of pelvic pain, years				
1-2	4	12.5	4	13.3
2-4	7	21.9	4	13.3
4-6	8	25	4	13.3
6-10	1	3.1	4	13.3
>10	12	37.5	14	46.7
Mean pelvic pain intensity, NRS	4.4	2.0	4.5	2.8

Abbreviations: BMI, body mass index; IQR, interquartile range; NRS, numeric rating scale; OASIS, obstetric anal sphincter injuries; SD, standard deviation.

<sup>a</sup>Completed ≥1 year at the University College or University.

**TABLE 2** Baseline characteristics of the participants in the intervention group and comparator group

**TABLE 3** Differences between the intervention and comparator groups regarding the changes in the primary outcome from baseline to 12 months

Mean pain, NRS 0-10	Baseline		12 months		Change baseline to 12 months		Difference in change between the groups					
	Mean	SD	Mean	SD	Mean	95% CI	Primary analysis			Sensitivity analysis <sup>a</sup>		
							Mean	95% CI	P	Mean	95% CI	P
Intervention group (n = 26)	4.7	2.0	3.0	2.4	-1.8	-2.6 to -1.0	-1.2	-2.3 to -0.2	.027	-1.2	-2.3 to -0.1	.030
Comparator group (n = 25)	4.5	2.8	4.0	2.9	-0.5	-1.3 to 0.3						

Abbreviations: NRS, numeric rating scale; SD, standard deviation.

<sup>a</sup>Adjusted for baseline values of mean pain intensity.

**TABLE 4** Descriptive statistics of mean, “worst” and “least” pain intensities at different time-points

	Intervention group (n = 26)						Comparator group (n = 25)									
	Baseline		3 months		6 months		12 months		Baseline		3 months		6 months		12 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Mean pain (NRS 0-10)	4.7	2.0	3.7	2.0	4.3	2.1	3.0	2.4	4.5	2.8	3.7	2.4	4.2	2.9	4.0	2.9
Worst pain (NRS 0-10)	6.5	2.5	6.0	2.5	5.9	2.7	4.0	3.3	6.3	2.6	5.5	2.8	5.9	2.7	5.0	3.1
Least pain (NRS 0-10)	2.2	2.0	1.9	2.9	1.8	1.8	1.7	2.0	2.2	2.5	1.5	2.0	1.5	2.0	1.5	1.6

Abbreviations: NRS, numeric rating scale; SD, standard deviation.

(50%) in the intervention group and 10 (63%) in the comparator reported reduced sexual desire. At baseline, nine (75%, four missing) in the intervention group and 11 (73%, one missing) in the comparator group reported painful intercourse. After 12 months, six (38%) women in the intervention group and 10 (63%) in the comparator group reported painful intercourse. Pain intensity during intercourse was reduced by 3.0 on the NRS from baseline to 12 months in the intervention group compared with a reduction of 1.1 reduction in the comparator group (difference in groups -1.9; 95% CI -5.6 to 2.0; *P* = .326). There were no differences in the total scores for incontinence or obstructed defecation between the groups (Table 5).

#### 4 | DISCUSSION

To our knowledge, this is the first RCT comparing a group-based treatment consisting of body awareness therapy, patient education, and cognitive techniques with primary-care physical therapy for women with CPP. We found a smaller than expected difference between the groups with respect to reduction in mean pelvic pain intensity after 12 months, but the difference was statistically significant. The intervention group showed additional improvements in the respiratory patterns and in pain-related fear of movements. However, changes in “worst” and “least” pain intensities, health-related quality of life, other movement patterns, symptoms of anxiety and depression, subjective health complaints, sexual function, incontinence, and obstructed defecation were not statistically different between the groups.

The strengths of this study are the RCT design, validated outcome measures, and the use of a definition and intervention in accordance with the clinical guidelines.<sup>2</sup> The primary outcome measure was defined as change in pain intensity, which reflects just one aspect of CPP,<sup>1</sup> and other end points might be better suited to this type of intervention. Comparing the study intervention with non-standardized physical therapy can be considered a limitation because of the heterogeneous treatment. However, there is no consensus on a standardized physical therapy approach in CPP,<sup>6</sup> and comparing the intervention with the “usual treatment” offered to these women provides real-world clinical data. Furthermore, the lack of blinding of the data collectors and patients is a limitation, and there might be a selection bias because one-third of the eligible women declined to participate. Reasons for not attending were economic concerns, and practical or emotional challenges of staying away from home. The dropout rate was 18%, which influences the generalizability of our findings. These results apply only to women with characteristics similar to the 51 participants included in the 12-month analyses of this study. The limited number of participants and the low power of the study mean that the results of all the secondary outcomes should be interpreted with caution.

The difference between the groups regarding the change in mean pain intensity was small compared with the results of a

**TABLE 5** Differences between the intervention (n = 26) and comparator (n = 25) groups regarding the changes in the secondary outcomes from baseline to 12 months

	Baseline		12 months		Change from baseline to 12 months		Difference in change between the groups		
	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean	95% CI	P
<b>Worst pain, NRS 0-10</b>									
Intervention group n = 24	6.8	2.4	4.0	3.3	-2.7	3.5	-1.4	-0.4 to 3.1	.117
Comparator group, n = 25	6.3	2.6	5.0	3.1	-1.3	2.5			
<b>Least pain, NRS 0-10</b>									
Intervention group n = 21	2.2	2.0	1.7	2.0	-1.7	2.1	0.3	-0.9 to 1.4	.651
Comparator group n = 22	2.2	2.5	1.5	1.6	0.5	1.4			
<b>Movement patterns, SMT 0-7</b>									
<b>Posture</b>									
Intervention group n = 24	4.8	0.7	5.0	0.5	0.2	0.7	0.3	-0.1 to 0.7	.104
Comparator group, n = 22	4.8	0.6	4.8	0.7	-0.1	0.7			
<b>Active movements</b>									
Intervention group n = 24	4.2	1.2	5.0	0.7	0.7	1.1	0.1	-0.5 to 0.8	0.637
Comparator group, n = 22	4.0	1.1	4.7	1.0	0.6	0.9			
<b>Sitting posture</b>									
Intervention group n = 23	5.1	1.3	5.5	1.1	0.4	1.0	0.1	-0.7 to 0.6	.838
Comparator group, n = 22	4.9	1.2	5.2	1.0	0.3	1.2			
<b>Gait</b>									
Intervention group n = 22	4.5	1.2	5.1	1.0	0.5	0.8	0.0	-0.6 to 0.6	.881
Comparator group, n = 22	4.2	1.3	4.7	1.4	0.5	1.1			
<b>Respiration</b>									
Intervention group n = 23	4.1	1.3	5.0	1.2	0.8	1.4	0.9	0.2-1.6	<b>.015</b>
Comparator group, n = 21	3.9	1.2	4.1	1.0	-0.1	0.9			
<b>Pain-related fear of movements, TSK 13-52</b>									
Intervention group, n = 24	24.4	4.8	19.4	4.3	-5.0	3.7	-2.9	-5.5 to -0.3	<b>.032</b>
Comparator group, n = 25	23.0	6.3	20.8	5.9	-2.1	5.3			
<b>Health-related quality of life, EQ5D-5L</b>									
<b>EQ5D index value, -0.624 to 1.000</b>									
Intervention group, n = 26	0.67	0.14	0.72	0.19	0.05	0.16	-0.01	-0.09 to 0.07	.814
Comparator group, n = 25	0.64	0.19	0.70	0.21	0.06	0.13			
<b>EQ-VAS, 0-100</b>									
Intervention group, n = 24	58.0	19.1	62.1	20.3	4.1	22.4	-2.0	-14.9 to 10.9	.757
Comparator group, n = 25	58.2	22.5	64.2	18.1	6.1	22.5			
<b>Symptoms of anxiety and depression, HSCL-25 0-4</b>									
Intervention group, n = 21	1.83	0.45	1.52	0.38	-0.30	0.46	-0.15	-0.41 to 0.11	.241
Comparator group, n = 22	1.78	0.51	1.64	0.54	-0.15	0.39			
<b>Subjective Health Complaints, SHC 0-87</b>									
Intervention group, n = 22	20.9	11.6	22.4	12.2	1.5	16.8	7.2	-2.6 to 17.1	.146
Comparator group, n = 25	20.3	11.6	14.6	11.2	-5.7	16.7			
<b>Urinary incontinence, ICIQ-UI, 0-21 (median, IQR)</b>									
Intervention group, n = 23	4.0	8.0	3.0	6.0	0.0	3.0			.370 <sup>a</sup>
Comparator group, n = 25	3.0	4.5	3.0	6.5	0.4	1.5			

(Continues)

**TABLE 5** (Continued)

	Baseline		12 months		Change from baseline to 12 months		Difference in change between the groups		
	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean	95% CI	P
Anal incontinence, St. Marks 0-24 (median, IQR)									
Intervention group, n = 24	0.0	2.0	0.0	2.0	0.0	0.0			.120 <sup>a</sup>
Comparator group, n = 25	0.0	7.5	0.0	4.0	0.0	2.0			
Obstructed defecation, ODS 0-25 (median, IQR)									
Intervention group, n = 25	5.0	8.0	6.0	7.0	-2.0	4.0			.337 <sup>a</sup>
Comparator group, n = 25	7.0	8.0	6.0	7.0	0.0	3.5			

Note: Bold values are statistically significant ( $P < .05$ ).

Abbreviations: HSCL-25, Hopkins Symptom Check List; ICIQ-UI; ICIQ -Urinary Incontinence Short Form; IQR, interquartile range; NRS, numeric rating scale; ODS, obstructed defecation score; SD, standard deviation; SHC, Subjective Health Complaints questionnaire; SMT, Standardized Mensendieck Test; TSK-13, Tampa Scale of Kinesiophobia.

<sup>a</sup>Mann-Whitney *U* test.

previous RCT by Haugstad et al<sup>25</sup> The clinical relevance of a difference of only 1.2 must be questioned, despite its statistical significance. Approximately one quarter of the women in the intervention group reported unchanged or worse mean pain intensity scores, which contrasts with results by Haugstad et al, where only one of the 19 women in the group receiving physical therapy combined with cognitive techniques reported unchanged pain intensity.<sup>25</sup> This possibly reflects the differences between the study samples, but it could also indicate a need for refining both the study intervention and selection criteria. Some women with CPP may respond better to individual treatment. Group-based treatment as well as treatments aiming to change personal habits can be challenging for some patients.<sup>7</sup> Future studies should investigate predictors for different treatment approaches.<sup>29</sup>

A recently published RCT on 49 women with CPP by Ariza-Mateos et al compared a combination of manual physical therapy, exercises, and pain education with manual physical therapy alone.<sup>30</sup> The primary outcome was fear-avoidance behavior, which showed significantly more improvement in the combined treatment group. The difference between the groups regarding pain reduction was 1.1, which was similar to our result. The larger difference between the groups in the study by Haugstad et al could be because the combined physical therapy treatment was compared with standard gynecological care only, and the participants had higher baseline pain scores.<sup>25</sup>

The greatest reduction in mean pain intensity in the intervention group was observed between 6 and 12 months. This suggests that the long duration of the treatment is important, which is in accordance with theories of behavioral change that emphasize that it takes time to integrate new experiences and obtain lasting changes.<sup>31</sup> A subject for future studies would be to perform another follow up 12 months after the end of treatment.

Reduced pain intensity reflects only one aspect of positive changes for women with the complex condition of CPP, and

selection of appropriate end points is challenging.<sup>1,2</sup> The greater improvements in respiratory patterns and pain-related fear of movement in the intervention group corroborate with the previous results presented by Haugstad et al<sup>25</sup> and Ariza-Mateos et al.<sup>30</sup> Improved respiratory patterns, in terms of increased deep respiration with abdominal expansion, may be related to the relaxation techniques and body awareness therapy applied in the study intervention, so may be related to pain reduction. Pain-related fear of movements is emphasized as a key mechanism for the development and maintenance of chronic pain, and hence it is a relevant outcome to include.<sup>32</sup>

For health-related quality of life, we observed that the baseline scores for EQ5D-5L were low compared with the population scores.<sup>33</sup> No significant differences in change were found for either the EQ5D-index or EQ-VAS scores. In future studies, a symptom-specific measure of health-related quality of life might add more information, because EQ5D-5L may not be sufficiently responsive to detect changes.<sup>34</sup> Differences between the groups for symptoms of anxiety and depression were not observed. The outcome measures for sexual, urological, and bowel functions were included according to the CPP definition,<sup>2</sup> and no group differences were detected.

Studying complex interventions for a complex condition such as CPP has several challenges. The optimal treatment is still uncertain, and more research is needed to refine the multimodal intervention, probably by tailoring the treatment for different subgroups of women with CPP.

## 5 | CONCLUSION

The reduction in the mean pelvic pain with group-based multimodal physical therapy was significantly more than that of primary-care physical therapy after 12 months. However, the expected difference

was not found, and we cannot conclude that a group-based intervention including body awareness therapy, patient education, and cognitive techniques is clinically better than primary-care physical therapy for women with CPP.

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## CONFLICT OF INTEREST

The authors report no conflicts of interest in connection with this paper.

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#### SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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