## **Research Article**

# Integrative Physical Therapy Versus Pelvic Floor Muscle Training for Post-Prostatectomy Stress Urinary Incontinence: A Randomized Controlled Trial

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**Running title:** Integrative therapy for post-prostatectomy incontinence

#### **Abstract**

**Background**: Post-prostatectomy stress urinary incontinence (PPSUI) is a common complication following radical prostatectomy. This study compared the efficacy of integrative physical therapy (IPT) and supervised pelvic floor muscle training (PFMT) in managing PPSUI.

**Methods**: Sixty-six men aged 50–80 years with PPSUI were randomly assigned to IPT, PFMT, or control groups. The IPT program included electrotherapy, manual therapy, diaphragmatic

breathing, and PFMT. The PFMT group received supervised PFMT. The control group received sham electrotherapy. All interventions were delivered in 12 sessions over four weeks. Outcome measures included voided volume, fluid intake, micturition frequency, incontinence frequency, and health-related quality of life assessed using the SF-12 questionnaire.

**Results**: Both IPT and PFMT significantly reduced micturition and incontinence frequency and improved SF-12 scores compared with the control group (p<0.001). The control group showed no significant improvements across any outcome measures. IPT demonstrated superior improvements relative to PFMT in micturition frequency, incontinence frequency, and SF-12 scores (p<0.05).

**Conclusion**: Both IPT and PFMT are effective for PPSUI, with IPT showing greater overall efficacy.

**Keywords**: Pelvic floor muscle training, Electrical stimulation; Urinary incontinence; Prostatectomy; Quality of life

#### Introduction

Radical prostatectomy (RP) is a common and effective treatment for localized prostate cancer; however, post-prostatectomy stress urinary incontinence (PPSUI) remains a substantial and persistent problem, impacting both men's physical function and quality of life (1). PPSUI arises primarily from disruption of the urethral sphincter mechanism, reduced peri-urethral support, and compromised neuromuscular coordination after surgery (2). The rhabdosphincter and pelvic floor muscles are crucial for urinary continence, acting in concert with the diaphragm to regulate intra-abdominal pressure (IAP) and maintain urethral closure. When these structures are impaired, the ability to modulate IAP and sustain pelvic floor contraction diminishes, which undermines postural-pelvic synergy and predisposes to leakage(3).

Given this interplay between muscular support and abdominal pressure, therapeutic strategies that simultaneously address pelvic floor activation and IAP regulation may offer superior benefits compared to interventions focused solely on isolated pelvic floor exercises (3,4). Pelvic floor muscle training (PFMT) is widely recognized as a first-line conservative therapy for PPSUI, with multiple studies showing improvements in sphincter strength and continence outcomes (5). However, PFMT alone may not fully correct deficits in diaphragmatic coordination, lumbopelvic stability, or neuromotor recruitment, all of which significantly contribute to functional continence (6).

Integrative physical therapy (IPT) is a multimodal rehabilitative approach designed to target these complex mechanisms. IPT combines diaphragmatic breathing, electrotherapy, manual therapy, and PFMT to promote neuromuscular recruitment, optimize IAP modulation, and enhance pelvic floor function within a cohesive, functionally integrated framework (7-9). Despite its theoretical advantages, there is limited empirical evidence directly comparing IPT with standard supervised PFMT in men suffering from PPSUI.

Thus, the objective of this randomized controlled trial was to compare the effectiveness of IPT versus supervised PFMT in reducing urinary incontinence symptoms and improving health-related quality of life in men with PPSUI following RP. We hypothesized that IPT would yield greater improvements due to its multimodal, physiologically integrated design.

## Material and methods Study design:

This randomized controlled trial compared the effects of two active interventions, integrative physical therapy (IPT) and supervised pelvic floor muscle training (PFMT), with a sham-

controlled group in men with PPSUI. Participants were randomly assigned to PFMT, IPT, and control groups. The study protocol was independently reviewed and approved by the relevant ethical board. This study was approved by the Rehabilitation Science School of the University of Medical Science Ethics Committee (IR.SBMU.RETECH.REC.1399.1317). This study was registered in the Iranian registry of clinical trials (IRCT20151028024751N1).

This study was conducted in collaboration with the urology department of regional hospitals. Patient recruitment occurred during routine visits between September 2020 and March 2021 and after that, the study procedure started. A total of 66 patients were selected according to study criteria and randomly assigned to one of three groups using a random number generator: PFMT, control, or an IPT approach. This study design, conduct, and reporting adhered to Consolidate Standards of Reporting Trials (CONSORT) guidelines.

All participants provided written informed consent before enrollment, with explicit acknowledgment of their right to withdraw from the study at any time without penalty. Upon entry, comprehensive baseline assessments were conducted, encompassing demographic data (age, height), detailed medical history, and complete medication reconciliation. Furthermore, baseline Health-related quality of life (HRQoL) status and voiding patterns (including voided volume (ml), fluid intake (ml), micturition frequency (per day), micturition frequency, and incontinence frequency (per day)) were characterized through the administration of the SF-12 Health Survey and 7-day Voiding diaries before the start of the study before randomization.

## Eligibility criteria:

Participants were male patients aged 50 to 80 years with a diagnosis of PPSUI confirmed by urological specialists. Exclusion criteria encompassed: pre-existing major neurological conditions (e.g., Parkinson's disease, multiple sclerosis, central nervous system anomalies); uncontrolled diabetes mellitus; peripheral neuropathy or other conditions affecting the peripheral nervous system; significant orthopedic comorbidities of the spine or pelvis; current use of duloxetine or other pharmacologic treatments for incontinence; and prior post-surgical rehabilitation for incontinence. Patients with a history of radiotherapy or chemotherapy for cancer were also excluded. The interval between radical prostatectomy and study enrollment was 1 to 3 months (3, 10).

#### **Outcome measures:**

HRQoL was evaluated using the 12-item Short-Form Health Survey (SF-12), which is a validated and reliable instrument commonly used in similar research (11). A previously validated Persian translation of the SF-12 was employed(12). This instrument assesses HRQoL across eight domains: 1) physical functioning (limitations in physical activities due to health problems); 2) social functioning (limitations in social activities due to physical or emotional problems); 3) role-physical (limitations in usual role activities due to physical health problems); 4) bodily pain; 5) mental health (psychological distress and well-being); 6) role-emotional (limitations in usual role activities due to emotional problems); 7) vitality (energy and fatigue); and 8) general health perceptions. SF-12 composite scores were interpreted according to established cut-points: 37-48 indicating good HRQoL, 25-36 indicating moderate HRQoL, and 12-24 indicating low.poor HRQoL according to established cut-points previously validated in HRQoL research (13). Voiding diaries were utilized to assess incontinence parameters, including voided volume, fluid intake, micturition frequency, and incontinence frequency. The validity and reliability of voiding diaries for this purpose have been previously demonstrated (14).

## **Procedure:**

To mitigate potential bias, a randomized, assessor-blinded, sham-controlled trial was conducted. The outcome assessor was blinded to group allocation, but participants were aware of their assigned group due to the nature of the interventions. Participants were allocated to receive either 12 sessions of active physiotherapy (IPT or PFMT groups) or a sham intervention (control group) over a one-month period. A blinded assessor, independent of the treatment allocation, collected all outcome measures at baseline and immediately following the intervention.

Baseline assessments included demographic data (height, weight, age), a one-week preintervention voiding diary, and the SF-12 Health Survey to evaluate baseline health-related quality of life. Weekly voiding diary entries were recorded by participants throughout the one-month intervention period, with an additional week of data collected post-intervention. The SF-12 Health Survey was re-administered at the end of the intervention to assess changes in health-related quality of life.

## **Intervention:**

The IPT group received 12 sessions of a multi-modal intervention comprising: (1) interferential current (IF) electrotherapy, (2) neuromuscular manual therapy, and (3) a targeted therapeutic exercise program (diaphragmatic breathing, the "knack" maneuver, and pelvic floor muscle training (PFMT)).

The rationale for this combined approach was to leverage synergistic effects. Electrotherapy and manual therapy aimed to facilitate targeted musculature, optimizing patient performance of breathing and pelvic floor exercises (3). Diaphragmatic breathing was incorporated to modulate intra-abdominal pressure, thereby enhancing the efficacy of PFMT (7). Each treatment session in the multi-modal arm lasted approximately 55 minutes, with both groups completing 12 sessions over four weeks (three sessions per week).

- 1. Electrotherapy: Interferential current (IF) was administered for 15 minutes at 100 Hz frequency, using a bipolar cross-configuration with electrodes placed bilaterally on the medial thighs and lower abdomen. This modality was employed to prepare the pelvic floor musculature for exercise and facilitate voluntary contractions, demonstrating positive effects on urinary incontinence (15).
- 2. Manual Therapy: Neuromuscular therapy was integrated to modulate IAP via targeted treatment of the diaphragm and iliopsoas musculature, with the potential to mitigate urinary incontinence. This mechanism is hypothesized to involve trigger point and myofascial release, promoting restoration of musculoskeletal and central nervous system homeostasis. Modulation of IAP can optimize PFMT, as pelvic floor muscle contraction can inadvertently elevate intra-abdominal pressure, potentially exacerbating PPSUI. Furthermore, this technique may enhance diaphragmatic excursion, supporting the subsequent breathing exercises (3).
- **3.** Exercise Therapy: All participants in the treatment group received initial instruction and a standardized home exercise program. Subsequent sessions included therapist supervision and exercise correction (16). Home exercise frequency was individualized based on participant presentation and capacity. The exercise program consisted of: 1) diaphragmatic breathing exercises to regulate IAP fluctuations during PFMT, mitigating the risk of PPSUI exacerbation (7); 2) the "knack" maneuver to enhance pelvic floor muscle awareness and control during activities that elicit increases in IAP(17), with potential synergistic benefits from the preceding diaphragmatic breathing exercises; and 3) PFMT, initiated after participants demonstrated

adequate pelvic floor muscle awareness and control (16). The IPT group received training from physiotherapists for diaphragmatic breathing in addition to knack and Kegel exercises (7). Home-exercise adherence was monitored using participant-reported daily logs, which were checked at each treatment session.

The PFMT group received a targeted therapeutic exercise program (the "knack" maneuver, and PFMT for 12 sessions (three sessions per week)). The IPT and PFMT group received training from physiotherapists for knack exercise first to get familiarized with pelvic floor muscles and then Kegel exercise to improve the performance of pelvic floor muscles in control of incontinence (5, 16).

The control group received 12 sessions of sham electrotherapy, utilizing identical electrode placement (bilateral medial thighs and lower abdomen) but with no current. The control group received only sham electrotherapy and did not perform any therapeutic exercises.

## Data analysis

Sample size was calculated a priori using G\*Power (version 3.1). Assuming a medium-to-large effect size (Cohen's f = 0.40) for between-group differences on the primary outcome (incontinence frequency), with an alpha level of 0.05 and power  $(1-\beta)$  of 0.80 for a one-way ANOVA with three groups, the required sample size was 60 participants (20 per group)(18). To account for an anticipated 10% attrition rate, the final target sample size was set at 66 participants. The assumed effect size (f = 0.40) was based on previous randomized controlled trials evaluating PFMT and multimodal rehabilitation interventions for post-prostatectomy urinary incontinence, which reported effect sizes in a comparable range (19, 20). The statistical analysis was used with SPSS-22 software. The Kolmogorov-Smirnov (K-S) test was used to assess the normality of the baseline and demographic variables. Since the K-S test showed no significant deviations from normality, ANOVA tests were then employed to compare the groups (IPT, PFMT, and control). Finally, where ANOVA revealed significant differences between groups, post hoc Tukey's Honestly Significant Difference (HSD) tests were used for multiple comparisons between three groups. The significant levels were considered <0.05.

#### **Results**

A total of 66 participants completed the study (Control n=22, PFMT n=22, IPT n=22). Table 1 presents demographic characteristics, baseline clinical variables, and Kolmogorov–Smirnov (K-S) test results for each group. No statistically significant baseline differences were observed among the groups for demographic or clinical variables (all p>0.05). K-S test values reflect baseline (preintervention) normality assessment.

Table 1. Demographic and baseline characteristics of participants in each group (Control n=22, PFMT n=22) and K-S test results.

		Control group (n=22)		IPT (n=22)		PFMT (n=22)	
Variable		mean ± SD	K-S result	mean ± SD	K-S result	mean ± SD	K-S result
Height (cm)		170.4±2.2	0.200	170.2±2	0.200	169.8±2.1	0.200
Weight (Kg)		67.1±3.1	0.200	68.4±3.6	0.142	68.5±3.7	0.135
BMI (body mass (kg.m²)	index)	23.1±1.2	0.200	23.6±1.4	0.200	23.7±1.5	0.200

Age (years)	64.4±3.5	0.158	64.6±3.7	0.200	65.5±2.8	0.200
SF12	29.1±0.9	0.200	30.4±0.9	0.200	36.0±0.7	0.200
Voided volume (ml)	1611.7±82.1	0.200	1601.6±66.7	0.200	1611.0±42	0.200
					.9	
Fluid intake (ml)	2031.5±120.9	0.200	1979.5±125.1	0.200	2198.8±15	0.200
			_		0.0	
			7		0.3	
Micturition frequency (per	10.1±0.4	0.200	9.8±0.4	0.200	0.3 10.2±0.4	0.200
Micturition frequency (per day)	10.1±0.4	0.200	9.8±0.4	0.200		0.200
	10.1±0.4 7.1±0.4	0.200	9.8±0.4 8±0.5	0.200		0.200
day)					10.2±0.4	

Notes: SD = standard deviation, K-S = Kolmogorov–Smirnov test, BMI = body mass index, IPT = integrative physical therapy group, PFMT = Pelvic floor muscle training group. Kolmogorov–Smirnov tests were conducted on baseline data only (pre-intervention).

Baseline clinical measurements, including fluid intake (p=0.39), voided volume (p=0.98), micturition frequency (p=0.75), incontinence frequency (p=0.33), and SF-12 composite score (p=0.59), showed no significant differences between groups (Table 1). This confirmed suitability for subsequent parametric analyses.

Table 2. ANOVA results for dependent variables before and after intervention (Control n=22, PFMT n=22, IPT n=22).

Variable		Control	IPT	PFMT	P-value
		Mean	mean	mean	
		± SD	± SD	± SD	
SF12	befor	29.1±0.9	$30.4\pm0.9$	$36\pm0.7$	p = 0.593
	e				
	after	30.8±1	42±0.5	36±0.7	P<0.001*
Voided volume (ml)	befor	1611.7±82.	1601.6±66.7	1611.0±42.9	P = 0.982
	e	1			
	after	1514±83.7	1343.3±74.4	1229.7±70.1	P=0.036*
Fluid intake (ml)	befor	2031.5±12	1979.5±125.1	2198.8±150.3	P= 0.392
	e	0.9	7		
	after	1895.5±12	1683.6±124.2	1639.05±116.1	P=0.288
		4.2	8		
<b>Micturition frequency (per</b>	befor	10.1±0.4	9.8±0.4	10.2±0.4	P = 0.756
day)	e				
	after	9.2±0.3	6.9±0.2	8.1±0.2	P<0.001*
<b>Incontinence frequency (per</b>	befor	7.1±0.4	8±0.5	7.2±0.5	P = 0.334
day)	e				
-	after	6.5±0.4	1.1±0.2	3.9±0.4	P<0.001*

Notes: \* =significant difference, IPT = integrative physical therapy group, PFMT = Pelvic floor muscle training group

Table 2 summarizes pre- and post-intervention values for all outcome variables. ANOVA revealed significant between-group differences following the intervention for SF-12 (p<0.001), voided

volume (p=0.036), micturition frequency (p<0.001), and incontinence frequency (p<0.001), whereas fluid intake showed no significant group effect (p=0.288)

SF-12 scores increased in all groups post-intervention, with the IPT group demonstrating the greatest improvement, followed by PFMT and control. Post hoc Tukey tests indicated significantly higher SF-12 scores in both IPT (p<0.001) and PFMT (p<0.001) compared with the control group, and significantly higher scores in IPT compared to PFMT (p<0.001).

Voided volume decreased in all three groups after the intervention. However, the reduction was significantly greater in the PFMT group compared with the control group (p=0.028), while no significant difference was observed between IPT and PFMT (p=0.547) or between IPT and control (p=0.261).

Fluid intake decreased slightly in all groups, with no statistically significant differences between groups (p=0.288), indicating comparable fluid behavior across groups during the intervention period.

Micturition frequency decreased in all groups following the intervention, with the IPT group showing the greatest reduction. Post hoc analysis revealed that IPT demonstrated significantly lower micturition frequency than both the control (p<0.001) and PFMT groups (p=0.036). The PFMT group also showed a significant reduction compared with the control group (p=0.045)

Incontinence frequency decreased in all groups, with the IPT group showing the most pronounced reduction. Tukey HSD tests showed that both IPT (p<0.001) and PFMT (p<0.001) significantly outperformed the control group, and IPT demonstrated significantly lower incontinence frequency than PFMT (p<0.001).

Table 3. Tukey HSD post hoc comparisons for dependent variables (Control n=22, PFMT n=22, IPT n=22).

	Group I	Group J	Mean difference	SE	P-value
Incontinence	Control	IPT	5. 36	0.549	P<001*
frequency (per day)	Control	PFMT	2.63	0.549	P<001*
	IPT	PFMT	-2.72	0.549	P<001*
Voided volume (ml)	Control	IPT	170.68	107.97	0.261
	Control	PFMT	284.22	107.97	$0.028^{*}$
	IPT	PFMT	113.45	107.97	0.547
<b>Micturition frequency</b>	Control	IPT	2.31	0.465	P<001*
(per day)	Control	<b>PFMT</b>	1.13	0.465	$0.045^{*}$
	IPT	PFMT	-1.18	0.465	$0.036^{*}$
SF12	Control	IPT	-11.27	1.12	P<001*
	Control	PFMT	-5.27	1.12	P<001*
	IPT	PFMT	6	1.12	P<001*

Notes: \* =significant, SE: standard error, IPT = integrative physical therapy group, PFMT = Pelvic floor muscle training group

## **Discussion:**

This study investigated the effectiveness of PFMT and a novel IPT approach for managing PPSUI. Our findings confirm that therapist-supervised PFMT, incorporating the "knack" maneuver

alongside the Kegel exercise, yields significant improvements in key clinical parameters, including incontinence and micturition frequency, voided volume, and HRQoL. These results are consistent with previous studies demonstrating the positive impact of PFMT on post-prostatectomy urinary incontinence (5, 16). The inclusion of the "knack" maneuver, designed to optimize pelvic floor muscle contraction during increased IAP, likely contributed to the observed improvements by enhancing patients' ability to proactively support the rhabdosphincter's function during periods of increased abdominal pressure. This is crucial, as the rhabdosphincter plays a vital role in maintaining continence, particularly after prostatectomy when other continence mechanisms (Proximal intrinsic sphincter and urethral suspensory mechanism) compromised(21). Previous studies have shown that the Knack maneuver improves pelvic floor muscle function and reduces stress incontinence episodes (10, 21).

However, recognizing the limitations of isolated PFMT in addressing the complex interplay of factors contributing to PPSUI, we explored the potential benefits of an IPT intervention. This multi-modal approach, combining electrotherapy, manual therapy, and therapeutic exercise, aimed to synergistically target pelvic floor muscle function, IAP regulation, and the coordination between these systems, ultimately supporting optimal rhabdosphincter function. Previous studies have reported that combining electrical stimulation and manual therapy with pelvic floor exercises can enhance continence outcomes compared to exercises alone (3, 6, 8, 9, 15). The IPT group also experienced significant improvements including incontinence and micturition frequency, and HRQoL, over both control and PFMT groups suggesting that this comprehensive strategy may offer advantages over PFMT.

The rationale behind the IPT approach was to address the multifaceted nature of PPSUI. To address the common challenge of patients struggling with effective pelvic floor muscle activation during PFMT, IF was included in the treatment. IF aims to stimulate muscle contractions, potentially leading to increased muscle strength. This enhanced muscle strength, in turn, may improve the function of the rhabdosphincter, a critical muscle for urinary continence, by providing indirect support.(22). Manual therapy targeting the diaphragm and iliopsoas aimed to optimize IAP regulation, a critical factor in continence, by improving pelvic stability and the coordinated action of the pelvic floor and diaphragm, which in turn influences the functional environment of the rhabdosphincter (3). Previous evidence supports that diaphragmatic breathing and targeted manual therapy can improve intra-abdominal pressure regulation and optimize pelvic floor function (4, 7). Furthermore, the inclusion of breathing exercises, particularly diaphragmatic breathing, aimed to further enhance IAP control and promote relaxation of abdominal muscles during PFMT, potentially maximizing the effectiveness of the exercises and reducing strain on the rhabdosphincter (7).

While the IPT intervention is more resource-intensive than standard PFMT, its design reflects an attempt to overcome the limitations of conventional physiotherapy for PPSUI. The superiority of IPT over PFMT was quantitatively evident in several outcomes. Incontinence frequency decreased by 2.72 episodes per day in the IPT group compared with PFMT, corresponding to a large effect size (Cohen's d  $\approx$  1.06). Micturition frequency also decreased by 1.18 episodes per day, representing a moderate effect size (d  $\approx$  0.54). Additionally, HRQoL improved by 6 points on the SF-12, a change associated with a large effect size (d  $\approx$  1.14) and exceeding established MCID thresholds. These findings indicate that the statistically significant improvements observed in the IPT group also translate into clinically meaningful benefits for continence and quality of life By integrating synergistic modalities, the IPT approach aimed to more effectively address the complex pathophysiology of PPSUI, particularly the often-overlooked role of IAP dysregulation and its

impact on rhabdosphincter function (23). Unlike previous multi-modal physiotherapy programs, the IPT protocol in this study incorporates several distinct elements. Earlier studies typically combined electrical stimulation with PFMT alone (3, 15), whereas our approach integrates targeted manual therapy to the diaphragm and iliopsoas specifically to modulate intra-abdominal pressure (IAP), followed by structured diaphragmatic breathing retraining to optimize pelvic floordiaphragm coordination. This sequencing (manual release → breathing correction → IF-assisted activation → supervised PFMT) has not been previously applied in post-prostatectomy patients. Additionally, most multi-modal reports have focused on non-post-prostatectomy populations (7, 9), while our protocol was designed for the unique continence mechanism deficits following radical prostatectomy. These distinctions support the novelty of IPT and may explain its superior clinical outcomes compared with PFMT. The combination of enhanced pelvic floor muscle activation through IF, coupled with targeted IAP management through manual therapy and breathing exercises, may explain the observed benefits of the IPT intervention by optimizing the rhabdosphincter's ability to effectively contribute to continence. These findings align with previous studies indicating that multi-modal interventions can more effectively improve continence outcomes than isolated PFMT (3, 8, 9, 15). Future research comparing IPT directly to PFMT is warranted to definitively determine the relative efficacy of these approaches and to further explore the mechanisms by which the IPT intervention exerts its effects, particularly concerning its influence on rhabdosphincter function and its interaction with IAP. Furthermore, investigations into the long-term effects of both PFMT and IPT are necessary to inform clinical practice and optimize the management of PPSUI.

## Limitation and suggestion

The main limitation of this study was the lack of long-term follow-up due to limitations in patients' visits. Future studies could follow up with patients to assess the long-term effects of treatments.

## **Conclusion**

The findings demonstrated that the IPT intervention resulted in significantly greater reductions in incontinence frequency and micturition frequency, along with significantly improved HRQoL scores, compared to the PFMT group. These findings suggest that the IPT approach offers superior efficacy in managing PPSUI. The observed benefits of combining IF with PFMT are consistent with previous research demonstrating the enhanced effects of combined electrotherapy and exercise. Similarly, the inclusion of breathing exercises aligns with studies indicating their synergistic benefits when combined with PFMT for improving UI outcomes.

PPSUI presents a significant clinical challenge with various management available strategies. The substantial improvements observed in both the IPT and the PFMT groups further support the value of targeted physiotherapy in managing this condition.

## **Ethical Considerations**

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (2002 version) and with the ethical standards of the country in which the research was performed. Ethical approval was obtained from the institutional ethics committee, and all participants provided written informed consent prior to inclusion in the study. The study protocol was independently reviewed and approved by the relevant ethical board. This study was approved by the Rehabilitation Science School of the University of Medical Science Ethics Committee

(IR.SBMU.RETECH.REC.1399.1317). This study was registered in the Iranian registry of clinical trials (IRCT20151028024751N1).

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#### Declarations of interest

- Mohammad Sheibanifar: The author declares that there is no conflict of interest
- Zahra Ebrahimabadi: The author declares that there is no conflict of interest
- Hoda Niknam: The author declares that there is no conflict of interest
- Farshad Okhovatian: The author declares that there is no conflict of interest
- Alireza Akbarzadeh Baghban :The author declares that there is no conflict of interest
- Marzieh Mortezanejad: The author declares that there is no conflict of interest

## **Author's participation**

- Mohammad Sheibanifar: Study design, implementation of intervention, manuscript drafting
- Zahra Ebrahimabadi: implementation of intervention, manuscript drafting
- Hoda Niknam: Data collection
- Farshad Okhovatian: Study design, data analysis
- Alireza Akbarzadeh Baghban :Data analysis

Marzieh Mortezanejad: Manuscript editing

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