JRSR 9 (2022) 110-117

Journal of Rehabilitation Sciences and Research

Journal Home Page: jrsr.sums.ac.ir

Original Article

Effects of Pelvic Floor Physiotherapy, with or without Weight Loss, on Urinary Incontinence in Obese Women: A non-Randomized Single Blind Clinical Trial

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ARTICLE INFO

Article History:
Received: 13/10/2021
Revised: 27/12/2021
Accepted: 30/01/2022

Keywords:
Obesity
Pelvic floor
Physiotherapy
Urinary incontinence

Please cite this article as:
Babazadeh-Zavieh SS, Vasaghi-Gharamaleki B, Nikjooy A, Haeri SMJ, Sarrafzadeh J. Effects of Pelvic Floor Physiotherapy, with or without Weight Loss, on Urinary Incontinence in Obese Women: A non-Randomized Single Blind Clinical Trial. JRSR. 2022;9(3):110-117.

ABSTRACT

Background: Obesity is known to be an important risk factor in the development of UI (urinary incontinence). Physiotherapy (exercise therapy and biofeedback) has been presented as a common treatment for the improvement of UI. Pelvic floor physiotherapy (PFPT) with weight loss (WL) may significantly improve UI in obese women. This study aimed to compare the effects of PFPT with and without WL on UI symptoms in obese women.

Methods: This non-randomized clinical trial was performed with 51 middle-aged obese women with UI. Twenty-nine women in the PFPT group received 12 sessions of PFPT, and 22 women in the PFPT+WL group received 12 sessions of PFPT and nutritionist recommendations for WL. The outcome measures included anthropometric measurements, strength and endurance of pelvic floor muscles, intravaginal pressure (IVP), international consultation on incontinence questionnaire (ICIQ-SF), visual analog scale (VAS), and quality of life (QOL). All measurements were taken at baseline and after the 12-session treatment.

Results: The PFPT+WL group had a 4.95 kg weight loss (P<0.001). Strength and endurance of PFM, IVP, ICIQ UI-SF, VAS, and QOL showed significant improvement in both groups (P<0.001). The ICIQ UI-SF and total I-QOL in the PFPT+WL group were significantly different from those in the PFPT group (P=0.015, P=0.033, respectively), (95% CI: 2.23-5.10 vs. 2.85-5.35 and 180.48-214.67 vs. 164.13-203.39, respectively).

Conclusion: The proposed protocol of applying PFPT with WL compared to PFPT alone led to more significant improvement in UI severity and QOL in middle-aged obese women with UI.

Introduction

According to the International Continence Society (ICS), urinary incontinence (UI) is any kind of involuntary leakage of urine that impairs personal hygiene and social relationships [1]. Three main types of UI are stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI) [1]. In 2021, a study reported that SUI affects about 40% of women in the United States [2]. Ahmadi et al. reported a 38.4% prevalence of UI among 40-50-year-old women in Iran [3].

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Obesity is known to be an important risk factor in the development of UI [4, 5]. According to the Centers for Disease Control and Prevention (CDC), overweight and obesity are defined as a body mass index (BMI) of 25.0–30.0 and >30 kg/m^2, respectively [6].

In obese people, it seems that increased intra-abdominal pressure applies mechanical stress to the pelvic floor muscles (PFM) and eventually leads to UI [7]. Factors associated with obesity such as impaired fasting blood glucose and type 2 diabetes can increase the risk of UUI in obese people [8]. According to Li et al., increased BMI, waist circumference (WC), and waist-height ratio (WHtR) increases the risk of developing SUI and MUI [9].

Evidence supports strengthening and retraining the PFM as the basic treatment for UI [10, 11]. Pelvic floor physiotherapy (PFPT) has been presented as a common therapeutic approach for the improvement of UI [10, 12, 13]. Several studies have examined the effects of weight loss (WL) on UI symptoms in obese women [10, 14, 15]. In a review study by Dumoulin et al., high WL improved QOL in obese people with UI, and moderate WL, if combined with exercise, was effective in reducing UI symptoms, too [10].

Weight loss followed by PFPT may result in greater improvements in UI symptoms and QOL scores in obese women with UI. Therefore, the purpose of the current study was to compare the effects of PFPT with and without WL on strength and endurance of PFM, intravaginal pressure (IVP), and UI severity in obese women with UI.

Methods

Study Design

This non-randomized single-blind clinical trial was conducted on 51 obese women who experienced urine leakage at least once a week, were aged 30 to 65 years, had a BMI of 30–55 kg/m^2, and were referred to the obesity treatment center of Iran University of Medical Sciences (IUMS) in Tehran, Iran. This study was published in the IRCT under registration number IRCT20140202016455N2, and the study protocol was approved by the Ethics Committee of IUMS (IR.IUMS.REC.1394.9311340001). The study was performed in the Rehabilitation Clinic of IUMS. UI was diagnosed by a gynecologist and also through patient completion of a self-administered incontinence questionnaire-urinary incontinence short form (ICIQ-UI SF). The PFPT group received a 12-session PFPT protocol (once/week), and the pelvic floor physiotherapy with weight loss group (PFPT+WL) received a 12-session PFPT protocol and nutritionist's recommendations for WL. The flow diagram of the study is shown in Figure 1.

Population

Obese and married women with UI were recruited for the study. Exclusion criteria comprised: 1) receiving any drug treatment for UI and genitourinary tract infection during the study; 2) history of pregnancy or delivery during the 6 months prior to the study; 3) history of any UI or pelvic surgery; 4) UI for neurological or functional

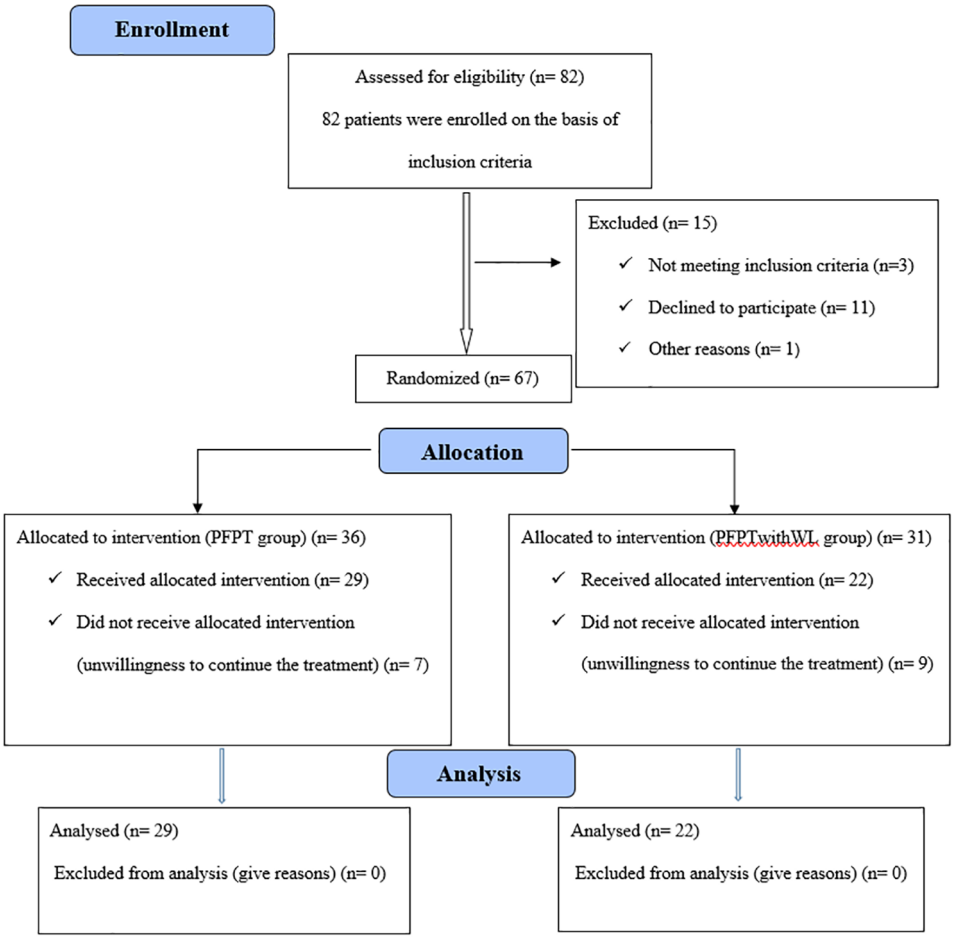

Figure 1: Study flow diagram

causes, and 5) coronary artery diseases or uncontrolled hypertension. Written informed consent was obtained from all patients before conducting the study protocol. Participation in the study was voluntary, and participants could withdraw from the study at any time.

Measurements

The primary outcomes were evaluated using anthropometric measurements, strength and endurance of PFM, IVP, severity of UI (based on the ICIQ UI-SF), visual analog scale (VAS)), and Incontinence Quality of Life questionnaire (I-QOL). Patients first completed a demographic information questionnaire and then anthropometric measurements (BMI, WC, waist-hip ratio (WHR), WHtR, and neck circumference (NC) ([16, 17] were taken. Subjects' weight was measured by a standard scale (Omron HBF -511) while they were wearing minimal clothing and no footwear [18]. To measure height, subjects were asked to stand without shoes next to a metric tape (Seca, Wall Mounted Height Meter, China) [18]. WC was measured from the narrowest point between the rib cage and iliac crest after full expiration, hip circumference (HC) was measured from the widest part of the hip with minimal clothing [18], and BMI, WHR, and WHtR were then calculated. NC was measured by measuring tape around the neck perpendicular to the neck axis just below the laryngeal prominence [19]. Each measurement was repeated three times, and the mean was recorded in the patient's file.

To assess PFM strength, patients were placed in the standard position (supine, knees bent, feet on the bed), and a vaginal examination was performed by a physiotherapist. The PFM strength was evaluated using the Oxford Scale with a 6-point classification (0-5) [20]. PFM endurance was measured by recording the duration of contraction in seconds. Maximum and average IVP were measured with a standard perineometer of ENRF NONIUS brand made in the Netherlands [20]. As there is no standard method for assessing PFM with a perineometer [21], patients were asked to lie in the standard position and perform three contractions for 5 seconds, with a rest interval of 8 second between each contraction, and the pressure recorded by the perineometer was obtained by calculating the area under the curve [20]. This test was repeated three times, and the mean value was recorded in the patient's file (Figure 2a). A standardized questionnaire of ICIQ-UI SF [22] and VAS were used to investigate UI severity. A standardized Persian version of the I-QOL questionnaire was used to assess patients' QOL [23]. This questionnaire contains 22 items and surveys the three features of limiting behavior (I-QOL A), psychosocial impacts (I-QOL PH), and social embarrassment (I-QOL S) [23]. All measurements were performed at baseline (T1) and after the 12-session treatment (T2).

Procedure

PFM performance and the treatment procedures were explained to the patients in each group. Patients in the PFPT group performed the PFPT protocol, which included PFM training with and without biofeedback once a week [24]. Participants in the PFPT+WL group received nutritionist recommendations for losing weight in addition to the PFPT protocol. The total duration of intervention in both groups was 3 months, and the two groups received the same PFPT protocol (12 sessions, once/week).

The PFPT protocol included PFM training in-clinic with biofeedback and at home without biofeedback. PFM training with biofeedback started the first week with 3 seconds contraction and 8 seconds of rest between each contraction for a total duration of 10 minutes. In the subsequent weeks, the exercises gradually reached 10 seconds contraction and 10 seconds rest for a total duration of 20 minutes. The patients had to contract the PFM to the maximum level specified on the biofeedback

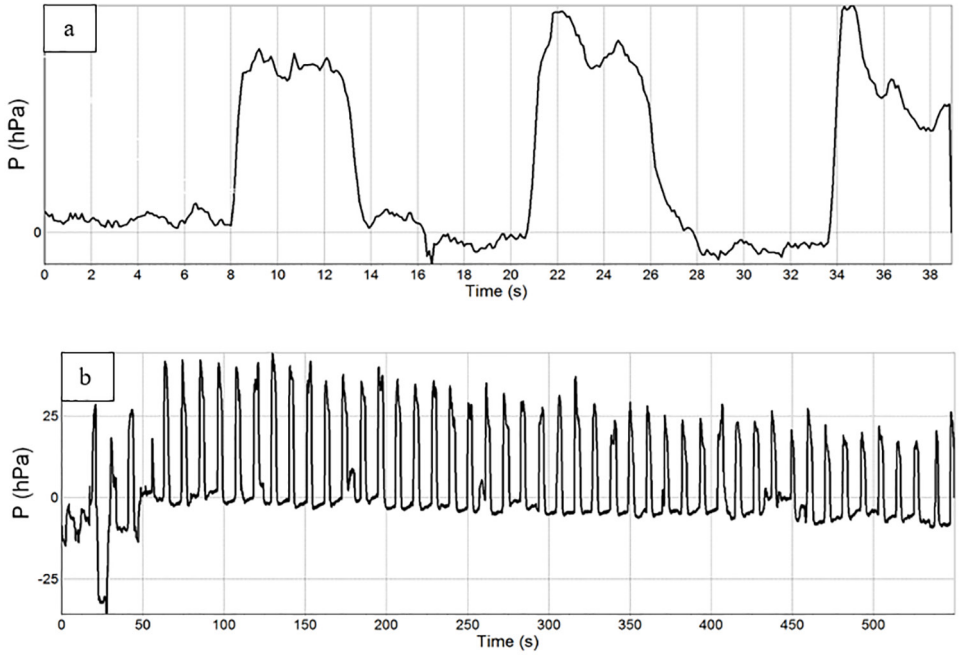

Figure 2: a. Perineometric test of one of the patients in the first session. b. Pelvic Floor Muscle (PFM) training with biofeedback of one of the patients in the first session. In the stated figures, each peak represents a contraction and the distance between two peaks represents the rest between the contractions.

chart by looking at the biofeedback monitor and using visual and auditory feedback (Figure 2b). Exercises on a Swiss ball and tilt board began in-clinic from the 9th session. Moreover, PFM training including Knack (contracting the PFM before and during a cough) and Kegel exercises, 10 repetitions in 3 sets, had to be performed once a day at home [24]. Patients were asked to do exercises in lying, sitting, and standing positions according to the progress of treatment (Table 1).

In the above figures, each peak represents a contraction, and the distance between two peaks represents the rest between the contractions.

Randomization and Blinding

In the current non-randomized control trial, patients were allocated into two groups based on their willingness to lose weight. A blinded and expert physiotherapist applied the clinical tests (assessor blind), and physiotherapy treatments were performed by another experienced physiotherapist who was also blinded to the assessment.

Sample Size

The required number of samples was calculated using the following formula:

$n=(Z_{1-\alpha/2}+Z_{1-\beta})^2 (S_1+S_2)^2/\Delta$

The sample size for the ICIQ-UI-SF of the current study, based on a similar study [25], was calculated to be 56 patients. With an estimated 20% dropout rate during treatment, 67 patients were recruited.

S_1=Standard deviation of group 1=3.5

S_2=Standard deviation of group 2=3.5

Δ=Difference in group means=3.7

$Z_{1-a/2}$=1.96 for 95% confidence interval

Z_{1-b}=power=85%

Among the 67 women recruited, five were unable to perform proper PFM contraction (7.4%), four could not tolerate the use of the perineometer vaginal probe (5.9%), and seven left the treatment for personal and unknown reasons (10.4%). Therefore, the dropout rate was higher than the estimated 20%, which may be because PFPT is a new treatment method in our country. Ultimately, 51 women participated in the study (Figure 1).

Statistical Analysis

SPSS (version 22) software was used for data analysis. Before performing any statistical analysis, the normal distribution of data was first assessed by the Kolmogorov-Smirnov test. Paired t-test was used to determine the effect of treatment on PFM endurance, UI severity, and QOL score, and the Wilcoxon test was used to evaluate PFM strength. The Independent t-test and Mann–Whitney U test were used to compare the effect of treatment in the two groups. The Pearson and Spearman correlation coefficient was used to examine the relationship between anthropometric and non-anthropometric variables. The significance level was set at ≤0.05 with a 0.95 confidence interval.

Results

Twenty-nine obese women with a mean age of 49.10±9.14 in the PFPT group and 22 women with a mean age of 51.40±7.22 in the PFPT+WL group completed the treatment. There was no statistically significant difference between the two groups in terms of age (P=0.335).

Anthropometric Indices

After treatment, no significant reduction was observed in any of the anthropometric indices in the PFPT group (P≥0.05). In the PFPT+WL group, however, all anthropometric indices decreased significantly (P<0.001) except for WHR (P=0.104). The average weight loss in this group was 4.95 kg (Table 2).

Strength and Endurance of PFM

There was no significant difference between the two groups at T1 (P=0.513 and P=0.535, respectively). Both groups showed significant improvement in PFM strength and endurance at T2 compared to T1 (P<0.001). There was no statistically significant difference between the two groups after treatment (P=0.353, P=0.962, respectively) (Table 3).

Table 1: Pelvic floor physiotherapy protocol prescription

Weeks	Biofeedback	Kegel exercises	Knack exercises
Weeks 1-4	Three to five seconds contraction of PFM, eight seconds rest, total duration of 10 minutes.	Three to five seconds contraction of PFM, eight seconds rest, three sets of ten repetitions, once a day while: 1. Sitting on a chair 2. Lying supine, hip joints 45°, and feet lying flat on the floor (crook lying) 3. Lying on the side 4. Lying supine, one leg raised towards the sky 5. Lying on the side, top leg raised towards the sky	Twenty contractions of PFM accompanied by coughing while: 1. Sitting on a chair 2. Standing 3. Squatting
Weeks 5-8	Six to nine seconds contraction of PFM, ten seconds rest, for a total duration of 15 minutes	Six to nine seconds contraction of PFM, ten seconds rest, three sets of ten repetitions, once a day while: 1.Standing with legs apart 2. Bridging while lying on the back 3. Lying prone, keeping legs straight and lifting one leg towards the sky 4. Standing, Keeping the leg straight, lifting it out to the side 5. Quadruped position, raise one hand to shoulder level	Twenty contractions of PFM accompanied by coughing while: 1. Sitting on a chair 2. Standing 3. Squatting
Weeks 9-12	Ten seconds contraction of PFM, ten seconds rest, for a total duration of 20 minutes	Ten seconds contraction of PFM, ten seconds rest, three sets of ten repetitions, once a day while: 1. Sitting on the ball 2. Sitting on the ball, extending one knee 3. Lying on the back, feet on the ball, bridging 4. Standing on the tilt board, raising arms to shoulder level	Twenty contractions of PFM accompanied by coughing while: 1. Sitting on a chair 2. Standing 3. Squatting

PFM: Pelvic floor muscles

Table 2: Anthropometric characteristics analysis in pelvic floor physiotherapy and pelvic floor physiotherapy with weight loss groups (n=51)

Variables (unit)	Groups	T1* Mean (±SD)	T2* Mean (±SD)	P value	95% CI (T1 vs. T2)
Weight (Kg)	PFPT*	93.08 (±15.41)	92.83 (±15.62)	0.174	87.22-98.95 86.89-97.77
	PFPT+WL*	104.47 (±23.05)	99.51 (±22.95)	<0.001	94.24-114.47 89.47-109.53
BMI (Kg/m^2)	PFPT	37.25 (±5.78)	37.14 (±5.84)	0.174	35.00-39.49 34.88-39.41
	PFPT+WL	41.06 (±7.47)	39.06 (±7.64)	<0.001	37.54-44.59 35.58-42.55
WC* (cm)	PFPT	111.20 (±11.36)	110.22 (±11.64)	0.062	106.88-115.53 105.79-114.65
	PFPT+WL	120.59 (±16.18)	116.68 (±16.72)	<0.001	113.41-127.76 109.26-124.09
HC* (cm)	PFPT	119.44 (±10.89)	118.91 (±11.38)	0.066	115.30-123.59 114.58-123.10
	PFPT+WL	124 (±14.94)	120.72(±14.47)	<0.001	117.37-130.62 114.30-127.14
NC* (cm)	PFPT	36.91 (±2.48)	36.84 (±2.54)	0.581	35.96-37.85 35.87-37.81
	PFPT+WL	38.36 (±3.27)	37.70 (±3.58)	<0.001	36.91-39.81 36.11-39.29
WHR*	PFPT	0.93 (±0.07)	0.92 (±0.07)	0.389	0.90-0.96 0.90-0.95
	PFPT+WL	0.97 (±0.08)	0.96 (±0.08)	0.104	0.93-1.01 0.92-1.00
WHtR*	PFPT	0.70 (±0.07)	0.69 (±0.07)	0.061	0.67-0.72 0.66-0.72
	PFPT+WL	0.76 (±0.10)	0.73 (±0.10)	<0.001	0.71-0.80 0.69-0.78

BMI: Body Mass Index, HC: Hip Circumference, NC: Neck Circumference, PFPT: Pelvic Floor Physiotherapy, PFPT+WL: Pelvic Floor Physiotherapy with Weight Loss, T1: Before treatment, T2: After 12-session treatment, WC: Waist circumference, WHR: Waist-Hip Ratio, WHtR: Waist Height Ratio. P<0.05

Intravaginal Pressure

There were no significant differences in average and maximum IVP between the two groups at T1 (P=0.52, P=0.197, restrictively). There was a statistically increase in average and maximum IVP at T2 compared to T1 in both groups (P<0.001). Between-group comparisons showed no significant differences at T2 (P=0.356, P=0.602, restrictively) (Table 3).

ICIQ UI-SF

There was no significant difference between the groups at T1 (P=0.123). Both groups showed a statistically significant improvement in ICIQ UI-SF score after treatment (P<0.001). There was a significant difference between the two groups after treatment (P=0.033) (Table 3).

Visual Analog Scale

There was no significant difference between the groups at T1 (P=0.526). Both groups showed a statistically significant improvement in VAS at T2 (P<0.001). There was no significant difference between the two groups at T2 (P=0.319) (Table 3).

I-QOL

There was no significant difference between the groups at T1 (P=0.104). Both groups showed a statistically increase in total scores of I-QOL at T2 compared to T1 (P<0.001). A significantly greater improvement was seen in all I-QOL subscales in the PFPT+WL group compared to the PFPT group at T2 (P=0.015) (Table 3).

Relationships

In this study, the relationship between the anthropometric and non-anthropometric indices was also examined. In the PFPT group, no statistical correlation was found between these indices.

In the PFPT+WL group, however, there was a statistically significant relationship between weight and PFM endurance (r=-0.497, P=0.019) and between HC and the average of IVP (r=-0.440, P=0.041).

A significant correlation was also found between NC and PFM endurance (r=-0.564, P=0.006), VAS (r=0.478, P=0.024), and I-QOL scores (r=-426, P=0.048). Moreover, there was a significant relationship between WHR and strength of PFM (r=-0.450, P=0.035) WHR and I-QOL score (r=0.478, P=0.025).

Discussion

The present study aimed to compare the effects of PFPT alone and PFPT with or without WL on UI symptoms in middle-aged obese women. After PFPT, the strength and endurance of PFM, severity of UI, and QOL scale improved in obese women with UI. The severity of UI and the QOL score showed a greater improvement in patients who lost weight (PFPT+WL group) than in those who did not (PFPT group).

In a review study in 2013, PFPT was declared the first-line treatment for UI [10] that improves muscle tone and prevents urinary leakage [26]. Abdulaziz et al. reported a significant improvement in PFM strength and UI severity after 3 months of doing PFM exercises in obese women

Table 3: Changes in non-anthropometric variables before and after treatment in both groups (n=51)

Variables (unit)	Groups	T1* Mean (±SD)	T2* Mean (±SD)	P value	95% CI (T1 vs. T2)
Strength (MOS*)	PFPT*	1.93 (±0.70)	2.72 (±0.59)	<0.001	1.66-2.19 2.49-2.94
	PFPT+WL	1.95 (±0.57)	3 (±0.61)	<0.001	1.69-2.20 2.72-3.72
Endurance (Sec*)	PFPT	3.37 (±1.59)	6.62 (±2.42)	<0.001	2.77-3.98 5.69-7.54
	PFPT+WL	3.63 (±1.25)	6.68 (±3.00)	<0.001	3.07-4.19 5.57-8.24
Average IVP* (hpa*)	PFPT	9.26 (±6.14)	23.06 (±10.43)	<0.001	6.92-11.59 19.09-27.03
	PFPT+WL	13.20 (±7.40)	24.77 (±7.77)	<0.001	10.08-16.32 21.32-28.22
Maximum IVP (hpa)	PFPT	19.12 (±11.18)	32.26 (±12.41)	<0.001	14.86-23.37 27.54-36.98
	PFPT+WL	23.07 (±0.1)	34.77 (±11.25)	<0.001	18.63-27.51 29.78-39.76
ICIQ UI-SF*	PFPT	10.48 (±4.85)	4.10 (±3.27)	<0.001	8.73-12.78 2.85-5.35
	PFPT+WL	12.91 (±4.47)	3.77 (±3.11)	<0.001	10.64-15.23 2.18-5.21
VAS*	PFPT	5.37 (±2.09)	1.79 (±1.39)	<0.001	4.58-6.17 1.26-2.32
	PFPT+WL	5.77 (±2.30)	1.59 (±1.77)	<0.001	4.69-6.90 0.76-2.43
I-QOL A*	PFPT	40.86 (±20.78)	58.87 (±17.33)	<0.001	32.95-48.76 52.10-65.65
	PFPT+WL	35.45 (±20.75)	65.10 (±13.95)	<0.001	26.25-44.65 58.91-71.28
I-QOL PH*	PFPT	51.37 (±21.33)	66.00 (±17.61)	<0.001	43.25-59.48 59.15-72.55
	PFPT+WL	39.66 (±25.77)	70.25 (±12.39)	<0.001	28.23-51.09 64.75-75.74
I-QOL S*	PFPT	41.51 (±19.81)	59.44 (±18.59)	<0.001	33.98-49.05 51.96-66.10
	PFPT+WL	29.81 (±22.91)	62.22 (±15.03)	<0.001	19.65-39.98 55.56-68.89

hpa: Hecto pascal=100 Pascal, ICIQ UI-SF: International Consultation on Incontinence Questionnaire-Short Form, I-QOL A: Avoidance and Limiting Behavior, I-QOL PH: Psychosocial Impacts, I-QOL S: Social Embarrassment, IVP: Intravaginal Pressure, MOS: Modify Oxford Scale, PFPT: Pelvic Floor Physiotherapy, PFPT+WL: Pelvic Floor Physiotherapy with Weight Loss, Sec: Second, T1: Before treatment, T2: After 12-session treatment, VAS: Visual Analog Scale. P<0.05

with SUI [12]. In the present study, PFPT resulted in a significant improvement in UI symptoms compared to before treatment; thus it appears that PFPT can improve PFM performance, UI severity, and QOL in affected obese women.

In a study by Gozukara et al., after 6 months of the WL program, this intervention improved incontinence frequency and reduced the incidence of urinary leakage in people with UI [14]. Subak et al. observed a significant improvement in the severity of UI and QOL in the affected population when BMI was reduced from 35 to 28 kg/m^2 [15]. In the present study, combining WL with PFPT resulted in significantly greater improvement in UI severity and the I-QOL compared to PFPT alone. Considering the statistically significant difference in the value of WC in the PFPT and PFPT+WL groups after the intervention, it seems that decreasing WC along with PFPT has reduced central fat mass, consequently reduced pressure on the pelvic floor elements, and improved UI severity. Furthermore, it appears that improving I-QOL in the PFPT+WL group was influenced by the psychological issues and placebo effect of the WL in obese women with UI.

In this study, no statistically significant difference in the other variables (strength and endurance of PFM, IVP, VAS) was seen between the two groups after treatment. This result might be due to low WL (4.95 kg), and it appears that the examination of the effects of WL on other variables in obese women needs a prolonged course of treatment and greater WL in these individuals.

Danforth et al. stated that UI is more prevalent in obese women with a BMI≥30 kg/m^2 compared to women with a BMI of 22-24 kg/m^2. They concluded that BMI alone is more strongly associated with UI [27]. In the present study, although a reduction in BMI in the PFPT+WL group was not enough to affect parameters such as strength and endurance of PFM, it seems it did have psychological effects and improved I-QOL in obese women with UI. It appears that in the PFPT+WL group, WL and the consequently decreased anthropometric variables resulted in well-being and a significantly greater improvement in I-QOL compared with the PFPT alone.

Increased health-deteriorating risk factors are not only dependent on the degree of obesity, but also on the distribution of abdominal fat [28]. The central distribution of fat is associated with elevated intra-abdominal pressure [28]. A study by Han et al. showed that high WC is a risk factor for SUI in women. By examining the association

between abdominal obesity and UI in women with an average BMI of 24.6 kg/m^2, they concluded that UI frequency had a direct correlation with BMI and WC, and increases in them will increase SUI. The increase in WC compared to BMI is a more important factor for UI incidence [29]. In the present study, WC and BMI were measured as measures of central and peripheral obesity, respectively; however, no relationship was found between WC and BMI with UI variables. This may be because the rate of WC and BMI reduction was insufficient. Reduced NC was significantly correlated with improvement in of PFM endurance, VAS, and QOL in the PFPT+WL group. Considering the relation of NC with the peripheral and central obesity criteria (BMI, WC, WHR) [30, 31], reducing NC can be acceptable as a criterion for improvement of UI symptoms in obese women.

One of the limitations of this study was insufficient WL in patients. Thus, studies to evaluate the effects of optimal WL (weight loss surgery, diet combined with exercise, …) on UI are recommended. Because patients' participation in the weight loss program was a requirement of entering the PFPT+WL group, patients were not randomly assigned to the groups. This lack of randomization in patient allocation is also one of the limitations of this study. The present study included no follow-up sessions after the treatment. It is recommended that patients be followed after treatment and the effects of continued WL or even weight gain on UL symptoms be investigated. In the protocol of the present study, there was no group of obese women with UI who received only WL treatment. It is recommended a study be conducted to compare the effects of WL and PFPT in obese women with UI.

Conclusion

Overall, this study showed that PFPT can improve PFM performance, UI severity, and QOL in obese women with UI. Applying PFPT with WL in comparison to PFPT alone leads to much improvement in UI severity and QOL score in obese women with UI.

Acknowledgment

The authors would like to thank the Research Deputy, Iran University of Medical Sciences, and all the patients participating in this study. Special thanks are expressed to Dr. Mohammad Salehi, Dr. Seyed Hassan Sanei, and Mohammad Reza Keyhani for their help in statistical analysis.

Conflict of Interest: None declared.

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