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Effect of Home-Based Functional Approach *vs*. Kegel Exercise on Quality of Life in Community-Dwelling Postnatal Women with Stress Urinary Incontinence during the COVID-19 Pandemic

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Abstract

Aims: To compare the effectiveness of 8 weeks home-based functional approach and Kegel exercise on Quality of Life (QOL), severity of incontinence, leakage volume, frequency of micturition and sagittal stabilization in postnatal Stress Urinary Incontinence (SUI) during the COVID-19 pandemic.

Methods: Single-blinded randomized controlled trial. Twenty-four participants were enrolled and randomized into either functional approach group or Kegel exercise group. QOL score, incontinence severity, leakage volume, frequency of micturition and sagittal stability were compared at baseline and after 8 weeks of home-based intervention. Wilcoxon signed-rank test and Mann-Whitney U test were used to identify within-group and between groups differences, respectively.

Result: Statistically significant differences were observed in general health perception (p=0.028), role limitation (p=0.012), physical limitation (p=0.021), sleep/energy (p=0.005), incontinence severity (p=0.006) domain of KHQ and sagittal stability (p<0.001) between the two groups. The result showed statistically significant differences in all the domains of KHQ, except in personal relationship in the functional approach group, whereas, in the Kegel exercise group, significant difference was not seen in general health perception, personal relationship and sleep/energy domain of KHQ. There were statistically significant differences in severity of incontinence (p=0.034), leakage volume (p=0.024), frequency of micturition (p=0.016) and sagittal stability (p=0.006) within the functional approach group but no significant differences were observed within the Kegel exercise group.

Conclusion: The home-based functional approach is superior to Kegel exercise in improving QOL and SUI symptoms. Therefore, functional approach could be the preferred intervention for postnatal SUI in home-based exercise during the COVID-19 pandemic.

Keywords: Pelvic floor muscle training; Quality of life; Postnatal stress urinary incontinence; Kegel exercise; home-based exercise; COVID-19 pandemic

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Introduction

Stress Urinary Incontinence (SUI) is an involuntary loss of urine when bladder pressure exceeds the urethral closure pressure [1]. SUI occurs during effortful or physical exertional activities such as lifting, coughing or sneezing that increases the Intra-Abdominal Pressure (IAP) [1]. Pregnancy and childbirth are major risk factors for UI [2]. Physiological and hormonal changes during and after pregnancy lead to decreased muscle tone, resulting in weakness of the pelvic floor muscles, together with pudendal nerve damage during vaginal delivery, resulting in Urinary Incontinence (UI) [2]. Weakness of the Pelvic Floor Muscles (PFM) during postnatal period causes inability to resist the increased IAP, thus resulting in UI [3]. SUI is a common type of UI that occurs during postnatal period, occurring with the prevalence of 20% to 34% [4]. Women with UI tend to isolate and withdraw from social life because of shame and embarrassment resulting from urinary leakage [5]. Thus, SUI increases anxiety, depression, lowers self-esteem and negatively affects the Quality of Life (QOL) [6]. Postnatal women are also reluctant to seeking medical help for UI due to lack of knowledge, embarrassment, and consider it as a natural process after pregnancy and childbirth

[5]. This may result in a long-term problem with high financial and psychosocial costs and has a negative impact on QOL [5]. Therefore, home-based intervention should be preferred, especially during the COVID-19 pandemic.

To maintain urinary continence, the timed and coordinated activation of core muscles, that is, the diaphragm, transversus abdominis, multifidus and pelvic floor muscles, is critical [3,6]. This result in proper regulation of IAP and spinal sagittal stability [3]. This mechanism is lost in SUI [7]. Therefore, retraining of core muscles and IAP regulation has been proven to be effective treatment approaches for women with SUI [7]. Kegel exercise is considered as the first-line treatment for postnatal SUI [8]. This exercise is repeated voluntary PFM contractions and follow-on hypertrophy; it increases neural drive and improves the strength and endurance of impaired PFM [8]. Thus, it improves bladder support, increases urethral pressure and reduces accidental leakage [6]. However, the long-term outcome of Kegel exercise is still not clear, and it focuses only on locally impaired PFMs, not other core structures that are needed for regulating IAP and improving the spinal sagittal stability to maintain urinary continence [4]. The functional approach is based on the developmental kinesiology with stabilizing patterns of the healthy baby where core stabilizers are activated reflexively and subconsciously [9]. It follows basic principles including optimal respiratory pattern and regulating IAP, Integrating Spinal Stabilizing System (ISSS) and joint centration [9]. It focuses on optimal co-activation of the diaphragm, pelvic floor muscles and deep abdominals which encourage the IAP regulation [7,9,10]. However, to date, there is no study conducted on the effectiveness of the functional approach in SUI. Beyond that, no study has compared the effectiveness of the functional approach with Kegel exercise among postnatal women with SUI. This study aimed to compare the effect of home-based functional approach and Kegel exercise on QOL, severity of incontinence, leakage volume, frequency of micturition and sagittal stabilization in postnatal SUI. It was hypothesized that 8-weeks home-based functional approach would show greater improvement in these outcomes when compared with the Kegel exercise during the COVID-19 pandemic.

Materials and Methods

Study design

This study is a single-blinded randomized controlled trial, parallel-group design, conducted on community-dwelling postnatal women residing in Dakshinkali Municipality, Kathmandu, Nepal from December 2020 to May 2021 as flow diagram of participants (Figure 1). The research study was approved by Mahidol University Central -IRB protocol number 2020/288 2309 and Nepal health research council protocol number 820/2020 MT. The trial was conducted according to the principles of the Declaration of Helsinki and registered in the TCTR20210202002. All study participants were provided written informed consent.

Study participants

This proposed study used a sample of convenience. The inclusion criteria were: Postnatal women with SUI evaluated by 3 Incontinence Questionnaire (3IQ) [11], mild and moderate severity in SUI evaluated by Incontinence Severity Index (ISI)-score (1-6) [12], age between 20 to 35 years, between 3 to 12 months after vaginal delivery, Body Mass Index (BMI) <30 kg/m^2, <3 vaginal delivery. The exclusion criteria were: depression score ≥ 11 using Hospital Anxiety and Depression Scale (HADS), recent spinal, pelvic or abdominal surgery, confirmed serious pathologies (musculoskeletal problems like contracture and deformities, lumbar or pelvic fracture, cancer, infectious diseases of the spine, neurological disorders, malignant condition), recurrent urinary tract or vaginal infections, SUI present before pregnancy, doing pelvic floor muscle exercise or having experience on it, and any treatment administered for UI. The initial evaluation occurs by physician following history, urinalysis, physical examination, demonstration of stress incontinence, assessment of urethral mobility, and measurement of post-void residual urine volume. Researcher 1 collected socio-demographic data (age, weight, height and body mass index), as well as obstetric history (parity, vaginal delivery and duration of delivery). The participants were randomized by using the lottery method with a closed sealed envelope, into the functional approach group and Kegel exercise group by researcher 2 in 1:1 ratios. Researcher 3 was an assessor who had 4 years of experience in using all the outcome measures and was blinded from the randomization of the group.

Outcome measures

The primary outcome was QOL measured by the King's Health Questionnaire (KHQ). It is widely used because it is simple to administer and covers several domains of life [13]. The total score is 100, where the higher score indicates a greater impact on QOL [13]. The Minimal Clinical Important Difference (MCID) for KHQ domain is 10 [13]. The secondary outcomes included the severity of incontinence measured by ISI [12], leakage volume measured by a 24-h pad test [14], the frequency of micturition assessed by a subjective questionnaire- "how many times you go to the toilet for urination?" which was noted in 3 days bladder diary [15], and sagittal stabilization measured by the Pressure Bio-feedback Unit [16]. For the measurement, participants were supine with a knee 90 flexion position [16]. Participants were categorized into the level of stability (level 0-6) using a clinical test for stability adapted from the study of Wattananon et al. [16]. Researcher 3 assessed all the participants at baseline and after 8 weeks of intervention.

Interventions

The intervention program was home-based, performed 3 days/week in alternate days for 8 weeks.

Functional approach exercise: The functional approach exercise has 5 positions, each position was repeated 10 times, close to maximum contraction of PFM of 3 sec hold and 3 sec rest after every contraction, 10 repetitions each position, 1 set/day, 3 days/week. Every position was accompanied by diaphragmatic breathing (Figure 2).

a) The first position: Chest and pelvis were in a parallel position where IAP was maintained. At first, the therapist held the leg in a 90/90 position of hip and knee with slight abduction and external rotation. After gaining control, participants held their legs by themselves. Participants breathed in while taking hip and knee at 90/90, and breathed out while taking back [9,17,18].

b) The second position (upper extremity): Starting position: Same as the 3-month model position, they took hand towards the opposite knee without any movement of the chest while breathing in and out while taking hand back to the normal position, and repeating on both sides [17,18].

c) The third position (lower extremity): Starting position: Same as the 3-month model position. Breathed in with the abduction

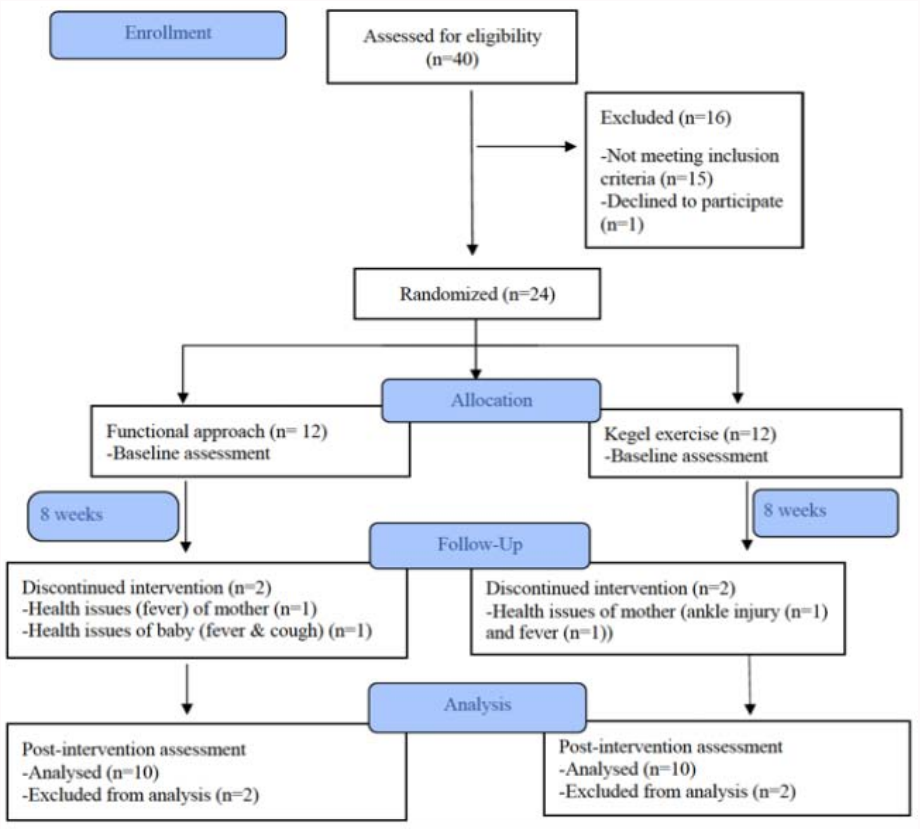

Figure 1: Flow diagram of participants.

Table 1: Demographic variables.

Variable Mean ± Standard Deviation	Group		*P* value
	Functional approach (n=10)	Kegel exercise (n=10)	
Age (years)	27.4 ± 4.5	24.3 ± 2.9	0.08
BMI (kg/m²)	27.1 ± 3.1	26.0 ± 3.0	0.42
Number of deliveries (n)	2 (1.0-2.0)	1 (1.0-2.0)	0.28
Duration after delivery (months)	5.9 ± 3.2	7.3 ± 2.5	0.3
Birth weight of baby (kg)	3.1 ± 0.4	3.1 ± 0.6	0.87

The baseline similarity of demographic between the groups was tested by independent t-test and Mann-Whitney U-test, level of significance was 0.05 for two-tailed hypothesis and power was 80%

of the leg without movement of spine and pelvis, returned to starting position while breathing out, and repeated it in both sides [17,18].

d) The fourth position: Spine was upright with diaphragm and PFM parallel to each other. Squatting was done with breathing in and returning to the normal position while breathing out [9,17,18].

e) The fifth position: Stood with the spine upright with both feet at the same line with pelvic width apart, arm raised at the level of shoulder and knee slightly flexed. Stepped forward from one side while breathing in, returned to starting position with breathing-out, and repeated on both sides [9,17,18].

Kegel exercise: Pelvic floor muscle training was performed in supine position with knee flexion, close to maximum contraction of PFM of 3 sec hold and 3 sec rest after every contraction, 25 repetitions. Two sets/day, 3 days/week (Figure 3) [19].

Statistical analysis

The sample size was calculated using the G*Power by the study done by Waraporn et al. [20]. The mean difference between the two independent means (two-group), mean ± SD in the experimental group (functional approach) was -30.00 ± 24.72, mean ± SD in the control group was -3.33 ± 7.46 using sleep/energy domain of KHQ, level of significance was 0.05 for two-tailed hypothesis and power was 80%. The sample size was a total of 24, 12 in each group, considering 20% dropout.

The Statistical Package for Social Science (SPSS) software for windows version 22 was used for the statistical analysis. *P*-value less than 0.05 was considered as the level of significance. Descriptive statistics were used for the mean, standard deviation for normally distributed quantitative data. Median and interquartile range was used for not normally distributed quantitative and ordinal data. The baseline similarity of demographic and clinical characteristics between the groups was tested by independent t-test and Mann-Whitney U-test.

The parametric assumption was performed using the Shapiro-

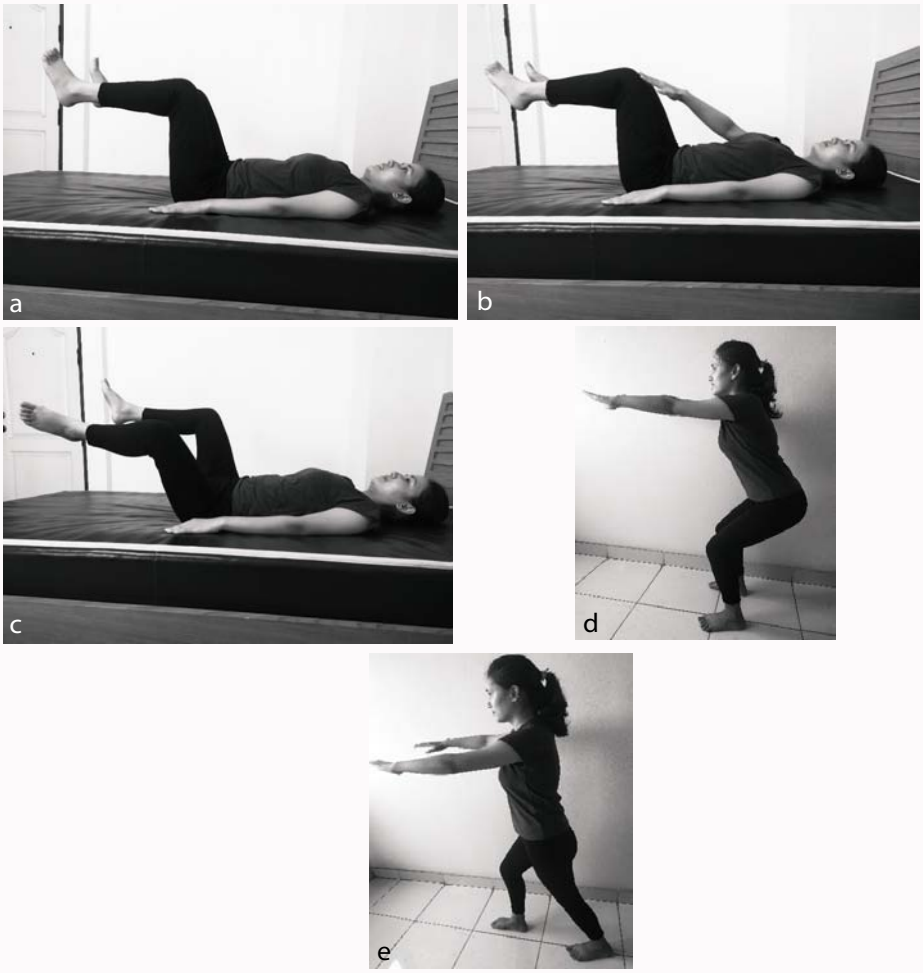

Figure 2: Functional approach (a) The first position (b) The second position (c) The third position (d) The fourth position (e) T.

Wilk test. Data did not meet parametric assumptions after the data transformation using *log10*. Non-parametric test, Wilcoxon signed-rank test and Mann-Whitney U test were used for within and between-group comparison.

Results

A total of 24 women were randomized into the functional approach and Kegel exercise groups and 4 women did not complete the study, resulting in 10 participants in each group (Figure 3). None of the participants presented any side effects during and after the 8 weeks of intervention. The demographic and clinical characteristics are shown in Table 1, 2.

In the functional approach group, there was a significant difference between baseline and post-measurement in QOL in all the domains of KHQ, except personal limitation (p=0.109), although, the change in score from baseline was clinically significant (Table 3). Similarly, for the Kegel exercise group, there was a significant difference between baseline and post-measurement in the incontinence impact (p=0.007), role limitation (p=0.004), physical limitations (p=0.016), social limitation (p=0.004), emotions (p=0.007) and incontinence impact (p=0.005), whereas in the general health perception, personal limitation and sleep and energy domains of KHQ, no significant difference was observed (Table 3). There was a significant difference in median score change between the two groups in general health perception (p=0.028), role limitation (p=0.012) physical limitation (p=0.021), sleep and energy (p=0.005), and incontinence severity domains of KHQ (p=0.006) but there was no significant difference in other domains of KHQ (Table 3).

In the secondary outcome, no significant difference was seen in the median score changes in both groups after 8 weeks of intervention in the severity of incontinence, leakage volume and frequency of micturition (p=0.073, p=0.221 and p=0.143, respectively) (Table 4). The changed median score in the severity of incontinence, leakage volume, and frequency of micturition in the functional approach group was 0.50, 1.50 g and 1, showing a significant difference between baseline and post-measurement (p=0.016, p=0.024 and p=0.016, respectively). The Kegel exercise group showed no change in median score in the severity of incontinence, leakage volume and frequency of micturition, resulting in no significant difference between baseline and post- measurement (p=0.102, p=0.059 and p=0.157, respectively) (Table 4).

A significant difference was observed in sagittal stability between both groups after the 8 weeks of intervention ($p \leq 0.001$). The changed median score in the functional approach group was -1.00 and 0.00 in the Kegel exercise group. A significant difference was observed between baseline and post-measurement (p=0.006) in the functional approach group but in the Kegel exercise group, there was no significant difference between baseline and post-measurement

Table 2: Clinical variables.

	Variable Median (Interquartile range)	Group		*P* value
		Functional approach (n=10)	Kegel exercise (n=10)	
KHQ	General health perception	50 (25.0-50.0)	25.5 (25.0-50.0)	0.18
	Incontinence impact	41.6 (33.3-66.6)	33.3 (33.3-33.3)	0.18
	Role limitations	58.3(33.3-66.6)	50 (33.3-66.6)	0.71
	Physical limitations	58.3 (29.1-66.6)	33.3 (33.3-50.0)	0.3
	Social limitations	22.2 (22.2-33.3)	22.2 (22.2-22.2)	0.55
	Personal relationships	16.6 (0.0-33.3)	16.6 (0.0-20.7)	0.75
	Emotions	33.3 (17.2-33.3)	22.2 (11.0-33.3)	0.48
	Sleep/Energy	24.9 (16.6-33.3)	8.3 (0.0-33.3)	0.24
	Incontinence severity	25 (16.6-41.6)	16.6 (14.5-16.6)	0.07
	Severity of incontinence	2.5 (1.0-3.0)	1 (1.0-2.0)	0.07
	Leakage volume (g)	5.0 (4.0-7.0)	4 (4.0-5.0)	0.33
	Sagittal stability	2.0 (0.7-3.0)	2 (1.0-2.0)	0.75
	Frequency of micturition	6.5 (5.7-8.5)	7 (8.7-8.0)	0.57

KHQ: The Kings Health Questionnaire

The baseline similarity of clinical characteristics between the groups was tested by independent t-test and Mann-Whitney U-test, level of significance was 0.05 for two-tailed hypothesis and power was 80%

Table 3: Comparison of QOL within and between functional approach and Kegel exercise group.

Variables	Functional approach			Kegel exercise			Difference
Median (Interquartile range)	Baseline	Post- measurement	*P* value	Baseline	Post- measurement	*P* value	*P* value
General health perceptions	50 (25.0-50.0)	25 (25.0-25.0)	.005*	25.5 (25.0-50.0)	25 (25.0-25.0)	0.083	0.028*
Incontinence impact	41.6 (33.3-66.6)	12.5 (0.0-33.3)	.003*	33.3 (33.3-33.3)	0 (0.0-33.3)	0.007*	0.164
Role limitations	58.3 (33.3-66.6)	0 (0.0-16.6)	.005*	50 (33.3-66.6)	24.9 (12.4-33.3)	0.004*	0.012*
Physical limitations	58.3 (29.1-66.6)	0 (0.0-16.6)	.007*	33.3 (33.3-50.0)	0 (0.0-16.6)	0.016*	0.021*
Social limitations	22.2 (22.2-33.3)	0 (0.0-0.0)	.004*	22.2 (22.2-22.2)	0 (0.0-11.1)	0.004*	0.143
Personal relationships	16.6 (0.0-33.3)	0 (0.0-20.7)	0.109	16.6 (0.0-20.7)	16.6 (0.0-16.6)	0.102	0.852
Emotions	33.3 (17.2-33.3)	0 (0.0-2.7)	0.007*	22.2 (11.0-33.3)	0 (0.0-2.7)	.007*	0.228
Sleep/Energy	24.9 (16.6-33.3)	0 (0.0-0.0)	0.007*	8.3 (0.0-33.3)	8.3 (0.0-20.7)	0.157	.005*
Incontinence severity	25 (16.6-41.6)	8.3 (0.0-8.3)	0.005*	16.6 (14.5-16.6)	8.3 (0.0-10.3)	0.005*	.006*

Non-parametric test, Wilcoxon signed-rank test and Mann-Whitney U test were used for within and between-group comparison, level of significance was 0.05 for two-tailed hypothesis and power was 80%

(p=1.0) (Table 4). The both groups received the physical therapist's telephone number for consultation about the intervention program. Compliance with the functional approach group and Kegel exercise group (as indicated by daily records) was 100%.

Discussion

The functional approach was found to be more effective in improving QOL, severity of incontinence, leakage volume, frequency of micturition, and sagittal stability, whereas, Kegel exercise was found to be effective in improving QOL only. In the current study, postnatal women with SUI within the functional approach group showed improvement in QOL. The result of this study matches with that of Kim et al. [3], where they concluded that 8 weeks of pelvic floor muscle training combined with trunk stabilization by deep abdominal contraction performed 3 days a week, was beneficial for reducing postpartum UI and improving QOL [3]. The functional approach exercise replicates the daily activities position, making it easy in doing daily activities and improving the QOL10 as greater motor performance is observed when intervention or practice is similar to the functional task [6]. Botelho et al. [21], also used the abdominopelvic kinesiotherapy for pelvic floor muscle training

Figure 3: Kegal exercise.

protocol in five positions: Supine, sitting on the floor, sitting on the gym ball, squatting and standing position, with correct breathing for 10 sessions, 3 times in a week, and observed it to be effective in improving pelvic floor muscle strength and reducing the incontinence symptoms [21]. The Kegel exercise group showed statistical improvement in QOL in incontinence impact, role limitation, physical limitation, social limitation, emotions and

Table 4: Comparison of severity of incontinence, leakage volume, sagittal stability, and frequency of micturition within and between functional approach and Kegel exercise group.

Variables Median (Interquartile range)	Functional approach			Kegel exercise			Difference
	Baseline	Post- measurement	*P* value	Baseline	Post- measurement	*P* value	*P* value
Severity of incontinence	2.5 (1.0-3.0)	1.0 (1.0-1.0)	0.016*	1.0 (1.0-2.0)	1.0 (1.0-1.0)	0.102	0.073
Leakage volume	5.0 (4.0-7.0)	4.0 (3.7-5.0)	0.024*	4.0 (4.0-5.0)	4.0 (4.0-4.0)	0.059	0.221
Sagittal stability	2.0 (0.7-3.0)	3.0 (2.7-4.0)	0.006*	2.0 (1.0-2.0)	2.0 (1.0-2.0)	1	<0.001*
Frequency of micturition	6.5 (5.7-8.5)	5.5 (5.0-7.0)	.016*	7.0 (8.7-8.0)	7.0 (6.0-7.2)	0.157	0.143

Non-parametric test, Wilcoxon signed-rank test and Mann-Whitney U test were used for within and between-group comparison, level of significance was 0.05 for two-tailed hypothesis and power was 80%

incontinence severity domains of KHQ. Significant improvement was not seen in the personal relationship domain of KHQ within both groups. In the functional group, although, statistical significance was not observed, changes in the score were clinically significant as score change was >10 as MCID for KHQ domain is equal to or >10 [13]. The personal relationship domain is related to aspects of family, partner and sex life. Majority of the postnatal women used in this study may not have reported to the family about the problem of urinary leakage and were not sexually active. Eighty percent of the participants stated that they were not sexually active after the birth of a baby. A significant difference was not observed in the sleep and energy, and general health perception domains of the Kegel exercise group. The median score of both domains was less in the Kegel exercise group as compared to the functional approach group during baseline. Hirakawa et al. [22] also demonstrated a non-significance difference in general health perception, personal limitation, sleep and energy, after 12 weeks of Kegel exercise [22]. The result of the present study showed no significant difference in incontinence impact, social limitations, personal relationship and emotion domains of KHQ between the two groups. The baseline score of these domains was low, indicating the low impact of postnatal women with SUI in these domains of QOL.

Many of the participants in the Kegel exercise group fall on slight severity, making it more difficult to detect the differences and resulting in a minor improvement in the severity of incontinence. This result is in contrast with that of Kashanian et al. [23], where they found improvement in the severity of incontinence score after Kegel exercise [23]. The treatment duration (12 weeks) was noticeably longer with more intensity of exercise (twice/daily) as compared to the present study [23]. The present study found significant improvement in urinary leakage volume after eight weeks of the functional approach exercise. The previous study also demonstrated improvement in leakage volume after 12 weeks of diaphragmatic, deep abdominal and pelvic floor muscle training in women with SUI [24]. The score of urinary leakage in the present study was small in baseline and post-measurement, which may be due to the fact that none of the participants had cough or cold or carryout stressful activities that provoke urinary leakage as mentioned in the participant's diary record sheet. A higher frequency of micturition was found at baseline (7 times) in the Kegel exercise group than the functional approach group (6.5 times). After 8 weeks of intervention, it decreased in the functional approach group (5.5 times) but remained the same in the Kegel exercise group (7 times). A previous study by Hung et al. [24], showed a significant reduction in the frequency of micturition with diaphragmatic, deep abdominal, and pelvic floor muscle retraining [24]. All the positions and movement of the functional approach engaged all the core muscles: Pelvic floor muscles, deep abdominals and diaphragm muscles, to regulate the IAP [10]. Proper regulation of IAP improves sagittal stability. Khorasani et al. [25], found home-based stabilization exercises focusing on the pelvic floor, to be effective in postnatal SUI and LBP [25]. Whereas, Kegel exercise focused mainly on strengthening the pelvic floor muscle and lacks activation of core muscles needed to improve the sagittal stability [4,10].

To the authors' knowledge, this study is the first randomized controlled trial that compares the effectiveness of the home-based functional approach and Kegel exercise on postnatal women with SUI.

The strength of the study includes the home-based interventions. Both interventions were performed in participants' home environment which made them easy and convenient to perform at their own and real scenario. Manuals of intervention and diary record sheets were given to every participant to increase the compliance and adherence to the intervention [26].

Limitations

This study has some limitations. First, during the COVID-19 pandemic, the study provided intervention to both groups which made it difficult to observe the changes between the groups. And second, follow-up was not measured and retention of intervention was not known. Further study should focus on measuring the strength of pelvic floor muscles which will directly measure the changes. The effect size calculation of KHQ and other variables should be performed for practical significance.

Recommendation

A larger clinical trial with long-term follow-up and a control group with no clinical intervention are recommended for better effectiveness of the intervention. The amount of physical activity should be assessed, which is obligatory to link with leakage volume. The translation and validation of KHQ in the Nepali language should be done.

Conclusion

Eight weeks of functional approach and Kegel exercise showed significant improvement in QOL. Moreover, the home-based functional approach improved the QOL, incontinence severity, leakage volume, spinal sagittal stability and frequency of micturition. Therefore, functional approach exercise may be the preferred intervention for physical therapists in their daily clinical practice among postnatal women with SUI and should be home-based, especially during the COVID-19 pandemic. However, facing COVID-19 has brought many changes in assessment and treatment of risk for patients. Well-structured public health system and the national system together have allowed clinicians to continue to provide best care.

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