|| ISSN(online): 2589-8698 || ISSN(print): 2589-868X ||
International Journal of Medical and Biomedical Studies
Available Online at www.ijmbs.info
NLM (National Library of Medicine ID: 101738825)
Index Copernicus Value 2020: 79.44
Original Research Article Volume 6, Issue 09; September: 2022; Page No. 35-43

Homoeopathy in cases of Stress Urinary Incontinence in Parous Women of Reproductive Age Group a Randomised Controlled Study

Dr. Sangeeta Jain[1*], Dr. A. N. Mathur[2], Dr. Arun Phophalia[3]

[1]Ph.D. (Hom) Head of the Department, Department of Anatomy, University College of Homoeopathy, Kekri, Ajmer, Rajasthan (A Constituent College of Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan)

[2]M.D. (Hom) President, Homoeopathy University, Saipura Sanganer, Jaipur, Rajasthan

[3]M.S. (Gen. Surgery) Medical Suprintendent, Dr. Girendra Pal Homoeopathic Hospital (Attached Hospital of Homoeoapthy University, Saipura Sanganer, Jaipur, Rajasthan)

Article Info: Received 5 September 2022; Accepted 7 October 2022
doi: https://doi.org/10.32553/ijmbs.v6i9.2606
Corresponding author: Dr. Sangeeta Jain
Conflict of interest: No conflict of interest.

Abstract

Background & Objective: Stress Urinary Incontinence (SUI) is an involuntary urinary leakage that occurs with transient increase in abdominal pressure as in coughing, laughing and sneezing. It is very common in females because of weakening of pelvic floor muscles followed by childbirth. Regular pelvic floor exercise (PFE) can overcome this problem slowly but individualized Homoeopathic medicines can fasten the improvement. The main objective of this study is to explore the role of Homoeopathy in the treatment of SUI in parous women of reproductive age group along with PFE in comparison to treatment with only PFE.

Methods: A prospective experimental randomized controlled study was conducted in which total 100 parous females of reproductive age group were studied. Baseline characteristics of all patients were involuntary urinary leakage on coughing, laughing and sneezing. Patients were randomized into two groups to receive individualized homoeopathic medicines (Group A; n=50) and placebo (Group B; n=50) along with PFE. Patients of both groups were compared according to scores of 1- hour Pad Weight Test (1-hr PWT). Baseline scores of both groups were measured and compared with the scores after 6 months follow-ups.

Results: The scores of 1-hr PWT after treatment in Group A and Group B were compared; the mean scores in Group A were lower than the mean scores of Group B. The paired t test and independent t test showed statistically significant difference (P<.05). The most frequently indicated homoeopathic medicine was *Sepia officinalis* (*n*=20).

Conclusion: The individualized homoeopathic medicines along with pelvic floor exercise produced promising outcome in the treatment of cases of stress urinary incontinence in parous females of reproductive age group.

Key words: Stress urinary incontinence, parous women, individualized homoeopathy, pelvic floor exercise, 1-hour Pad weight test.

Introduction

Stress Urinary Incontinence (SUI) is defined as loss of urine of less than 50 ml when there is increased abdominal pressure due to strain on the internal urethral orifice of the bladder, as in laughing, coughing and sneezing.[1] According to International classification of diseases (ICD) code N 39.3 SUI is a meatal urinary leakage that occurs as a result of physical activities with transient increase in abdominal pressure in the absence of detrusor muscle activity or overdistended bladder.[2] It is very common in females and seen most frequently after parturition which is followed by weakening of pelvic floor muscles.[3] Stress urinary incontinence (SUI) affects the quality of life of at least one third of women. This problem is more common in India, where women are not aware for their reproductive health problems and do not vocalize their symptoms.[4] This condition is creating a negative impact on one's physical, psychological, sexual, social and overall quality of life and incontinent women are much more likely to suffer from depression than their continent peers.[5] This study proposed a treatment strategy based on the experience of treating this patient population by homoeopathic medicines selected after individualization along with pelvic floor exercise. The primary aim of this study is to show the effectiveness of individualized homoeopathic medicines in cases of stress urinary incontinence in parous women of reproductive age group. The objective of the study is to compare the role of Homoeopathy along with pelvic floor exercise and the treatment by only pelvic floor exercise, in cases of stress urinary incontinence in parous women of reproductive age group through 1-hour Pad Weight Test (1-hr PWT).

Materials and Methodology

This experimental randomized controlled study (*Pretest-Posttest design*) was conducted at Dr. M.P.K. Homoeopathic Medical College, Hospital & Research Centre, Jaipur (a constituent college of Homoeopathy University). Sample size (100) was determined by taking into account by effectiveness of treatment and power of test.[6] A total of 341 parous females of reproductive age group were screened (through Questionnaire for Urinary Incontinence Diagnosis (QUID),[7] out of which 100 females were enrolled for the study, after taking consent, who have had pure stress urinary incontinence having baseline characteristics of involuntary urinary leakage on coughing, laughing and sneezing. Pregnant and lactating parous women of reproductive age group were excluded from the study. Women who were taking diuretics (antihypertensives, analgesics, antipsychotics, etc.) and alcoholics also were excluded. The study duration was 18 months and each case was followed by every 15/30 days, till six months. Randomization was performed with allocation concealment using sequentially numbered, opaque, sealed envelopes (SNOSE)[8] without blinding. All women were divided equally and randomly into two study groups; Group A was intervened by individualized homoeopathic medicines along with pelvic floor exercise and Group B was prescribed placebo along with pelvic floor exercise.

Primary outcome in this study was the decrease in amount of urine loss during increased abdominal pressure and its assessment was done through 1 hour Pad-weight test[9] (pre and post test scores). This test is done to quantify the volume of urine lost by weighing a perineal pad before and after some type of leakage provocation, and also to distinguish continent from incontinent women. A pad weight gain >1 g is considered positive for 1-hour pad test and a pad weight gain >4 g is positive for 24-hour test.Data analysis was carried out by data sorting method, classification by tabulation and interpretation by histograms and pie diagrams. Data analysis was done using SPSS (Version 16.0.2)[10] and excel. Statistical method, paired t test,[11] was used to compare 1- hour pad weight test (1-hr PWT) before and after treatment in both Groups A and B. Independent t test[11] was

also used to compare 1-hr PWT between both Groups A and B to see the difference after treatment. The ethical clearance was obtained from the Institutional Ethical Committee (IEC) of Homoeopathy University, Jaipur, prior to conducting the study.

Observations and Results

A total of 341 parous females of reproductive age group were screened. Females having urinary incontinence were 229 (67.16%) in number and pure SUI was found in 170 (74.24%) females. Out of 170 SUI females 100 females were enrolled for the study after taking consent. Since there was no drop out case in the study, analysis was carried out as per protocol.

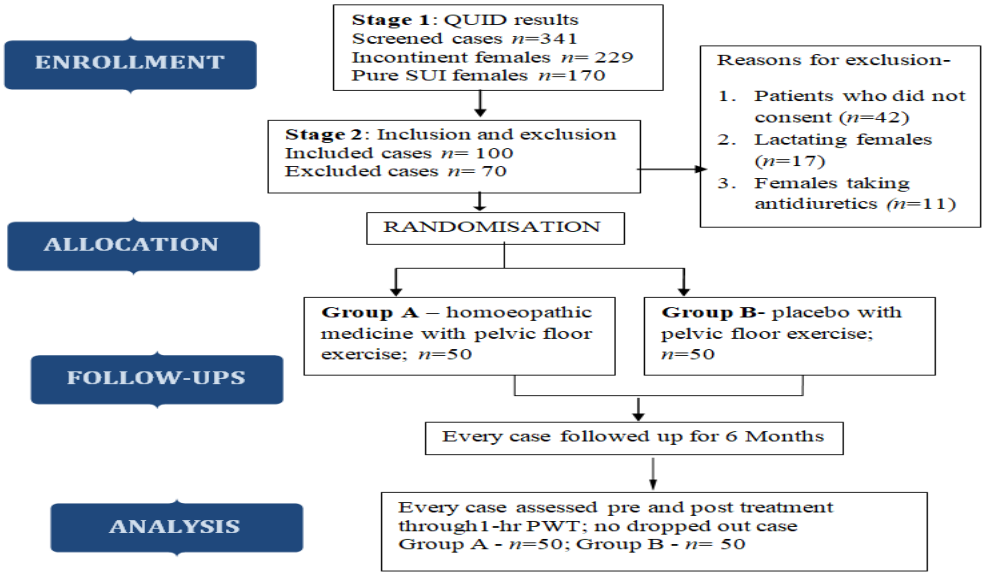

Figure 1: Consort Flow Diagram[12] Of Patients Included/ Excluded For The Study

Distribution of Study Population according to Age: Females of any age group can be affected with SUI after parturition, but in this study maximum cases (31%) were found in the age group of 36-40 years as observed in both the study groups (Fig. 2 & 3); 36% cases in group A (Fig. 2) and 26% cases in group B (Fig. 3).

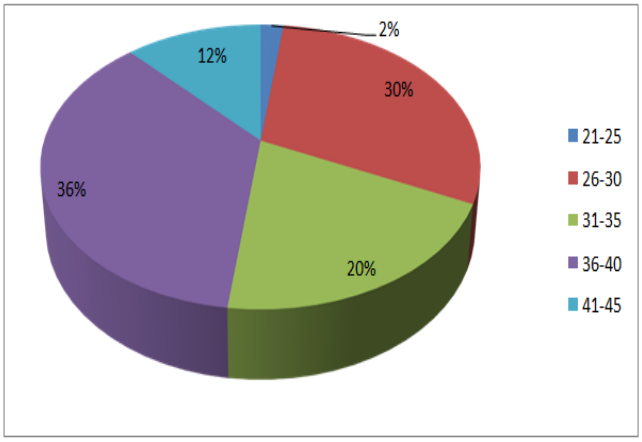

Figure 2: Distribution of study population according to age in Group A

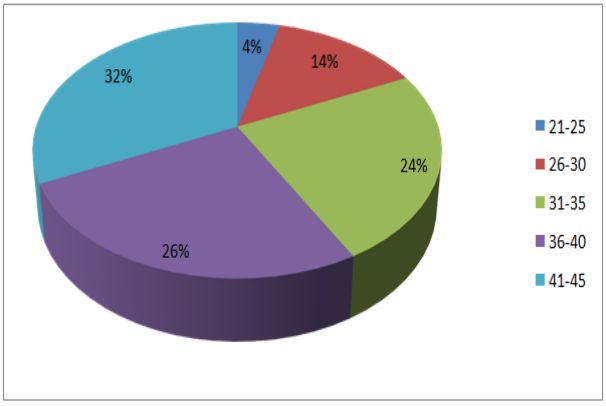

Fig. 3: Distribution of study population according to age in Group B

Distribution of Study Population according to Parity: In this study, stress urinary incontinence was found to be greatest (63%) in females of reproductive age group with parity of 2 (Fig. 4). In the Group A, 29 females and in Group B 34 females with parity of 2 were found to be suffering from SUI.

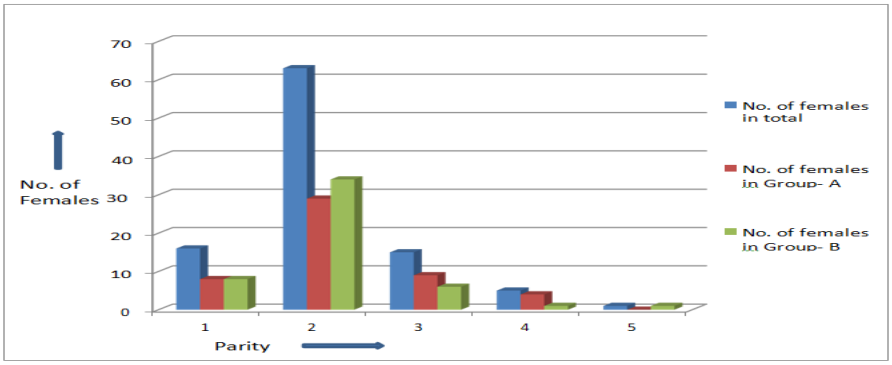

Fig. 4: Distribution of study population according to their parity

Presenting complaints of study population in both study groups: From the study analysis, it was observed that the presenting complaints in almost all females of both study groups were other than SUI. The complaints for which the females came to hospital were bearing down sensation, leucorrhoea, skin disorders, hair fall, fever, gastric disorders, allergic rhinitis, cough, pain abdomen, haemorrhoids, burning urination etc. there was only one patient who came for involuntary urination.

Response to homoeopathic remedies with PFE in patients of Group A: Table 1 shows the response to the homoeopathic remedies with PFE in patients of Group A and changes noticed in 1-hr PWT after treatment. Sepia officinalis was found to be most indicated medicine prescribed in 20 patients, followed by Natrum muriaticum, Pulsatilla, Nux vomica, Causticum, Sulphur and Calcarea carbonica. In Group A, 100% improvement achieved by 15 (30%) patients. Sepia officinalis showed 100% improvement in 6 patients.

Table 1: Response to homoeopathic remedy with PFE in study Group A (n=50):

S. no	Medicine given with PFE	Number of patients	Response to remedies in patients after treatment				
			100%	75-99%	50-74%	25-49%	<25%
			1-hr PWT	1-hr PWT	1-hr PWT	1-hr PWT	1-hr PWT
1.	*Sepia officinalis*	20	6	10	3	1	0
2.	*Natrum muriaticum*	9	2	3	4	0	0
3.	*Pulsatilla*	9	3	5	1	0	0
4.	*Nux vomica*	7	1	3	3	0	0
5.	*Causticum*	2	1	0	1	0	0
6.	*Sulphur*	2	1	1	0	0	0
7.	*Calcarea carbonica*	1	1	0	0	0	0
	Total	**50**	**15**	**22**	**12**	**1**	**0**

Response to Placebo with PFE in patients of Group B: Table 2 shows the response to the placebo with PFE in patients of Group B and changes noticed in 1-hr PWT after treatment. Only 2 patients showed 100% improvement in scores of 1-hr PWT.

Table 2: Response to Placebo with PFE in study Group B (n=50):

S. no.	Medicine given with PFE	Number of patients	Response to remedies in patients after treatment				
			100%	75-99%	50-74%	25-49%	<25%
			1-hr PWT	1-hr PWT	1-hr PWT	1-hr PWT	1-hr PWT
1.	Placebo	50	2	4	16	26	2

Statistical Tools Application:

Independent t test (before treatment): The results presented in Table 3 show that the value of significance level is .851 in 1-hr PWT which is greater than .05 ($P > .05$), hence we accepted the null hypothesis, *i.e*. there is no statistically significant difference between the average scores of 1-hr PWT of the two groups (Group A and Group B) before treatment which means both groups are comparable.

Table 3: Independent Samples Test- 1 hr PWT (before treatment)

Particulars	F	Sig.	t	df	Sig. (2-tailed)	Mean diff.	Std. Error diff.	95% Confidence Interval of the Difference	
								Lower	Upper
1-hr PWT scores Gp A- Gp B (BT)	1.672	.199	-.188	98	.851	-.4168	2.21922	-4.8208	3.98717

Paired t test: To analyze the changes in the scores of 1-hr PWT, paired t test was applied in both groups (Tables 4 & 5). The mean scores of 1-hr PWT reduced from 41.7020 to 7.6386 in Group A, and from 42.1188 to 22.8760 in Group B. The changes were relatively greater in Group A, however the changes were statistically significant in both groups.

Table 4: Paired Samples Test- 1-hr PWT in Group A

Particulars	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
GpA (1-hr PWT,BT) – GpA (1-hrPWT,AT)	34.0634	7.14168	1.00999	32.0338	36.093	33.727	49	0

(BT= before treatment; AT= after treatment)

Table 5: Paired Samples Test- 1-hr PWT in Group B

Particulars	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
GpB (1-hr PWT,BT) – GpB (1-hrPWT,AT)	19.2428	7.43918	1.05206	17.12861	21.35699	18.291	49	0

(BT= before treatment; AT= after treatment)

Independent t test (after treatment): Further, the scores of both groups (Group A and Group B) compared after the treatment to assess the outcome of treatment. The results presented in Table 6 show that the mean scores in Group A were lower than the mean scores of the Group B, and the difference was statistically significant. Hence, we reject the null hypothesis and accept the alternative hypothesis that there is a difference between Homoeopathic intervention and Placebo in the treatment of patients suffering from SUI. It means the homoeopathic medicines selected after individualization are effective in the treatment of stress urinary incontinence.

Table 6: Independent Samples Test- 1 hr PWT (after treatment)

Particulars	F	Sig.	t	df	Sig.(2-tailed)	Mean diff.	Std. Errordiff.	95% Confidence Interval of the Difference	
								Lower	Upper
1-hr PWT scores Gp A- Gp B (AT)	17.236	0	-7.707	98	0	-15.237	1.97716	-19.161	-11.314

(AT= after treatment)

Evaluation of improvement in 1-hr PWT before and after treatment in Group A and Group B: It can be observed from Figures 5 and 6 that the changes in 1-hr PWT scores before and after treatment were relatively greater in Group A; however, the changes were statistically significant in both groups. 15 females out of 50 got 100% reduction in 1-hr PWT scores in Group A; and 2 females out of 50 got 100% reduction in 1-hr PWT scores in Group B.

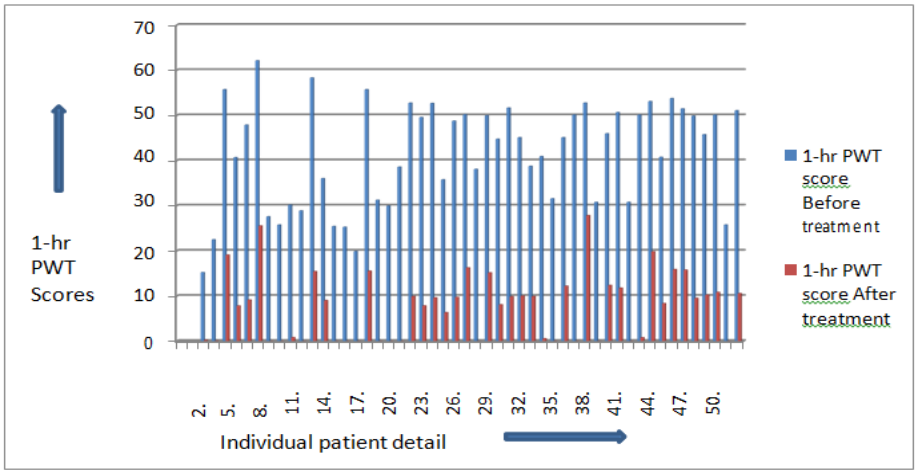

Figure 5: Distribution of individual patient's 1-hr PWT score in Group A before and after treatment

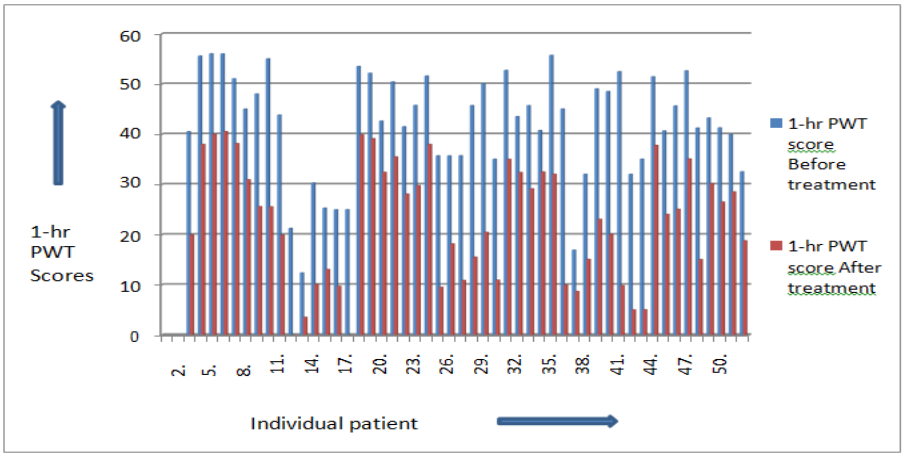

Figure 6: **Distribution of individual patient's 1-hr PWT score in Group B before and after treatment**

Discussion

In present study, maximum cases of SUI (31%) were found in 36-40 years of age group. Karl M Luber[13] in his review study showed similar results found by Hampel & colleagues and Thom that older women were more likely to experience urge incontinence and younger women were proportionately more likely to experience SUI. Uma Singh[14] and colleagues also reported the same statements.

In this study, the females with parity of 2 showed highest incidence of SUI (63%) and it was changing towards urge incontinence as the parity increases. This is comparable to the observation of Uma Singh[14] and others who reported that incontinence is positively associated with increasing parity; differentially stress incontinence showed an increasing trend towards urge incontinence with increasing parity. The study of Karl M Luber[13] also showed that the data available regarding the influence of pregnancy and route of delivery on the pelvic floor disorders such as SUI.

The parous females included in this study, came for other clinical conditions which were not directly related to urinary incontinence. Theywere screened for urinary incontinence and found to be stress urinary incontinent. Only one parous

female directly came for urinary incontinence. Karl M Luber[13] stated that many women with SUI do not seek care for their condition; the occasional symptom of stress loss may not translate into a level of bother that qualifies as the disease of stress incontinence. Others are embarrassed to speak with a health care provider about their condition or fear that treatment will require surgery.

In this study, results indicate the effectiveness of the individualized homoeopathic medicines in cases of SUI in parous females of reproductive age group. Since there are no studies of the effects of homoeopathic medicines in cases of SUI, the produced changes in this study cannot be discussed. The effects of pelvic floor exercise in patients of Group B were also remarkable, and can be compared with the study of Borello DF[15] and his friends who concluded that Pelvic-floor muscle exercise is 50-69% effective in reducing urine loss episodes in women. However, there are problems with pelvic floor exercises; improvement is more common than cure.

Statistical analysis: The baseline data (scores of 1-hr PWT) were not significantly different between Group A and Group B. At endpoint of study, 100% reduction was found in scores of 1-hr PWT in 12 (24%) females of Group A. The mean scores of 1-hr PWT reduced from 41.7020 to 7.6386 (95% CI 32.0338, 36.093) in Group A, and from 42.1188 to 22.8760 (95% CI 17.1286, 21.3569) in Group B. The scores of 1-hr PWT after treatment in Group A and Group B were compared; the mean scores in Group A were lower than the mean scores of the Group B. The paired t test and independent t test showed statistically significant difference ($P< .05$).

Conclusion

Individualized homoeopathic medicines along with PFE produced a remarkable reduction in the scores of 1-hr PWT which substantiated the potential of the homoeopathic medicines in the effective treatment of SUI. The outcomes proposed in the study were steady and permanent and achieved through conducting the clinical trial; and no adverse effect was noted during the study. Hence, this research study conclusively establishes the effectiveness of individualized homoeopathic medicines in the treatment of stress urinary incontinence in parous females of reproductive age group.

Limitations and Strength: Though it was very difficult to convince the females in beginning for the study as they came for other clinical conditions which were not directly related to urinary incontinence but the results produced showed that they were satisfied.

Future aspect: In future we can conduct this type of research on large sample size to establish the effectivity of Homoeopathic medicines in cases of stress urinary incontinence.

Acknowledgement: We acknowledge Dr. Girendra Pal sir (Chairperson of Homoeopathy University) and Dr. Chaturbhuja Nayak (former President of Homoeopathy University), for providing us a platform to conduct research in Homoeopathic science and for their constant encouragement and scientific suggestions in completing this task successfully.

References

1. Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health [Internet]. 7th ed. Saunders: Elsevier; 2003. Stress urinary incontinence [cited 2018 Apr 28]. Available from: http://medical-dictionary.thefreedictionary.com.
2. American Medical Association. ICD 10-CM 2017: the complete official code book. Chicago, Illinois: American Medical Association; 2016.
3. Goddard J, Turner AN. Kidney and urinary tract disease. In: Walker BR, Colledge NR, Ralston SH, Penman ID, editors. Davidson's Principles & Practice of Medicine. 22nd ed. Edinburgh: Churchill Livingstone Elsevier; 2014.
4. Baranitharan R, Mahalakshmi V. Prevalence of type of urinary incontinence

and their association with types of delivery. Indian Journal of Physiotherapy and Occupational Therapy 2009;3(4):9-12.

5. Vigod SN, Stewart DE. Major Depression in Female Urinary Incontinence. Psychosomatics 2006; 47(2): 147-51.

6. Robbins BH. Hypothesis Testing, Power, Sample Size and Confidence Intervals (Part-1) [Internet]. 2010 [updated 2010 Jun 3; cited 2017 Jan 13]. Available from: http://biostat.mc.vanderbilt.edu/wiki/pub/Main/AnesShortCourse/HypothesisTestingPart1.pdf

7. Bradley CS, Rovner ES, Morgan MA, Berlin M, Novi JM, Shea JA et al. A new questionnaire for urinary incontinence diagnosis in women: development and testing. Am J Obstet Gynecol. 2005;192: 66–73.

8. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. Journal of Critical Care June 2005;20(2):187-191.

9. Krhut J, Zachoval R, Smith PP, Rosier PF, Valanský L, Martan A, et al.. Pad weight testing in the evaluation of urinary incontinence. Neurourol Urodyn. 2014;33:507–10.

10. SPSS [computer program]. Version 16.0.2. USA: IBM Corporation; 2015.

11. Pallant J. SPSS SURVIVAL MANUAL: A step by step guide to data analysis using SPSS for Windows. Crows Nest, Australia: Allen and Unwin Publishing Company; 2001.

12. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.

13. Luber KM. The Definition, Prevalence, and Risk Factors for Stress Urinary Incontinence. Reviews in Urology 2004; 6 (3): 3–9.

14. Singh U, Agarwal P, Verma ML, Dalela D, Singh N, Shankhwar P, et al. Prevalence and risk factors of urinary incontinence in Indian women: A hospital-based survey. Indian journal of urology 2013; 29(1): 31–6.

15. Borello DF, Downey PA, Zyczynski HM, Rause CR. Continence and Quality-of-Life Outcomes 6 Months Following an Intensive Pelvic-Floor Muscle Exercise Program for Female Stress Urinary Incontinence: A Randomized Trial Comparing- Low and High-Frequency Maintenance Exercise. Physical Therapy 2008; 88(12):1545–53.