

Comparison of Effectiveness of Home-Based Verses Supervised Pelvic Floor Muscle Exercise in Women with Urinary Incontinence

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INTRODUCTION

Man kind witnessed an unparalleled transformation in human health in the 20th century. A demographic transition followed by an epidemiologic transition not only altered the population structure but also changed the morbidity pattern from infectious diseases to chronic conditions.^[1] Countries like India face double the burden in the form of rising noncommunicable diseases in the presence of persistent communicable diseases.^[1] The noncommunicable conditions require long-term/lifelong

management that poses enormous burden on developing economies with poorly funded health care.

Urinary incontinence (UI) is defined as “the complaint of any involuntary leakage of urine” by the International Continence Society in 2002. It is a

ABSTRACT

Background: Urinary incontinence (UI) is a significant health problem with serious physical, psychological, and social consequences. Pelvic floor muscle exercise (PFME) is proven efficacious in the prevention and management of UI. A lack of trained physiotherapist in rural areas mars the uptake of physiotherapy and therefore innovative mechanisms are required. The present study was undertaken to evaluate the usefulness of home-based physiotherapy in the management of UI. **Materials and Methods:** A total of 49 women, who screened positive for UI from a larger study conducted in 4 randomly selected villages of Charutar region, were included in the study. They were assigned home-based or supervised regimens randomly. All participants received education about UI and its management. A structured PFME schedule was developed. Participants in the supervised group received PFME by a trained physiotherapist, while those in the home-based group received training on exercise. Details of each session were documented through a daily diary in both groups. Revised urinary incontinence scale (RUIS) and incontinence impact questionnaire (IIQ-7) were administered at baseline and after 6 months to assess and compare the impact across groups.

Results: Analysis of variance (with *post hoc* comparisons) was employed to compare the effect of physiotherapy across groups. Only 18 (10 supervised and 8 home-based group) out of 49 women participated. Another 10 provided the required data, albeit had not done any exercises. The mean standard deviation of RUIS ($P = 0.84$) and IIQ-7 ($P = 0.55$) scores was similar at baseline across the groups. The RUIS ($P = 0.01$) and IIQ-7 ($P = 0.006$) improved significantly; however, *post hoc* analysis revealed that both RUIS and IIQ-7 improved significantly only in the supervised group. **Conclusion:** Supervised exercise worked better, whereas home-based exercise failed to achieve the desired impact. Identifying barriers in home-based exercise and finding feasible solutions would prove a breakthrough in the management of UI in resource-limited settings.

KEYWORDS: *Physiotherapy, randomized control trial, urinary incontinence*

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worldwide dynamic condition predominantly affecting middle-aged and elderly women in which the patients switch between continence and incontinence.^[2] UI impacts physical, social, and psychological domains besides financial hardship, thereby reducing the quality of life significantly.^[3] The prevalence of UI in the general population reported huge variation from 5% to 69% owing to the definition of UI and study design.^[4] However, most of the data regarding prevalence as well as impact of UI originate from developed economies, while data from developing economies especially from rural community settings are lacking.^[5] The trend analysis suggests a steady increase in the number of people suffering from UI and similar conditions.^[6] The management of UI is an artful combination of various therapies such as surgery, medications, lifestyle modifications depending on type and severity of the UI.^[7] Pelvic floor muscle (PFM) strengthening exercise is proven beneficial to all types of UI particularly stress incontinence if introduced at early stage or used as a preventing measure. It is also easy to implement and cost-effective.^[8]

In India, there were few attempts to assess the prevalence of UI. Studies from various parts of India reported the prevalence of UI between 20%–30%.^[9–13] These prevalence figures in India have manifold repercussions. Historically, woman's health needs were not addressed beyond reproductive health until recently. Medical sociologists persistently advocated for the gender analysis of health keeping in mind social roles and responsibilities of women.^[14] In patriarchal societies like India, the health needs of women are often decided by men albeit women being the primary caregiver of the entire family. The poor autonomy coupled with the tendency to “suffer in silence” hinders the ability of a woman to seek treatment early.^[15] Because of shyness, embarrassment, and a sensitive nature of the problem, poor treatment seeking is reported for UI.^[13,16]

Due to sociocultural adversities in health seeking for a woman in a rural part of India, a home-based PFM exercise program could be a boon to women with mild to moderate UI. It will also ensure optimal use of deficient trained physiotherapists. Evidence suggest that group pelvic floor muscle exercise (PFME) and individual PMFE are equally effective when supervised by a trained physical therapist. However, group supervised exercise was more effective than unsupervised home-based exercise.^[17] Such comparative studies are important in India as the outcome of the PMFE regimen is greatly influenced by sociocultural milieu. A randomized controlled trial was conducted to evaluate comparative

effectiveness of supervised versus home-based PMF training in the management of UI.

MATERIALS AND METHODS

Study settings

The current study was an extension of a larger study conducted in the rural community to determine the UI prevalence in women of the Charutar region of Gujarat. Charutar Arogya Mandal's extension program was operational in 27 villages. This community-based study was conducted in four villages, which were randomly selected from these 27 villages in the Anand district. A total of 883 women who participated in the main study were screened for UI, of which 49 women were found suffering from UI.^[18]

Study design

All 49 women were included in this randomized controlled trial. To avoid contamination, a block of 2 villages (Ardi and Boriya) was randomly allotted for a supervised exercise interventional program and the remaining two villages (Agas and Valetva) from another block were offered home-based exercise intervention. Written informed consent was obtained from all participants.

A special education session was conducted in each village and all the women who screened positive for UI were asked to gather at a common place like the extension center of our hospital, Anganwadi in the village, or at public health center of the village. The main purpose of this session is to empower the women about simple but effective exercise regimen that can be performed easily without any special aid. In this session, a video prepared by the investigators in the vernacular language was shown, which depicted the mechanism of normal continence, causes of incontinence, risk factors, and role of physiotherapy in the form of PFME. PFM strengthening exercises were explained through another video when simultaneously being demonstrated. Volunteers from the participants were asked to perform the exercises with real-time feedback of correctly recruiting the pelvic floor muscles. To motivate the participants, a video interview of 2 women who visited the physiotherapy department for UI and had benefited by PFM exercise was shown (prior consent for video recording was taken).

In the supervised group, the investigator (therapist) visited them once a week for the 1st month of intervention. Subsequently, the investigator visited every fortnight for 2 months and then once a month for next 3 months. During the visit, the women who attended the session were made to exercise under supervision.

A home exercise program prepared for this study was distributed and women were encouraged to exercise as taught and as per the pamphlet given to them. Participants were instructed to complete a daily minimum of 30 repetitions of PFME with slow contractions (3 sets of 10 repetitions) with a hold lasting a count of 5 s every day. Along with this, they were also taught static abdominal exercises. The total duration of the intervention was 6 months for the assessment of outcome.

Study tools

Revised urinary incontinence scale (RUIS) to assess the severity of incontinence and incontinence impact questionnaire (IIQ 7) short form to measure the quality of life were used as outcome measures. Both questionnaires were translated to Gujarati and back translated to English by different experts and validated for accuracy of translation by another independent person. Further, each question of the questionnaires was explained to the participants by the investigator before baseline as well as before final assessment at 6 months.

An exercise diary and a bladder diary were provided to all participants. Number of exercise sessions done per day and number of repetitions done per day were recorded in the exercise diary, while the amount of liquid consumed in a day and accidental leakage of urine per day was recorded in bladder diary. A village health worker of each village, who was appointed by the extension program of Charutar Arogya Mandal, visited each participant every alternate day to ensure the completeness of the diaries.

The study was approved by the Institutional Ethics Committee (IEC) of H. M. Patel Centre for Medical Care and Education (HMPCMCE; Reg No: ECR/1123/Inst/GJ/2018), and it was also registered under Clinical Trials Registry-India (CTRI) (CTRI/2018/03/012638).

Statistical analysis

Descriptive statistics (mean standard deviation [SD], frequency [%]) were used to depict the profile of the study participants. Analysis of variance (ANOVA) was performed to compare change in RUIS and IIQ7 scores across groups. Whenever the P value for ANOVA was statistically significant, *post hoc* comparisons using Scheffe's method were performed to identify groups having significant differences. The data were entered into Microsoft Excel and then exported to STATA (14.2) after logical checks and cleaning. The analysis was performed in STATA (14.2) (StataCorp, Texas, USA). $P < 0.05$ was considered statistically significant.

RESULTS

Based on the main survey conducted in four villages, 49 (5.5%) of the 883 women screened positive for

UI using RUIS. The mean (SD) age of these women was 45.61 (11.83) years. A majority of them were Hindus (39 [79.6%]) followed by Muslims (9 [18.4%]) and others (1 [2%]).

Out of the 49 women screened positive for incontinence, mixed incontinence (33 [67.35%]) was the most common, while 11 (22.47%) women had only urge and 5 (10.20%) had only stress incontinence. Further 41 (83.67%) had mild incontinence (RUIS score of 4–8) and 8 (16.33%) had moderate incontinence (RUIS score of 9–12). The mean (SD) (median [Q1, Q3]) RUIS score was 7.27 (2.88) (8 [5.50, 9]). The mean (SD) (median (Q1, Q3)) IIQ7 score was 6.08 (4.88) (6 [1.50, 9]), whereas the mean (SD) (median (Q1, Q3)) extrapolated score on 0–100 scale was 28.96 (23.22) (28.57 [7.14, 42.86]). The most commonly affected domain of QOL was physical activity (35 [71.4%]), followed by emotional health (32 [65.3%]), travel (29 [59.2%]), and social/relationship (26 [53.1%]).

A total of 22 participants from Agas (10 women) and Valetva (12 Women) villages were offered home-based physiotherapy, whereas 27 participants from Ardi (12 Women) and Boriya (15 Women) villages were offered supervised physiotherapy interventions. 7 participants from home-based physiotherapy group and 12 participants from supervised physiotherapy group refused to participate. Further, 7 participants from home-based physiotherapy and 5 participants from supervised physiotherapy groups did not perform the required exercise at all, but permitted measuring their RUIS and IIQ7 score at 6 months. Thus, 3 groups were available for comparisons: home-based physiotherapy (8 participants), supervised physiotherapy (10 participants), and no exercise (12 participants). The last group was added in the analysis as a control group.

The severity as well as quality of life was similar across groups at baseline. The groups were significantly different at endline (6 Months). However, the difference in endline and baseline was contrasted for adjusting for baseline values. The ANOVA on difference scores confirmed that the groups are significantly different [Table 1 and Figures 1 and 2].

Post hoc comparisons revealed that the participants in supervised group had significantly reduced severity and improved quality of life as compared to both homebased and no exercise groups. However, performance of home-based group was similar to no exercise group [Table 2].

A total of 360 exercise sessions were expected during a span of 6 months. The mean (SD) exercise sessions were

Table 1: Comparison of revised urinary incontinence scale and percentage incontinence impact questionnaire 7 scores across groups

	Mean (SD)			ANOVA (P)
	Supervised physiotherapy (n=10)	Home-based physiotherapy (n=8)	No exercise (control) (n=12)	
RUIS score				
Baseline	7.8 (3.91)	6.88 (2.85)	7.58 (3.6)	0.84
Endline (6 months)	1.9 (1.45)	5 (2.83)	6.75 (2.63)	<0.001
Difference	5.9 (3.31)	1.88 (5.0)	0.83 (2.98)	0.01
Percentage IIQ7 score				
Baseline	36.67 (28.13)	20.83 (19.87)	26.98 (26.66)	0.55
Endline (6 months)	0.95 (2.01)	17.26 (15.88)	21.83 (18.33)	0.006
Difference	35.71 (28.59)	3.57 (23.84)	5.16 (16.55)	0.006

SD: Standard deviation, RUIS: Revised Urinary Incontinence Scale, IIQ7: Incontinence impact questionnaire 7, ANOVA: Analysis of variance

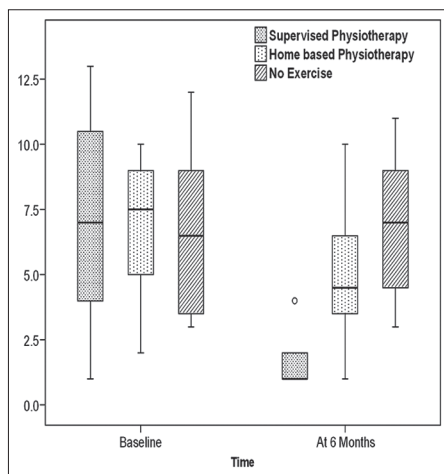


Figure 1: Box plots showing comparison of revised urinary incontinence scale across groups

significantly less in home exercise group as compared to the supervised group (114.50 [74.49] vs. 333.55 [51.19], $P < 0.001$). Out of a possible 360 sessions, 250 or more sessions were considered adequate. It was observed that not a single participant from the home-based group performed adequate (250 or more) sessions, whereas 100% women from the supervised group performed 250 or more sessions.

DISCUSSION

The study results confirmed the utility of PFM training in the management of UI. However, the utility was only noted for the supervised group. The home exercise regimen failed to demonstrate any benefit as compared to the no exercise (control) group. An astute reader might doubt the generalizability of the study results in light of small sample sizes across groups and may suggest power calculation. First, there is no recommended minimum sample size for applying an ANOVA. However, considering the instability of the distribution, a minimum sample size of 5 per group is suggested by

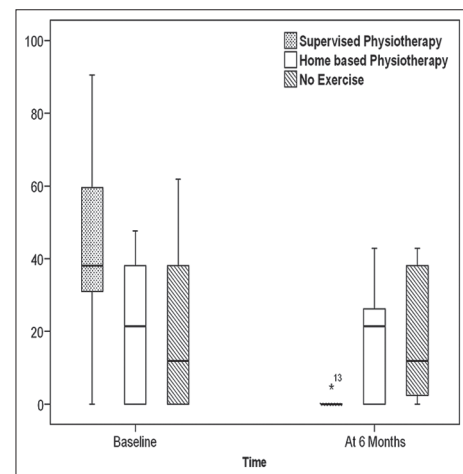


Figure 2: Box plots showing comparison of incontinence impact questionnaire 7 percentage scores across groups

Norman J. In addition, power calculations are suggested if the study fails to detect a significant effect. If you detect a significance, you have enough power.^[19]

PFM training has been consistently recommended as the first line of treatment for uncomplicated UI by the International Continence Society.^[7] It can prove to be a boon to underprivileged communities due to its simplicity, affordability, and efficacy. The mechanism and pathways of PFM training in the management of UI are elaborately documented.^[20] However, adherence and self-efficacy were reported as major hurdles in optimizing the benefit of PFM training. Strategies to improve adherence have also been reported.^[21]

After India's independence, the evolution of the holistic health-care system lost its glory in the last 4–5 decades due to its focus on vertical programs, family planning, and medicalization of health. The initiation of the National Rural Health Mission in the first decade of the 21st century provided a ray of hope in improving rural health care, especially women's health.^[22] India has achieved some milestones in women's health over

Table 2: Post-hoc analysis of revised urinary incontinence scale and incontinence impact questionnaire 7 between groups

Outcome measures	Group	Versus Group	Mean difference	P
RUIS	Supervised exercise	Home-based exercise	4.03	0.03
	Supervised exercise	No exercise	5.07	0.004
	Home based exercise	No exercise	1.04	0.54
IIQ 7	Supervised exercise	Home-based exercise	32.14	0.007
	Supervised exercise	No exercise	30.56	0.005
	Home based exercise	No exercise	1.59	0.88

RUIS: Revised Urinary Incontinence Scale, IIQ7: Incontinence impact questionnaire 7

the last 70 years, most of which are related to maternal and child health and life expectancy. However, sexual abuse, dowry related abuse, as well as domestic violence are still prevalent in the Indian society.^[23] In the current scenario of rising noncommunicable conditions, principles of public health are even more relevant.

In dealing with conditions like UI, primary and secondary prevention strategies play a crucial role. Early detection is better (cheaper, safer) in such conditions. However, even in developed economies, women shudder to seek medical advice for UI^[24] where only about 25% of women consult a doctor. The reasons for not seeking medical advice seem identical in developed as well as developing economies with some variations in the magnitude of proportions.^[13,16,18,24]

The gender role of women in the rural Indian setting hinders the adherence to PFM exercise at home.^[18]

The projection of women with UI in America is alarming^[25] and similar trends can be expected in developing economies with some time lag. The rural health-care system in India is strengthened with Anganwadi worker, adequate network of primary health centers, and introduction of accredited social health activist under the national rural health mission. All this available infrastructure can be leveraged along with the empowerment of women including financial independence.^[23]

CONCLUSION

Although supervised PFM training is beneficial in UI, these beneficial effects disappeared in home-based regimen mainly due to nonadherence. Group exercise at a suitable place in the village ensuring privacy along with general support from a physiotherapist should be attempted to enhance adherence to PFM training.

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Conflicts of interest

There are no conflicts of interest.

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