



Faculty of Medicine
University of Dhaka

**Effectiveness of pelvic floor muscle training on quality of life of
women with urinary incontinence: A randomized clinical trial**

By

Parvin Akter

Master of Science in Physiotherapy

Registration no: 797

Roll no: 11

Session: 2018-19



Department of Physiotherapy

Bangladesh Health Professions Institute (BHPI)

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Submitted in Partial Fulfillment of the Requirements for the Degree of Master of
Science in Physiotherapy



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We the undersigned certify that we have carefully read and recommended to the Faculty of Medicine, University of Dhaka, for acceptance of this thesis entitled, “**Effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence: A randomized clinical trial**”, submitted by Parvin Akter, for the partial fulfillment of the requirements for the degree of Master of Science in Physiotherapy.

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Declaration Form

- This work has not previously been accepted in substance for any degree and isn't concurrently submitted in candidature for any degree.

- This dissertation is being submitted in partial fulfillment of the requirements for the degree of M.Sc. in Physiotherapy.

- This dissertation is the result of my own independent work/investigation, except where otherwise stated. Other sources are acknowledged by giving explicit references. A Bibliography is appended.

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CONTENTS

	Page No.
List of Tables	i
List of Figures	ii
List of Abbreviations	iii
Abstract	iv-v
CHAPTER I: INTRODUCTION	1-9
1.1 Background	1-4
1.2 Rationale	5
1.3.1 General objective	6
1.3.2 Specific objectives	6
1.4 Research Hypothesis	7
1.5 Operational definition	8-9
CHAPTER II: LITERATURE REVIEW	10-17
CHAPTER III: METHODOLOGY	18-27
3.1 Study design	18
3.2 Study area	18
3.3 Study population	18
3.4 Study duration	18
3.5 Subject inclusion criteria	19
3.6 Subject exclusion criteria	19
3.7 Sample size	19
3.8 Sampling technique	20
3.9 Data Collection Procedure.	22
3.10 Data Collection Tools	22
3.11 Research instruments	22-25
3.12 Intervention	25

3.13 Data analysis (Statistical Test)	25-27
3.14 Level of Significance	27
3.15 Informed consent	28
3.16 Ethical Approval	28
CHAPTER IV: RESULTS	29-45
CHAPTER V: DISCUSSION	46-49
CHAPTER VI: LIMITATIONS	50
CHAPTER VII: CONCLUSION AND RECOMMENDATIONS	51
BIBLIOGRAPHY	52-61
APPENDICES	vi-xxxi

List of Tables

List of Tables	Page no
Table-1: Baseline Data	29
Table -2: Mean differences at within group statistics	43
Table 3: Paired sample 't' test	44
Table 4: Independent 't' test	45

List of Figures

List of Figures	Page no
Fig-1: Flow chart for experimental research design	21
Fig 2: Educational status of the participants	30
Fig 3: Types of incontinence	31

LIST OF ABBREVIATIONS

BHPI	Bangladesh Health professions Institute
CRP	Centre for the Rehabilitation of the Paralysed
IRB	Institutional Review Board
KHQ	King’s Health Questionnaire
PF	Pelvic Floor
PFM	Pelvic Floor Muscle
PFT	Pelvic Floor training
QOL	Quality of Life
RCT	Randomized Clinical Trial
LUTS	Lower Urinary Tract Syndrome
OAB	Overactive Bladder
UI	Urinary Incontinence
BOO	Bladder Outlet Obstruction
EG	Experimental Group
CG	Control Group
UDI	Urogenital Distress Inventory
IIQ-7	Incontinence Impact questionnaire

Abstract

Background: Urinary incontinence (UI) is an important public health & social problem predominantly in women. According to the International Incontinence Society (ICS), UI is defined as an involuntary loss of urine which affects in all ages especially in fifth decade of life. **Objective:** The aim of this study was to investigate the effectiveness of pelvic floor muscle training on quality of life (QOL) of women with Urinary Incontinence (UI). **Methods:** Prospective clinical trial with 41 women (21 in experimental group and 21 in the control group) with a diagnosis of UI confirmed by urinary distress inventory (UDI). Women with neuromuscular diseases, using hormone replacement therapy, and with history of prolapse were not included. The exercise protocol for the PFMT group consisted of slow contractions (according to muscle power or strength) followed by rapid contractions (participants' endurance capacity) followed by PFM contraction with coughing, sneezing for 4 weeks, 2 times per week and supervised abdominal strengthening exercise. Control group received only supervised abdominal strengthening exercise. We evaluated the impact of supervised PFMT on QOL using the King's Health Questionnaire (KHQ), 24hours voiding diary for the measurement of incontinence episodes during the initial evaluation and after 8 sessions of treatment. Data were analyzed by parametric test of Independent t test and paired t test. **Results:** There was a significant decrease in the mean scores of the domains assessed by the KHQ regarding the perception of health, impact of the incontinence, limitations of daily activities, physical limitations, social limitations, personal relationships, emotions, sleep/disposition, and measures of severity. Also decrease the episodes of daily incontinence after treatment than initial score of experimental group than control group. After the independent 't' test in

between group analysis is significantly higher for supervised PFMT group ($p < 0.05$). But in within group analysis by paired sample 't' statistic both group showed significant improvement on QOL in KHQ domain except one. So, supervised pelvic floor muscle training along with supervised abdominal strengthening exercise statistically significant to decreases daily incontinence episodes and improve quality of life of women with UI. **Conclusion:** PFM training resulted in significant improvement in reduction of involuntary urinary leakage. Therefore improve the quality of life of women with UI and also their family members.

Trial Registration: CTRI/2020/07/026729 [Registered on: 22/07/2020] - Trial Registered Retrospectively

Key words: *Pelvic Floor Muscle Training (PFMT), Quality of life (QOL), King's Health Questionnaire (KHQ), Urinary Incontinence (UI)*

1.1 Background

Urinary incontinence (UI) is an important public health & social problem predominantly in women (Milsom et al., 2013). According to the International Incontinence Society (ICS), UI is defined as an involuntary loss of urine which affects in all ages especially in fifth decade of life (Chang et al., 2017). Prevalence of this problem is of 25-45% all over the world. Daily incontinence affects between 5% and 15% of middle aged and older women. Prevalence estimates of urinary incontinence during pregnancy & postpartum period are even higher, as it is reported in 42% of pregnant women & 38 % of post-partum women (Morkved & Bo, 2014).

There are three main types of UI: Stress Urinary Incontinence (SUI), Urge Urinary Incontinence (UUI) and Mixed Urinary Incontinence (MUI). Among these the most common is Stress Urinary incontinence (SUI) and its prevalence varies at 10-39%, mixed urinary incidence (MUI) has a prevalence of 7.5-25% (Botlero, Davis, Urquhart, Shortreed, & Bell, 2009). Thus, SUI and MUI constitute nearly two-thirds of the women with urinary incontinence. Another study only mentioned the prevalence of UUI worldwide and found that 1.8-30.5% in European populations, 1.7-36.4% in US populations and 1.5-15.2% in Asian populations though prevalence dependent on age and gender (Milsom et al., 2014).

In 2008, a study conducted about worldwide prevalence of Lower Urinary Tract Syndrome (LUTS), Overactive Bladder (OAB), Urinary Incontinence (UI), Bladder Outlet Obstruction (BOO) and found that among 4.3 billion population, the prevalence of this condition were 45.2%, 10.7%, 8.2% and 21.5% respectively. In this study, they made an estimation that 2.3 billion individuals may affected with at least

one LUTS (18.4% increase) by 2018, 546 million by OAB (20.1%), 423 million by UI (21.6%) and 1.1 billion by BOO (18.5%) (Irwin, Kopp, Agatep, Milsom, & Abrams, 2011). Among nulliparous adolescent and middle-aged women, the reported prevalence of UI has been ranged from 1% to 42.2% (Almoussa & van Loon, 2018).

In UK, 40% of women suffered urinary incontinence and among them 8.5% had caused significant problems. That study also found that among the type of UI, stress UI was the most common type of incontinence. Also, 10% had symptoms of voiding dysfunction. But it is very alarming that only 17% of women went for professional help. Also they supposed urinary incontinence as a part of their ageing process and that's why their expectation was low on successful treatment (Cooper et al., 2015).

Prevalence of Urinary Incontinence (UI) and Overactive Bladder (OAB) in Spain varied according to age and gender. Between 25 to 64 years women, prevalence was near about 10% and 5% between 50 and 64 years men, above 50% in persons over 65 years (Martínez et al., 2009).

In a study it was found that in Bangladesh, the prevalence of UI was 23.7% and 35.3% had at least one Pelvic Floor Dysfunction among 40-49 years women (Islam, Bell, Billah, Hossain, & Davis, 2016). Furthermore they also found in another study that among the UI, the prevalence of stress UI was 5.4%, urgency UI 11.3% and mixed UI was 7.0%. So, urgency UI was the most prevalent form of UI at mid-aged women but postmenopausal women were significantly more likely to have urgency UI (Islam, Bell, Hossain & Davis, 2018).

In Pakistan the prevalence of UI was 11.5% and the most common UI was stress incontinence which prevalence was 4.7%. Also, the prevalence of urge incontinence was 3.2%, mixed incontinence was 2.8%. We found that 52% of women with UI

reported leakage at least daily, and 45% reported a great or moderate impact on their daily life (Jokhio, Rizvi, Rizvi, & Macarthur, 2013).

The prevalence of UI in India was 21.8%. They also found that stress incontinence was most common with prevalence of 73.8%, followed by mixed 16.8% and urge incontinence was 9.5% (Singh et al., 2013).

A study conducted with 276 females living in Bayamon, Puerto Rico, aged range 21-64 years. Study found that the prevalence of UI was 34.8% and among women with UI, most frequent UI was stress incontinence and the percentage was 46.8%. Also, mixed UI 41.5% and urge incontinence was 11.7% (Lopez, Ortiz, & Vargas, 2009).

UI affects Quality of Life (QOL) of women. In Pakistan, 52% of women with UI reported leakage at least daily and 45% reported a great or moderate impact on their daily life. But only 15.7% of women with UI had consulted a doctor (Jokhio et al., 2013). Due to UI, anxiety and depression developed in women who have SUI plus OI and MUI women (Coyne et al., 2012). Study suggested that women have more negative impact on QOL and life style who have MUI than other UI (Dedicação, Haddad, Saldanha & Driusso, 2009).

The pregnancy and vaginal delivery have a significant impact on pelvic floor structures, which may lead to pelvic floor dysfunction due to damage to muscles, ligaments, fascias and peripheral nerves (Ahlund et al., 2013). Mode of delivery also seems to have an impact on SUI. Vaginal delivery seems to be associated with an increased risk for lower urinary tract symptoms nine months after birth in primiparous women when compared to women undergone elective cesarean section (Ekstrom, A., Altman, D., Wiklund, I., Larsson, C., & Andolf, 2008).

Incontinence problems in two or three months post partum has been reported to be 3-38% (Ahlund et al., 2013). Among the women who visit to the multicenter hospital for treatment of Low Back Pain (LBP), prevalence of UI is 43% (Gavira, Walker, Rodríguez, & Gavira, 2014).

Half the women studied reported moderate to severe UI but only 15-18% had consulted a medical professional about the problem. So clearly these issues are under-reported, possibly due to society's prevailing belief that they are "normal" & "to be expected" if they had children. People only seek professional help when feeling very uncomfortable with their condition. Several studies have reported the negative impact of this condition on quality of life, leading to social isolation, concerns, decreased self-esteem and embarrassing situations (Riss, & Kargl, 2011). Pelvic floor muscle training after child birth has been demonstrated to be effective in prevention and treatment of urinary incontinence. It is recommended to be the first choice of treatment for UI with the aim to improve strength and function of the pelvic floor muscles (Abrams et al., 2010). Pelvic floor muscle training improves the muscle strength and decreases episodes of incontinence (Dumoulin et al., 2015).

1.2 Rationale of the study

Women are more vulnerable than men as because they cannot expose their all problems. Usually they hide their problem if it related to gynecological. Along with this, women who lived in rural place depend on other person of the family members in case of treatment. Urinary incontinence (UI) is a kind of problem which specifically affects older age person and women are more affected than men in urinary incontinence. In context of our country, women ashamed of to explain her complain to her husband or son. That's why, mostly urinary incontinence cases don't consider as a problem. But, many of our women face a lot of problem due to urinary incontinence in their lifetime. UI affects their quality of life but they do not receive any sorts' of treatment for this problem. Current study suggested that, women who are suffering with Low Back Pain (LBP) also may have urinary incontinence and the percentage is around 68.4 % (Nipa, 2016). But, they only came for the treatment of LBP not about the urinary incontinence. It is alarming for us that, very few numbers of women go for treatment for this problem. Various study suggested that, physiotherapy interventions are very effective for urinary incontinence as it mainly caused by the weakness of pelvic floor muscles. Also, women with LBP have weakness of pelvic floor muscle as well as back muscles and surroundings. Therefore, when women came for receiving physiotherapy treatment for LBP, core stability exercises and other physiotherapy interventions are usually provided with the LBP treatment protocol. Some study also suggested that core stability exercise decreases LBP as well as urinary incontinence. Therefore, researcher wishes to find out the effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence.

1.3 Objectives

1.3.1 General Objectives

To determine the effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence (UI).

1.3.2 Specific Objectives

1. To find out the socio- demographic profile of the participants.
2. To know the effectiveness of pelvic floor muscle training combined with abdominal strengthening exercise in within and between groups on quality of life of women with urinary incontinence.
3. To determine the effectiveness of pelvic floor muscle training combined with abdominal strengthening exercise in within and between groups in daily incontinence episodes of women with urinary incontinence.

1.4 Research hypothesis

Null Hypothesis (H_0):

H_0 : $\mu_1 - \mu_2 = 0$ or $\mu_1 = \mu_2$, Pelvic floor muscle training combined with supervised abdominal strengthening exercise is no more effective than only supervised abdominal strengthening exercise on quality of life of women with urinary incontinence.

Alternative Hypothesis (H_a):

H_a : $\mu_1 - \mu_2 \neq 0$ or $\mu_1 \neq \mu_2$, Pelvic floor muscle training combined with supervised abdominal strengthening exercise is more effective than only supervised abdominal strengthening exercise for the treatment of women with urinary incontinence.

Here,

H_0 = Null hypothesis

H_a = Alternative hypothesis

μ_1 = Mean difference in initial assessment

μ_2 = Mean difference in final assessment

1.5 Operational Definition

1.5.1 Pelvic Floor (PF)

The pelvic floor is a funnel-shaped structure. It attaches to the walls of the lesser pelvis, separating the pelvic cavity from the perineum inferiorly. Pelvic floor consist of a group of 12 straighten muscles arranged in 3 layers. The striated muscle fibres of each muscle run in the same direction to the other muscles of the pelvic floor group. It is the main support structure for the pelvic organs such as: bladder, uterus and bowel.

1.5.2 Pelvic Floor Muscle (PFM)

PFMs are the deep muscle group which remains within pelvic cavity that has some similarities in their neural control as axial muscles. The pelvic floor muscle extends from the pubic symphysis through the side wall of the ileum to the coccyx. This group of muscle plays an important role in maintaining urinary and fecal continence as well as in providing support to the pelvic organs. The PFM has two types of muscle fibers- Type I or slow twitch muscle fibers and type II, fast twitch muscle fibers.

1.5.3 Pelvic Floor Muscle weakness

Pelvic Floor Muscle weakness is a condition which occurs when PFM cannot function properly. PFM weakness develops due to pregnancy, childbirth, straining to empty the bladder or bowel with or without constipation, persistent heavy lifting, chronic cough (from smoking or any respiratory disease) and obesity, lack of general fitness, restricted mobility, menopause, and age.

1.5.4 Pelvic Floor Muscle Training (PFMT)

Pelvic Floor Muscle Training is a kind of physiotherapy intervention to strengthen pelvic floor muscle as well as to treat urinary incontinence. In this training programme mainly emphasize on pelvic floor muscle contraction in different way and in participants' endurance and power level.

1.5.5 Quality Of Life (QOL)

Quality of life (QOL) is the general well-being of individuals which may draw negative and positive features of life. According to the World Health Organization (WHO), quality of life is defined as “the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals. In health care, Health-Related Quality of Life (HRQoL) is an assessment of how the individuals' well-being may be affected over time by a disease, disability or disorder. Also, it's an evaluation of QOL and its relationship with disease.

1.5.6 Urinary Incontinence

Urinary incontinence is the involuntary leakage of urine due to lack of control of urination. According to International Continence Society, UI is defined as “any complaint of involuntary leakage of urine”. There are three main types of UI. Men and women suffer with UI but women have more chance to develop UI. Weakness of pelvic floor muscle is the direct cause of UI. Urinary incontinence develops with coughing (stress UI), urgency (urge UI) or both stress and urgency (mixed).

Urinary incontinence, as defined by The International Continence Society, is the complaint of any involuntary leakage of urine that is a social and hygiene problem (Haylen et al., 2010). Therefore, Urinary incontinence (UI) is a health problem affecting mainly the quality of women's lives at different stages of their life (Ptak et al., 2019). It can result from a variety of different conditions and accordingly to the cause it can be classify. According to The International Continence Society common types of urinary incontinence in women are Stress Urinary Incontinence (SUI), Urge Urinary Incontinence (UII) and Mixed Urinary Incontinence (MUI) (Haylen et al., 2010). Usually mechanism of different types incontinence are not similar. SUI usually occurs in situations such as coughing, sneezing, laughter, jumping, and during activities like walking or changing position (Hirakawa, Suzuki, Kato, Gotoh & Yoshikawa, 2013). Stress Urinary Incontinence (SUI) is likely to be due to anatomical defects in the structures that support the bladder and urethra, resulting in suboptimal positioning of these structures at rest or on exertion, or dysfunction of the neuromuscular components that help control the urethral sphincter or urethral pressure. As a result, the bladder outlet (urethra) is not closed off properly during exertion, which results in leakage (Dumoulin, Cacciari & Hay-Smith, 2018).

UII is characterized by involuntary loss of urine, associated with a strong urge to urinate, with or without a full bladder; it is also associated with the increase in urinary frequency, nocturia (Haylen et al., 2010). UII usually caused by the over activity of detrusor muscle or low compliance, the over activity of detrusor muscle characterized by an involuntary contraction during filling phase of micturition and this over activity

may be neurogenic or idiopathic (Nascimento-Correia, Santos-Pereira, Tahara & Driusso, 2012). The neurogenic theory suggested that the detrusor muscle can be overactive due to denervation at the spinal or cortical level leads to hyperactive voiding.

MUI is defined as urine loss associated with urgency and situations of increased intra-abdominal pressure, a combination of the two types previously described ((Haylen et al., 2010). Urodynamic studies sometimes reveal that urine leakage results from a combination of urodynamic SUI and detrusor over activity (Dumoulin, et al., 2018).

Cause of UI is often multifactorial. Although urinary incontinence prevalence is more in older female but it is not related with female ageing process (Dedicação, Haddad, Saldanha & Driusso, 2009). A study conducted among Kigali women and found a number of social demographic factors, which predispose Rwandan women to developing UI. Age is therefore a predisposing risk factor a risk of UI. Even though prevalence increased with age, UI is never normal and it remains treatable regardless of age. Due to reduction of hormone after menopause, urinary incontinence develops after menopause (Legendre, Ringa, Fauconnier & Fritel, 2013). From Generalized Estimating Equations, women who became perimenopausal ('pre-peri') or those experiencing perimenopause for >1 year ('peri-peri') were more likely to have symptoms of stress UI than were postmenopausal women (Mishra, Cardozo, & Kuh, 2010). Other predisposing factors are pregnancy and vaginal delivery (which suggest neuromuscular trauma to the pelvic floor muscles), deficiency or inadequate function of PFM resulting pelvic floor dysfunction, neurological or biochemical changes frequently associated with the aging process (Menezes, Pereira & Hextall, 2010).

One-third of Bangladeshi women aged 30–59 years had at least one symptomatic PFD; risk factors included greater age, higher parity, lower wealth status and self-reported diabetes (Islam et al., 2016).

During the first 3 months postpartum, the pooled prevalence of any postpartum incontinence was 33% in all women; the mean prevalence of weekly and daily incontinence was 12% (95% CI 11–13%) and 3% (95% CI 3–4%), respectively and mean prevalence was double in the vaginal delivery group (31%) compared to the cesarean section group (15%) (Thom & Rortveit, 2010). A study showed that the antenatal development of stress incontinence lead to an 18-times higher risk of developing stress incontinence during the year following child birth (van Brummen et al., 2007) and two fold higher risk to develop long term SUI that delivered vaginally compared to cesarian section (Tähtinen et al., 2016). Urinary incontinence increases with parity and, in primiparas who deliver vaginally, it has been associated with decreases in pelvic muscle strength of 22–35% between pregnancy and the postpartum period (Özdemir, Bakar, Özençin & Duran , 2015). The reported prevalence of urinary incontinence among nulliparous adolescent and middle-aged women ranged from 1% to 42.2% (Almoussa & van Loon, 2018). In Pakistan, Older age, higher parity and marriage at an early age were independently associated with UI (Jokhio et al., 2013). Parity is also a very strong determinant of the predisposition of UI.

Presence of predisposing diseases such as diabetes mellitus, multiple sclerosis, dementia, depression, obesity, bladder cancer, lithiasis, chronic urinary infections and Parkinson's disease are also the causes of UI (Corcos, & Przydacz, 2018). Obesity (body mass index of over 30), high impact sports (e.g. trampolining, pole vaulting),

chronic respiratory disorders causing a chronic cough, and intra-abdominal masses causing an increase in the intra-abdominal pressure that leads to develop UI (Moreno-Vecino et al., 2015)

UI is a symptom, which decreases a person's overall quality of life (Riss & Kargl, 2011). QoL of individual who have urinary incontinence vary according to types of incontinence; urge incontinence have worse impact on quality of life than stress UI ((Riss & Kargl, 2011). Also negative impact on lifestyle is greater who have mixed type of UI (Dedicação, Haddad, Saldanha & Driusso, 2009). UI can have multiple effects on daily activities, social interactions and the perception of health; the major problems are related to social and mental wellbeing, including sexual problems, social isolation, low self-esteem and depression which affect more on quality of individual and their family (Bartoli, Aguzzi & Tarricone, 2010). Therefore, it can cause social and hygienic discomfort, poor health condition; due to the fear of loss of urine, the smell of urine, need for wearing sanitary pads, and more frequent changes of clothing, low intake of water (Abrams, Smith & Cotterill, 2015). Women with UI loss their sexual function and partnership relationship which leads to severe depression; therefore between 25-50% women with UI have sexual dysfunction and it is more in case urge or overactive bladder than stress UI (Sinclair & Ramsay, 2011). In general, UI appears to adversely affect daily activities, social relationships and emotional wellbeing in women of all ages. It is also possible that UI may affect the young and old differently and UI negatively affect children's QOL similar to adult though QoL affecting factors may be different children (Thibodeau, Metcalfe, Koop & Moore, 2013). Exercise restriction or sexual dysfunction due to UI may be more problematic in young women than in much older adults; depression, disturbances in sleeping, and anxiety were common in women who suffered from UI regardless of age or marital

status (Brazell, O'Sullivan & LaSala, 2013). Treatment of UI for children is different within 24 hours duration, night-time and day time incontinence for children are different and the cause also different (Chang et al., 2017).

The assessment of QOL for UI has been shown to be a predictor of treatment-seeking for UI because without knowing QOL of individual with UI, no outcome of treatment effectiveness will be found (Fitz et al., 2012). Several questionnaires have been developed and tested to measure the impact of UI on the QOL (Naughton et al., 2004). Among the dimensions studied, the impact on daily life, personal relationships, the psychological and emotional aspects, and the social and physical limitations are important factors measured by these instruments (Hebbar, Pandey & Chawla, 2015). There are several questionnaire to measure QOL in women with UI and these includes; Urogenital Distress Inventory (UDI), Urinary Incontinence Quality of Life Instrument (I-Qol), Incontinence Impact Questionnaire (IIQ), King's Health Questionnaire (KHQ), Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ), International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF). Recent publications have shown improvement in the QOL of women undergoing conservative treatment and most important questionnaire which was used for evaluation is the King's Health Questionnaire (KHQ) ((Naughton et al., 2004). King's Health Questionnaire (KHQ) is widely used as these questionnaires are simple to administer, easily understandable by the participant and cover several domains of life (Price, Dawood & Jackson, 2010). Several reports on medical and surgical interventions in urinary incontinence have generously used KHQ system of QOL assessment not only to exhibit improvement in the condition before and after the procedure, but also the persistence and continuation therapeutic benefits during short term and long- term observations.

There are more than 45 language versions of KHQ available (French, Dutch, Italian, German, Portuguese, Spanish, South African English, Japanese, Korean, Chinese etc.) and the most important factor to use this questionnaire is that it requires short time to administer and complete the questionnaires (on average 5 minutes), also used for various bladder conditions (stress incontinence, urge incontinence, mixed incontinence, over-active bladder) (Hebbar et al., 2015). The KHQ is a valid instrument for measuring the quality of life of patients with different types of UI (Okamura et al., 2002). Study suggested that the validity and reliability of KHQ has been proved by psychometric property (Badia et al., 2000). Another study also mentioned that KHQ is a valid and reliable instrument for the assessment of health-related quality of life among women with anal and urinary incontinence (Kelleher et al., 2000). KHQ has undergone psychometric tests for reliability and validity and responsiveness to change (Bugg et al., 2001). KHQ may be useful to assess the detailed urination-related QOL status of elderly men and women with UI (Dolan et al., 2004).

A systemic review conducted with 24 studies to assess the effectiveness of pelvic floor muscle training (PFMT) in the treatment of urinary incontinence (UI) in women, with a particular focus on the impact of this form of therapy on the patients' quality of life (QOL) and the most commonly used questionnaire for QOL was the KHQ; it was mentioned in 8 out of 24 studies (Radzimińska, Strączyńska, Weber-Rajek, Styczyńska, Strojek, & Piekorz, 2018).

Therefore, assessment of QOL in women who undergo interventions for the treatment of UI becomes mandatory, as the UI has an impact not only on the QOL of individuals who have it, but also affects the QOL of family members and caregivers.

A study conducted on UI to show the physiotherapy effectiveness on quality of life and the information was obtained using a validated QoL questionnaire (KHQ), a survey of women without other medical complaints. Therefore, assessing the quality of life of UI as a whole is important not only in the field of assessment but also promoting continence, rehabilitation and physiotherapy management (Price, Dawood & Jackson, 2010).

One of the goals of physiotherapy is to investigate and intervene in the impact of incontinence on quality of life of affected women. Physiotherapists are involved in promoting health in women through antenatal exercises, management of urinary incontinence with pelvic floor exercises, as well as patient education (BØ, 2003). The pelvic floor muscle (PFM) training has proved to be an effective treatment for female incontinence. Further the author noted that it has no side effects, and is cost effective compared to surgery (BØ, 2003). Promoting urinary continence by pelvic floor exercises reduced the prevalence of UI after giving birth, particularly its severity and at three months after delivery in women who had forceps or ventouse deliveries or babies weighing 4000g or more (Chiarelli & Cockburn, 2002). Moreover, PFM training programme can easily be implemented as one part of a public health strategy to prevent UI in childbearing women (Mørkved & Bø, 2014).

Treatment by a specialized physiotherapist potentially produces better results than instruction by a general practitioner (Janssen, Lagro-Janssen & Felling, 2001). Patients can then practice more intensive pelvic floor exercises and bladder training under supervision. Physiotherapy methods vary, including approaches with or without appliances like biofeedback, electrostimulation, vaginal cones, and the duration and frequency of therapeutic sessions (Janssen et al., 2001).

Our review confirms that pelvic floor muscle exercise is particularly beneficial in the treatment of urinary stress incontinence in females. Studies have shown up to 70% improvement in symptoms of stress incontinence following appropriately performed pelvic floor exercise. This improvement is evident across all age groups. There is evidence that women perform better with exercise regimes supervised by specialist physiotherapists or continence nurses, as opposed to unsupervised or leaflet-based care. There is evidence for the widespread recommendation that pelvic floor muscle exercise helps women with all types of urinary incontinence. However, the treatment is most beneficial in women with stress urinary incontinence alone, and who participate in a supervised pelvic floor muscle training programme for at least three months. (Price, Dawood & Jackson, 2010).

The assessment of the impact of PFMT on the QOL of women with UI was conducted among 2,394 women in 24 selected studies. After the end of treatment, the majority of patients in the experimental groups noted a statistically significant improvement in QOL. The results of this literature review demonstrate that PFMT is an effective treatment for UI in women. PFMT significantly improves the QoL of women with UI, which is an important determinant of their physical, mental, and social functioning (Radzimińska et al., 2018)

3.1 Study design

The aim of this study was to find out the Effectiveness of Pelvic Floor Muscle training on Quality of Life of Women with Urinary Incontinence. So, Experimental design of quantitative research type of Randomized Clinical Trail (RCT) had been chosen because the experimental study of RCT is the best way to find out the effectiveness of the study. The researcher had conducted the study with experimental group and control group with an aim to compare between experimental group and control group (Ortiz et al., 2015). It was a double blinded study where the assessor and participants were blinded.

3.2 Study area

Data was collected from the outpatient, Musculoskeletal Physiotherapy unit of the department of physiotherapy at Centre for the Rehabilitation of the Paralyzed (CRP), Savar, and Dhaka. Because these patients came at CRP from all over the Bangladesh, from all economic groups for comprehensive rehabilitation, so it reflects the entire population.

3.3 Study population

Patient with Low Back Pain (LBP) with Urinary Incontinence (UI) from all over Bangladesh.

3.4 Study duration

The duration of this study was November 2019 to September 2020.

3.5 Inclusion criteria

- Patients who had LBP with urinary incontinence were selected for this study (Bush et al., 2013).
- In this study, participants' age range were 40 years to 60 years. (Konstantinidou et al., 2013).
- Female were selected for this study participants (Price et al., 2010).
- Those who were motivated and willing to give their consent were considered as participants for this study.

3.6 Exclusion Criteria

- Patients with any neurological involvement were excluded for participation (Radziminska et al., 2018).
- Patients with hearing impairments were also excluded for participation (Kaya et al., 2015).
- Those who received treatment previously for urinary incontinence could not participate in this study (Sherburn et al., 2011).
- Participants whose age below 40 years and more than 60 years were excluded in this study (Konstantinidou et al., 2013).

3.7 Sample Size

Data had been collected from December 2019 to September 2020. During this time period 41 participants matched the criteria and gave their consent for participation

3.8 Sampling technique

All patients who had LBP attended at CRP Physiotherapy outdoor from December 1, 2019 to September, 2020 had been chosen as subject. From the participants, screening procedure had been performed by qualified Physiotherapist to examine the inclusion and exclusion criteria. From the eligible respondents, consecutive 41 patients had been taken as a sample by hospital randomized sampling. The setting was CRP- Savar. As these patients attended in these CRP randomly without the choice of CRP authority or the researcher's choice, so they may be considered as a random sample authorized as hospital randomization. Therefore, simple random sampling (Therapist randomization) had been used to select the participants for group allocation.

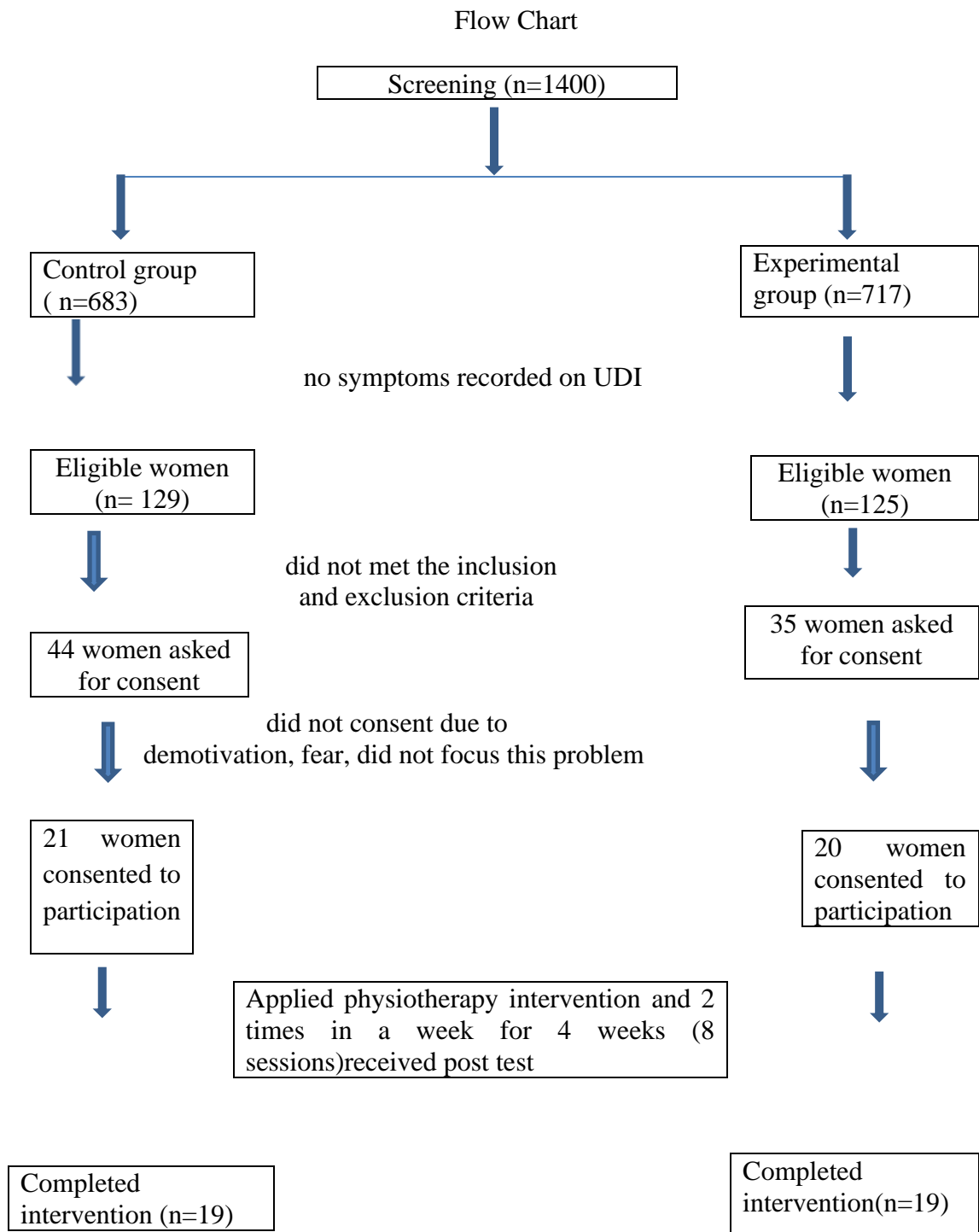


Fig-1: Flow chart for experimental research design

3.9 Data collection procedure

A data collector assigned to conduct for data collection for the study time frame. Therefore trained her about the procedure of data collection Screening and interventions had been carried out by respective physiotherapists. Data collector had been collected information from the subjects for the pretest when met the eligibility criteria. The patient had been enrolled in schedule and after 8 sessions, in 4 weeks the posttest had been carried out. Post data were collected after 8 sessions of treatment. But participants those did not continue 8 sessions, in that case data collected received post data through phone call. It is good point of KHQ that this questionnaire is the subjective questionnaire that's why data was collected by phone call

3.10 Data collection tools

During data collection, collector used informed consent for ethical issues. A structured questionnaire was used for details from participants of this study. Also used other accessories of pen, pencil, record file etc to make the collection fruitful.

3.11 Research instruments

Part-I: Self-structured demographic questionnaire to identify socio-demographic information.

- This section of the questionnaire consists of collecting information pertaining to the socio-demographic characteristics such as age, marital status, health status, and level of education of the participants.

Respondents were not required to include their names on any of the questionnaires.

Part –II: This section consists of the “King’s Health Questionnaire”, which was used to assess incontinence impact and general health perceptions and overall measure the quality of life of patients with UI. Before (pretest) and after (posttest) the treatment, KHQ on quality of life was applied.

This questionnaire has 30 questions distributed in nine domains: the patients report perception of health, impact of incontinence, task performance or activity limitations, physical limitations, social limitations, personal relationships, emotions, sleep/disposition, and measures of severity. KHQ is a patient self-administered self-report and has 3 parts consisting of 21 items. Part 1 contains general health perception and incontinence impact (one item each). Part 2 contains role limitations, physical limitations, social limitations (two items each), personal relationships, emotions (three items each) and sleep/energy (two items), severity measures (four items). Part 3 is considered as a single item and contains ten responses in relation to frequency, nocturia, urgency, urge, stress, intercourse incontinence, nocturnal enuresis, infections, pain, and difficulty in voiding. The responses in KHQ have four point rating system. The KHQ is scored in each of its domains and, therefore, there is no overall score. The eight subscales (domains) scored between 0 (best) and 100 (worst). The Symptom Severity scale is scored from 0 (best) to 30 (worst). Decreases in KHQ domain scores indicate an improvement in quality of life. The higher the score, the worse the quality of life related to that domain. Numerical values are assigned to all answers, added, and evaluated by domain.

This questionnaire was developed over a number of years at Kings College Hospital in London as part of a large ongoing quality of life study. The aim of the questionnaire was not only to measure multidimensional quality of life amongst UI women, but also to include incontinence coping strategies, global health questions and a symptom impact subscale (Abrams et al.,2010). King's Health Questionnaire (KHQ) was formulated by Dr. C. J. Kelleher with his other colleagues under the guidance of Professor Dr. L. D. Cardozo in 1997 in department of urogynaecology, King's College, London. After six different pilot studies, validity and reliability testing, final version of this questionnaire established. There were 293 respondents and the article was published in British Journal of Obstetrics and Gynaecology in December 1997. Now, KHQ is a valid and reliable material for the assessment of quality of life in women with urinary incontinence. They also opined that KHQ will be useful for the rapid appraisal and follow-up in many clinical trials involving new treatments for urinary incontinence. Also, required short time to administer and complete the questionnaires (on average 5 minutes), age and gender suitability (valid for both male and females between 17 and 85 years) and coverage of all bladder conditions (stress incontinence, urge incontinence, mixed incontinence, over active bladder). European Clinical Practice Guidelines also recommended this questionnaire (Viktrup, Summers & Dennett, 2004).

Part-III: 24 hours voiding diary in Bangla to measure daily episodes of urinary incontinence.

- Before and after the treatment, 24 hours voiding diary was used to measure urinary loss or incontinence episodes. This voiding diary is used to know the episodes of incontinence and amount of leakage of

urine. Chose woke up or bed time hours and count 24 hours later in the same time. In this diary how many times incontinence occurred were assess.

3.12 Intervention

Treatment has been provided by physiotherapist for both groups having at least graduation in Physiotherapy and experience of treating musculoskeletal patients for more than 3 years. The treatment protocol was defined by the department of Physiotherapy in Centre for the Rehabilitation of the Paralyzed (CRP). The departmental treatment protocol has been developed according to current evidences reviewed by professors and clinician experienced more than 20 years. Control group received McKenzie treatment approach, soft tissue mobilization, supervised abdominal muscle strengthening (Abdominal drawing exercise, ball punching with both knees). Experimental group received previous group treatment along with supervised Pelvic floor muscle training (Pelvic floor muscle contractions like vaginal contraction sustained for each participants' power (sec), Pelvic Floor Muscle contractions according to each participants' endurance (repetition), Pelvic floor muscle contraction with coughing. Each group treatment sessions continue for 30 minutes and received treatment for LBP also UI as they came for treatment of LBP.

3.13 Data Analysis (Statistical analysis)

Statistical analysis refers to the well-defined organization and interpretations of the data by systemic and mathematical procedure and rules (DePoy and Gitlin, 2015). Statistical analysis was performed by using statistical package for social science (SPSS) version 20. Data were analyzed by description

statistics and inferential statistic of parametric test of Independent 't' and paired t test (Hicks, 2009).

Hypothesis Test

Paired t test

Paired t-test was used to compare difference between means of paired variables.

Selection of test of hypothesis is mean difference under t distribution.

Assumption

Paired variables

Variables were quantitative

Parent population of sample observation follows normal distribution.

Formula: Paired "t" test statistic t is follows:

$$t = \frac{\bar{d}}{SE(\bar{d})} = \frac{\bar{d}}{\frac{SD}{\sqrt{n}}}$$

Where,

\bar{d} = mean of difference (d) between paired values,

SE (\bar{d})= Standard Error of the mean difference

SD= standard deviation of the differences *d* and

n= number of paired observations.

Unrelated or Independent t test

Unrelated t test was used to compare difference between two means of independent variables. Selection of test of hypothesis was two independent mean differences under independent t distribution.

Assumption

Different and independent variables

Variables were quantitative

Formula: test statistic t is follows:

$$t = \frac{\bar{x}_1 - \bar{x}_2}{s \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

Where,

\bar{x}_1 = Mean of the Experimental Group,

\bar{x}_2 = Mean of the Control Group,

n_1 = Number of participants in the Experimental Group,

n_2 = Number of participants in the Control Group

S = Combined standard deviation of both groups

3.14 Level of Significance

In order to find out the significance of the study, the “p” value was calculated.

The p values refer to the probability of the results for experimental study. The

word probability refers to the accuracy of the findings. A p value is called

level of significance for an experiment and a p value of <0.05 was accepted as

significant result for health service research. If the p value is equal or smaller

than the significant level, the results are said to be significant (DePoy and

Gitlin, 2015). Also, calculated the 't' value to compare with tabulated t value. If the observed t value is greater than the table t value, the results are said to be significant.

3.15 Informed consent

Informed consent had been taken from each participant prior to data collection. Data collector maintained the confidentiality of the participants. Participants had the rights to proceed or withdrawal from the study anytime. Withdrawal of participation from the study did not affect their treatment in the physiotherapy department and they still had the chance to receive same facilities.

3.16 Ethical approval

Research proposal had been applied for approval to Institutional review board (IRB) of BHPI. The investigator followed the guideline given by IRB. This research project had been done by following the World Health Organization (WHO) and national (BMRC) guidelines. At the beginning of data collection, researcher had been obtained the permission from the head of Physiotherapy department, CRP for data collection and ensuring the safety of the participants. Also, researcher had taken permission from MAPI research trust for using the KHQ questionnaire. Another important point is that researcher had taken WHO clinical trial registration. All the consent copies were attached in the Appendix part.

Results of Descriptive Statistics**Table-1:** Baseline Data

Variables	Experimental Group(n=20)		Control Group(n=21)	
	Mean with SD	Min.-Max.	Mean with SD	Min.-Max.
	Or n	Or %	Or n	Or %
Age (yrs.)	48.4(\pm 7.71)	40-60	49.76(\pm 7.64)	40-60
Occupation	Housewives=20	100%	Housewives=17 Other =4	81% 19%
Marital status	Married=19 Divorced=1	95% 5%	Married=19 Divorced=1 Widow=1	90.5% 4.8% 4.8%
Area of Living	Urban=11 Rural=9	55% 45%	Urban=6 Rural=15	28.6% 71.4%
Incontinence Episodes (Pre)	4.75(\pm 1.372)	3-8	4.57(\pm 1.83)	2-8
Incontinence Episodes (Post)	1.68(\pm 1.455)	0-5	3.42(\pm 1.21)	2-6

This table describes about baseline characteristics of different variables. In the experimental group mean age of the participants were 48.4 years, in control group 49.76 years. Most of the participants were housewives in both groups. Initially mean episodes of incontinence in experimental group was 4.75 and in control group 4.57.

4.2 Educational status:

In this study participants of experimental group were 20, among them up to sign 35% (n=7), complete primary education 20% (n=4), secondary passed 20% (n=4) and 3 participants complete higher secondary (15%) and only 2 participants complete graduation (10%). In the control group, among 21 participants, 11 participants (52.4%) complete primary education only, 4 (19%) give sign only, 3 participants passed secondary level (14.3%), 2 complete graduation (9.5%), only 1 passed HSC.

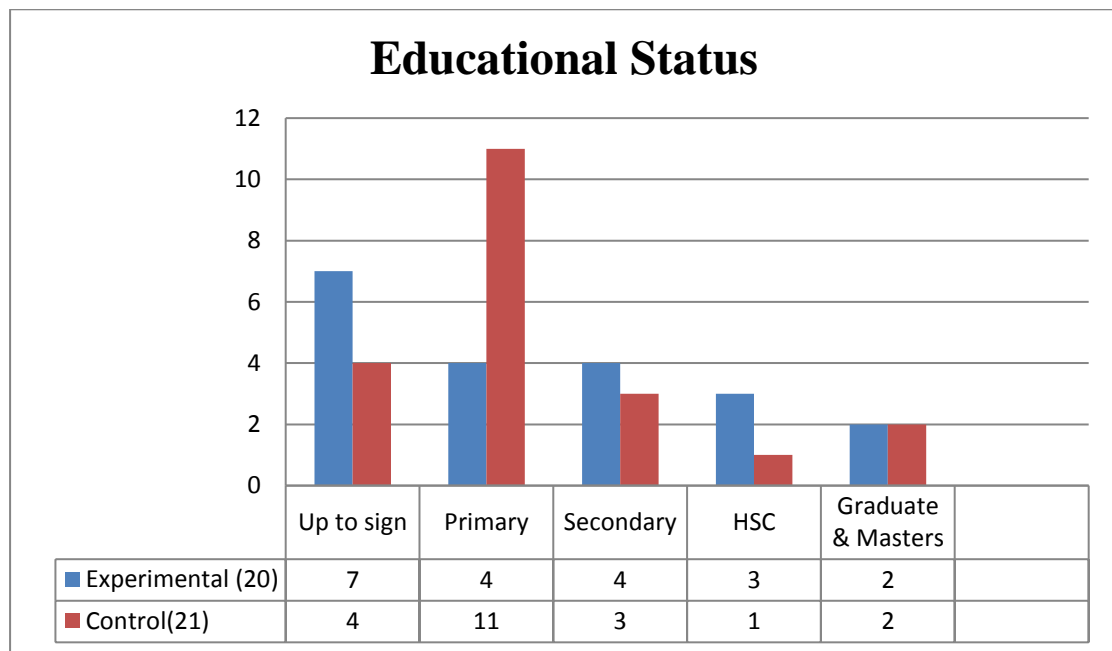


Fig 2: Educational status of the participants

4.3 Types of incontinence

Most of the participants had MUI between two groups, 9 in experimental group and 12 in control group. 9 participants' had SUI in each group. In the experimental group, only 2 had UUI but in control group none had UUI.

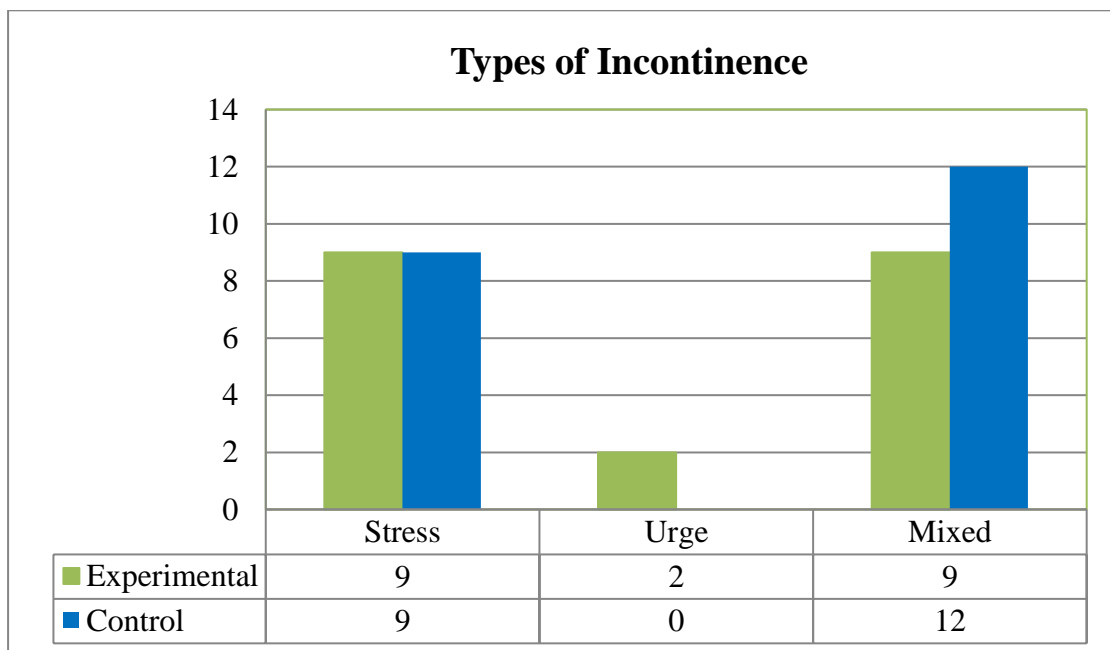


Fig 3: Types of incontinence

Results of Parametric Test

Results of general health perception

At 5% level of significant and 33 degrees of freedom standard table value was 2.036 for unpaired/independent t test in between group analysis. And at the same significant level and same degree of freedom, observed t value was 4.412. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in.

This study found that in the general health perceptions, observed t value was 5.72 (36.84±28.0) in the experimental group at two tailed paired t test while this same variable for control group observed value was 5.72 (18.42±14.05) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in general health perceptions in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of general health perceptions were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group In this study, for general health perception analysis in within group were statistically significant where ($p < .05$) and the level was 0.001% .In between group analysis for incontinence impact domain in KHQ, the observed value was statistically significant after treatment session ($p < .05$).

Results of incontinence impact

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 3.89. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life.

This study found that in the incontinence impact, observed t value was 6.83 (25.9±42.10) in the experimental group at two tailed paired t test while this same variable for control group observed value was 2.19 (7.03±13.98) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in general health perceptions in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of incontinence impact were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of role limitations

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 3.09. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life.

This study found that in the role limitations, observed t value was 6.3 (37.44±25.86) in the experimental group at two tailed paired t test while this same variable for control group observed value was 4.1 (16.65±17.56) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in role limitations in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of role limitations were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of physical limitations

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 2.45. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in case of physical limitation.

This study found that in the physical limitation , observed t value was 5.1 (30.7 ± 26.22) in the experimental group at two tailed paired t test while this same variable for control group observed value was 3.99 (12.29 ± 13.43) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in physical limitation in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of physical limitation were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise for improving Quality of life.

Results of social limitations

At 5% level of significant and 33 degrees of freedom standard table value was 2.036 in the Unpaired/independent t test in between group and at the same significant level and same degree of freedom observed t value was 2.76. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in social limitation.

This study found that in the social limitation , observed t value was 5.01 (26.29±22.87) in the experimental group at two tailed paired t test while this same variable for control group observed value was 3.33 (9.06±11.88) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value for social limitation in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of social limitation were significant at 0.004% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of personal relationship

The Unpaired/independent t test in between group at 5% level of significant and 28 degrees of freedom standard table value was 2.048 and at the same significant level and same degree of freedom observed t value was 2.44. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in personal relationship.

This study found that in the personal relationship, observed t value was 1.76 (4.62±11.14) in the experimental group at two tailed paired t test while this same variable for control group observed value was 1.47 (2.22±5.88) in within group. 5% level of significant at 14 (eighteen) degrees of freedom standard t value was 2.11 and observed t value in personal relationship in both groups were less than standard t value that meant alternative hypothesis was rejected and null hypothesis was accepted in the within group. Both groups in aspect of personal relationship were not significant at 0.164% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was no more effective than supervised core stability exercise for improving Quality of life.

Results of emotions

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 5.80. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life including emotional factor.

This study found that in the factor of emotion, observed t value was 10.67(54.35±22.18) in the experimental group at two tailed paired t test while this same variable for control group observed value was 6.34 (30.41±20.90) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in emotion in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of emotional factor were significant at 0.000% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise for improving Quality of life.

Results of sleep/Energy

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 2.74. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in case of sleep.

This study found that in the general health perceptions, observed t value was 4.31(28.07±28.37) in the experimental group at two tailed paired t test while this same variable for control group observed value was 4.06 (9.26±9.94) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in case of sleep or energy in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of sleep or energy were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of severity Measure

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 4.452. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life in severity measure.

This study found that in the severity measure, observed t value was 6.54(23.68±15.78) in the experimental group at two tailed paired t test while this same variable for control group observed value was 3.13 (10.09±14.04) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in severity measure in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of severity measure were significant at 0.006% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of symptom severity scale

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 5.38. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for improving Quality of life of UI in part of symptom severity scale.

This study found that in symptom severity scale, observed t value was 7.73 (8.11 ± 4.57) in the experimental group at two tailed paired t test while this same variable for control group observed value was 7.02 (3.68 ± 2.29) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value in symptom severity scale in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of symptom severity scale were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in for improving Quality of life.

Results of incontinence episodes

The Unpaired/independent t test in between group at 5% level of significant and 33 degrees of freedom standard table value was 2.036 and at the same significant level and same degree of freedom observed t value was 4.247. The observed t value was greater than the table value that meant null hypothesis was rejected and alternative hypothesis was accepted which means pelvic floor muscle training for urinary incontinence were statistically significant. So, pelvic floor muscle training was very much effective than supervised core stability exercise in between group comparison for decreasing the incontinence daily episodes.

This study found that in case incontinence episodes, observed t value was 8.42 (3.05 ± 1.58) in the experimental group at two tailed paired t test while this same variable for control group observed value was 4.25 (1.05 ± 1.07) in within group. 5% level of significant at 18 (eighteen) degrees of freedom standard t value was 2.101 and observed t value for incontinence episodes in both groups were greater than standard t value that meant null hypothesis was rejected and alternative hypothesis was accepted in the within group. Both groups in aspect of incontinence episodes were significant at 0.001% level, but the mean difference of the experimental group was greater than the control group mean that means pelvic floor muscle training for urinary incontinence was more effective than supervised core stability exercise in decreasing episodes of daily incontinence.

Table -2: Mean differences at within group statistics

Variables	Control group		Experimental group	
	Mean	Std. Deviation	Mean	Std. Deviation
General health perception- Pre	65.78	17.09964	64.47	25.43
General health perception- Post	47.36	18.43671	27.63	11.47
Incontinence impact- Pre	73.64	21.04084	77.16	24.99
Incontinence impact- Post	66.61	19.25465	35.06	25.98
Role limitations- Pre	59.57	20.25821	60.49	23.04
Role limitations- Post	42.93	21.74739	23.05	15.84
Physical limitations- Pre	48.22	24.77168	51.71	25.39
Physical limitations- Post	35.92	24.99637	21.01	15.56
Social limitations- Pre	39.72	16.67702	42.65	18.22
Social limitations- Post	30.66	16.99497	16.36	14.96
Personal relationships- Pre	15.54	30.50510	4.62	11.13
Personal relationships- Post	13.32	26.85618	.00	.00
Emotions- Pre	77.15	22.38525	69.54	27.42
Emotions- Post	46.73	20.12302	15.18	11.82
Sleep/ energy- Pre	43.44	27.53633	47.33	32.99
Sleep/ energy- Post	34.18	23.22547	19.25	17.78
Severity measures- Pre	39.88	24.62936	41.62	17.13
Severity measures- Post	29.79	19.32248	17.95	10.85
Symptom severity scale- Pre	16.68	4.78484	14.05	5.016
Symptom severity scale- Post	13.00	4.21637	5.95	3.09
Incontinence episodes- Pre	4.47	1.712	4.74	1.40
Incontinence episodes- Post	3.42	1.216	1.68	1.45

Table 3: Paired sample ‘t’ test

Variables	Control group		Experimental group	
	<i>t</i>	P value	<i>t</i>	P value
General health perception	5.715	.000	5.715	.001
Incontinence impact	2.191	.042	6.834	.001
Role limitations	4.132	.001	6.312	.001
Physical limitations	3.990	.001	5.104	.001
Social limitations	3.325	.004	5.010	.001
Personal relationships	1.468	.164	1.761	.096
Emotions	6.341	.000	10.678	.001
Sleep/ energy	4.060	.001	4.313	.001
Severity measures	3.134	.006	6.541	.001
Symptom severity scale	7.023	.000	7.732	.001
Incontinence episodes	4.253	.000	8.420	.001

Table 4: Unpaired/Independent ‘t’ test

Variables	<i>t</i>	P value
General health perception	4.412	.001
Incontinence impact	3.894	.001
Role limitations	3.091	.004
Physical limitations	2.446	.020
Social limitations	2.762	.009
Personal relationships	2.434	.022
Emotions	5.800	.001
Sleep/ energy	2.742	.010
Severity measures	2.598	.014
Symptom severity scale	5.377	.001
Incontinence episodes	4.247	.001

The effects of the PFMT have been widely described in literature in more than 50 randomized clinical trials and also systemic review. Many study summarized that PFMT is considered the most standard for the treatment of UI in addition to the level of significance (Dumoulin et al., 2018). An increase in abdominal pressure due to physical exertion puts stress on the bladder, causing urine to leak. The basic mechanisms responsible for UI that reaction are poor urethral support by the pelvic floor muscles and intrinsic sphincter deficiency. The rationale of PFMT for SUI is that a strong pelvic floor muscle contraction will clamp the urethra, increasing the urethral pressure to prevent leakage during an abrupt increase in intra-abdominal pressure. In case of urge urinary incontinence, PFMT may inhibit reflexively or voluntarily the involuntary detrusor contraction, therefore decreases the involuntary leakage. Additionally, this treatment also results in the improvement of patient's perception of the disease, decrease episodes of UI and change their QOL which affected due to this unwanted leakage. When measured with precision and reliability, the assessment about the severity and impact of the disease is an important parameter for the assessment and treatment of affected patients. Although assessment procedure is subjective, these data are significantly relevant, as they indirectly reflect the quality of care provided. In this study, the urinary episodes were counted by using 24 hours voiding diary. The improvement can be attributed to the quality of the instituted protocol, which recommended a maintenance time of 6 to 8 seconds. Therefore, the improved daily incontinence and QOL were associated with improvement in urinary incontinence. This study aims to show the effectiveness of pelvic floor muscle training compared to the supervised abdominal strengthening exercise, trial group

received pelvic floor training along with supervised abdominal strengthening exercise and another group received supervised abdominal strengthening exercise only. In a similar study applied pelvic floor muscle training (PFMT) and abdominal training for urinary incontinence (Kucukkaya & Kahyaoglu Sut, 2020). In this study, a decrease in daily urinary loss events from 4.88(\pm 1.41) to 1.17(\pm 1.03) was observed in the experimental group and 4.57(\pm 1.83) to 3.52(\pm 1.21) was observed in the control group. From this study it was found in the baseline data that from total 41 participants, experimental group had 20 and control group had 21. In a similar study it was revealed that their total participants were 36 women who received pelvic floor muscle training for UI (Fitz et al., 2012). In this current study it was found that mean age of the participants were 48.4 years and 49.76 years for experimental and control group respectively. Another similar study which deal with effectiveness of pelvic floor muscle training and suggested that their participants mean age 55.2 for home group and 55.6 years for health centre group (Vaz, Sampaio, Saltiel & Figueiredo, 2019). From baseline data, most of participants' occupation was housewife of this in this study, all participants were housewife at experimental group and in the control group 81% (n=17) were housewife and rest of participants were service holder or do business or other. Also in this study the marital status was married and divorced found in both experimental and control group. Majority of the participant lived in the urban place (n= 11) in the experimental group, other lived in the rural area (n=9). But in the control group, n=15 lived in the rural area, n=6 lived in the urban area. Recent publication showed that 74.6 % women were lived in the city or town and 25.4 5 women lived in village (Ptak et al., 2019). After the treatment, incontinence episodes and QOL were assessed by two standard questionnaires; 24 hours voiding dairy and KHQ respectively.

Also, Similarly to this study, used 7 day voiding diary to observed the urinary leakage (Konstantinidou, Kalaitzi, Mytilekas, Ioannides, Hatzichristou & Apostolidis, 2013). Another related article, applied PFMT for EG compared to no treatment for CG and used KHQ to observe the QOL status of women who suffered SUI (Pereira, De Melo, Correia & Driusso, 2012). In this study, after the treatment, improvement was observed in all nine domains the KHQ (general health perception, incontinence impact, role limitation, physical limitations, social limitations, personal relationships, emotions and sleep/energy, severity measures) in between group analysis using independent t test. But only the domain personal relationship was not statistically significant after treatment in within group analysis and this may be happened because of missing value from the respondents, many of them may not have reported to the family about the prob In this study, for general health perception analysis in within group were statistically significant where ($p < 0.05$) and the level was 0.001%.

In between group analysis for incontinence impact domain in KHQ, the observed value was statistically significant after treatment session ($p < 0.05$). Relevant study suggested that mean score was 40.9 & 29.8 and significant value was ($p < 0.05$) after PFM training exercise for urinary incontinence (Fitz et al., 2012).

For the domain of role limitations, statistical test showed significant level .001 in between group analysis that mean null hypothesis rejected and alternate hypothesis accepted in two tail hypothesis. In contrast to another study it was found PFMT significantly improved role limitation, the initial mean score was 37.6 and after treatment mean score was 19.6, level of significance was .001 ($p < 0.05$) (Balmforth, Mantle, Bidmead & Cardozo, 2006).

Physical limitation t value level is greater than the observed t level and there was significant change in between group analysis and significant level was .001 ($p < .05$). Another domain of social limitation found significant improvement after PFMT in statistical analysis. The significant P value level was .004, which was less than $< .05$ in between group analysis. After statistical analysis, personal relationship found significant level in between group analysis but in within group analysis, but there was not significant level in within group analysis because of decreased t value. Another domain of KHQ, emotions and sleep / energy were significantly change after analysis in both group and the significant level were .001. Severity measure and symptom severity were significantly found in this study and level of significance were .006 and .001 respectively. In contrast, another recent study conducted with 372 women with a mean age of 53.2 years years were selected and treated using PFMT. After the treatment, the authors observed an improvement in had significant improvement in their urinary symptoms and QOL after PFMT in UDI and IIQ-7 measurement tools (Fan, Chan, Law, Cheung, & Chung, 2013).

In a recent publication, the voiding diary was considered an important tool for the objective measurement of urinary loss, with good correlation with the patients' reports on their symptom (Bradley, Brown, Van Den Eeden, Schembri, Ragins & Thom, 2011).

This study aims to find out whether pelvic floor muscle training was effective or not. During this study conduction there were some limitation faced. The main limitation was unable to develop a sampling frame or sampling pool, which lacks external validity in the study. As samples were collected only from CRP- Savar, it could not represent the wider population of urinary incontinence that's why lack of generalizability of results to wider population was found. In addition, the study was conducted with 41 patients of urinary incontinence, which was a small size of samples in compare with the real-world prevalence. Another factor is that in this study only participants scanned who have LBP with UI, because of this criteria sample size decreases. No patient complain their urinary symptoms directly, during the screening of Mckenzie assessment and UDI we found their urinary complication. Most of the patients' main concern is LBP that's why they couldn't continue treatment session for UI. So drop out came and decrease percentage of women receiving 8 sessions treatment. Data were collected only two times, initial and 8 sessions after treatment during study and it created study limitation as it lacks follow up daily or weekly basis changes in dependent variables. The study did not offer any follow up for participants which was essential component to find out effectiveness of treatment as well as QOL of individual for longer period of time. Dropout rate of participants were relatively minor in percentage but inclusion of their data by adherence might have influence on study results. However, participants and assessor were blinded and it lacks the absolute minimization of physiotherapist's bias during treatment applied.

CHAPTER-VII: RECOMMENDATION AND CONCLUSION

The results of this study demonstrate that supervised PFMT is an effective treatment for UI in women. PFMT appears to be an effective non-surgical intervention for women with all types of UI (SUI, UUI, MUI). It could also be recommended as the first-line conservative treatment for elderly women. PFMT significantly improves the QOL of women with UI, which is an important determinant of their physical, mental, and social functioning. The duration of PFMT in this study was 8 sessions within 4 weeks. It is advised to provide supervised PFMT for 4- 6 weeks and follow up 1 month later or 3- 6 months later to maintain their better QOL. PFMT can be used either as a monotherapy or as a combined therapy for the treatment of UI in women. The KHQ is useful for following up on the QOL of women with UI in many different clinical settings and in controlled clinical trials.

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APPENDIX- A

Verbal Consent Form

Assalamualaikum / Greetings,

I am Parvin Akter, Part-(II) M.Sc. in Physiotherapy student of Bangladesh Health Professions Institute (BHPI) under Medicine faculty of University of Dhaka. To obtain my Master’s degree, I shall have to conduct a thesis and it is a part of my study. The participants are requested to participate in the study after reading the following:

My research title is “**Effectiveness of Pelvic Floor Muscle Training on Quality of Life of Women with Urinary Incontinence: A Randomized Clinical Trial**”. Through this study, I will find the effectiveness of pelvic floor muscle on quality of life for patient with urinary incontinence. If I can complete the study successfully, quality of life (QoL) of women who are suffering with urinary incontinence may be drawn out. To implement my thesis, I need to collect data from Musculoskeletal unit, CRP. Therefore, you could be one of my valuable subjects for the study.

I am committed that the study will not pose any harm or risk to you. You have the absolute right to withdraw or discontinue at any time without any hesitation or risk. I will keep all the information confidential which I obtained from you and personal identification of the participant would not be published anywhere.

If you have any query about the study, you may contact with me and Mohammad Anwar Hossain, Associate Professor, BHPI & head of physiotherapy department, CRP.

Do you have any questions before I start?

So, may I have your consent to proceed with the interview?

Yes.....

No.....

Signature of the participant & Date

Signature of the Physiotherapist & Date

Signature of data collector & Date

Signature of the researcher & Date

সম্মতিপত্র

আসসালামু-আলাইকুম/ শুভেচ্ছা নিবেন, আমি পারভিন আক্তার, ২য় বর্ষ ঢাকা বিশ্ববিদ্যালয়ের মেডিসিন অনুষদের অধীনে বাংলাদেশ হেলথ প্রফেশন ইনস্টিটিউট (বিএইচপিআই) এর এম.এস.সি. ফিজিওথেরাপি বিভাগ এর একজন শিক্ষার্থী। অধ্যয়নের অংশ হিসেবে আমাকে একটি গবেষণা সম্পাদন করতে হবে এবং এটা আমার প্রাতিষ্ঠানিক কাজের একটা অংশ। নিম্নোক্ত তথ্যাদি পাঠ করার পর অংশগ্রহণকারীদের গবেষণায় অংশগ্রহণের জন্য অনুরোধ করা হলো:

আমার গবেষণার শিরোনাম “অনিয়ন্ত্রিত প্রস্রাব সমস্যায় ভুক্তভুগি মহিলাদের জীবনমানের উপর পেলভিক ফ্লোর মাংসপেশীর প্রশিক্ষণ এর কার্যকারিতাঃ একটি রেন্ডমাইজড ক্লিনিকাল ট্রায়াল”। এই গবেষণার মাধ্যমে আমি অনিয়ন্ত্রিত প্রস্রাব সমস্যায় জড়িত মহিলাদের জীবন মান সম্পর্কে জানার চেষ্টা করব এবং এই সমস্যা কমাতে পেলভিক ফ্লোর মাংসপেশীর প্রশিক্ষণ এর কার্যকারিতা সম্পর্কে জানার চেষ্টা করব। যদি আমার গবেষণাটি সফলভাবে সম্পূর্ণ করতে পারি তবে অনিয়ন্ত্রিত প্রস্রাব সমস্যায় ভুক্তভুগি মহিলারা উপকৃত হবেন এবং আমাদের দেশের আর্থ সামাজিক প্রেক্ষাপটে এ ধরনের রোগের ক্ষেত্রে ফিজিওথেরাপি চিকিৎসার কার্যকারিতা সম্পর্কে অবগত হবেন এবং এটি হবে একটি পরীক্ষামূলক প্রমাণ।

আমার গবেষণা প্রকল্প বাস্তবায়ন করার জন্য, কোমর ব্যথাসহ অনিয়ন্ত্রিত প্রস্রাব সমস্যায় ভুক্তভুগি মহিলাদের কাছ থেকে তথ্য সংগ্রহ করা প্রয়োজন। আমার গবেষণায় অংশগ্রহণে আপনার কোন ক্ষতি বা বিপদ হবে না। প্রশ্নাবলীর উত্তরদানে যে কোনো সময় আপনি নিজেকে এ গবেষণা থেকে আংশিক বা সম্পূর্ণরূপে প্রত্যাহার করতে পারেন। এই গবেষণার প্রাপ্ত তথ্য সম্পূর্ণভাবে গোপনীয় থাকবে এবং অংশগ্রহণকারীর ব্যক্তিগত তথ্য অনুমতি ব্যতিরেকে অন্য কোথাও প্রকাশ করা হবে না।

এই গবেষণা সম্পর্কে কোনো জিজ্ঞাসা থাকে তবে আপনি অনুগ্রহপূর্বক যোগাযোগ করতে পারেন গবেষক পারভিন আক্তার আথবা গবেষণার সুপারভাইজার মোহাম্মদ আনোয়ার হোসেন, সহযোগী অধ্যাপক (বিএইচপিআই) এবং বিভাগীয় প্রধান, ফিজিওথেরাপি বিভাগ, সিআরপি, সাভার, ঢাকা-১৩৪৩ এ।

শুরু করার আগে আপনার কোন প্রশ্ন আছে কি?

আমি কি শুরু করতে পারি ?

হ্যাঁ

না


অংশগ্রহণকারী (স্বাক্ষর ও তারিখ)

ফিজিওথেরাপিস্ট (স্বাক্ষর ও তারিখ)

তথ্য সংগ্রহকারী (স্বাক্ষর ও তারিখ)

গবেষক (স্বাক্ষর ও তারিখ)

APPENDIX- B

 <p>OREGON HEALTH & SCIENCE UNIVERSITY</p> <p>Urology</p>	Patient Name: _____ Date of Birth: _____ MRN: _____ Date of Service: _____ Physician: _____
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Urinary Distress Inventory, Short Form (UDI-6)

For each question, circle the number that best describes this problem for you over the past month.

Do you experience and, if so, how much are you bothered by:

	Not at All	A Little Bit	Moderately	Greatly
Frequent Urination?	0	1	2	3
Urine leakage related to urgency?	0	1	2	3
Urine leakage related to physical activity? (walking, running, laughing, sneezing, coughing)	0	1	2	3
Small amounts of urine leakage? (drops)	0	1	2	3
Difficulty emptying your bladder or Difficulty urinating?	0	1	2	3
Pain or discomfort in your lower abdominal, pelvic, or genital area?	0	1	2	3

Adapted from Uebersax JS, Wyman FF, Shumaker SA, et al. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and urogenital distress inventory. NeuroUrol Urodyn 1995; 14: 131.

Code No:

Effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence: A randomized clinical trial

Part: 1- Personal details:

CRP ID:

1.1 Patients name:

1.2 Age:

1.3 Address:

Village:

Post office:

Thana:

District:

1.4 Phone number:

Part: 2-Socio-demographic information:

2.1 Occupation:

2.2 Marital status:

1. Married 2. Unmarried 3. Widow 4. Divorce

2.3 Educational status:

1. Illiterate 2. Up to sign 3. Primary 4. Secondary
5. HSC passed 6. Graduate & Masters

2.4 Area of Living:

1. Urban 2. Rural

Part: 3- Incontinence Questionnaire:

3.1. When you lose urine, what is the usual cause? / Incontinence types?

- A. Coughing, sneezing, laughing, or performing physical activity
B. A sudden or urgent need to go to the bathroom
C. Both A and B equally
D. Other circumstances

KING'S HEALTH QUESTIONNAIRE 1993

How would you describe
your health at present?

Please tick one answer

Very good

Good

Fair

Poor

Very Poor



How much do you think
your bladder problem
affects your life?

Please tick one answer

Not at all

A little

Moderately

A lot



Please turn the page

We would like to know what your bladder problems are and how much they affect you. From the list below choose ONLY THOSE PROBLEMS that you have at present. LEAVE OUT those that do not apply to you.

How much do they affect you?

To choose please tick



A little

Moderately

A lot

FREQUENCY: going to the toilet very often	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NOCTURIA: getting up at night to pass urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
URGENCY: a strong and difficult to control desire to pass urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
URGE INCONTINENCE: urinary leakage associated with a strong desire to pass urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
STRESS INCONTINENCE: urinary leakage with physical activity eg. coughing, sneezing, running	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NOCTURNAL ENURESIS: wetting the bed at night	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
INTERCOURSE INCONTINENCE: urinary leakage with sexual intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FREQUENT WATERWORKS INFECTIONS:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
BLADDER PAIN:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty PASSING URINE:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OTHER SPECIFY:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Below are some daily activities that can be affected by bladder problems. How much does your bladder problem affect you?

We would like you to answer every question. Simply tick the circle that applies to you.

<u>ROLE LIMITATIONS</u>	Not at all	Slightly	Moderately	A lot
To what extent does your bladder problem affect your household tasks (e.g. cleaning, shopping, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Does your bladder problem affect your job, or your normal daily activities outside the home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	-----------------------	-----------------------	-----------------------

<u>PHYSICAL/SOCIAL LIMITATIONS</u>	Not at all	Slightly	Moderately	A lot
Does your bladder problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Does your bladder problem affect your ability to travel?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	-----------------------	-----------------------	-----------------------

Does your bladder problem limit your social life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Does your bladder problem limit your ability to see/visit friends?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	-----------------------	-----------------------	-----------------------

<u>PERSONAL RELATIONSHIPS</u>	N/A	Not at all	Slightly	Moderately	A lot
Does your bladder problem affect your relationship with your partner?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Does your bladder problem affect your sex life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Does your bladder problem affect your family life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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EMOTIONS

Not at all Slightly Moderately Very much

Does your bladder problem make you feel depressed?

Does your bladder problem make you feel anxious or nervous?

Does your bladder problem make you feel bad about yourself?

SLEEP/ENERGY

Never Sometimes Often All the time

Does your bladder problem affect your sleep?

Do you feel worn out/tired?

Do you do any of the following?

If so how much?

Never Sometimes Often All the time

Wear pads to keep dry?

Be careful how much fluid you drink?

Change your underclothes when they get wet?

Worry in case you smell?

Get embarrassed because of your bladder problem?

THANK YOU, NOW CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS.

Your Daily Bladder Diary



This diary will help you and your health care team figure out the causes of your bladder control trouble. The "sample" line shows you how to use the diary.

Time	Drinks		Trips to the Bathroom			Accidental Leaks			Did you feel a strong urge to go?		What were you doing at the time? <small>Sneezing, lifting, arriving home, sleeping, etc.</small>	
	What kind?	How much? oz, mL, cups	How many times?	How much urine?			How much urine?					
Sample	Juice	8 ounces	✓✓	<input checked="" type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input checked="" type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input checked="" type="radio"/> Yes	<input type="radio"/> No	Running
6-7 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
7-8 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
8-9 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
9-10 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
10-11 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
11-12 noon				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
12-1 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
1-2 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
2-3 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
3-4 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
4-5 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
5-6 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
6-7 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
7-8 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
8-9 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
9-10 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
10-11 p.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
11-12 mid.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
12-1 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
1-2 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
2-3 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
3-4 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
4-5 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	
5-6 a.m.				<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> sim	<input type="radio"/> med	<input type="radio"/> lg	<input type="radio"/> Yes	<input type="radio"/> No	

Use this sheet as a master for making copies that you can use as a bladder diary for as many days as you need.

I used _____ pads today. I used _____ diapers today (write number).

Questions to ask my health care team: _____

কিংস হেলথ প্রশ্নপত্র

পর্ব ক

১. আপনি কিভাবে আপনার স্বাস্থ্যের বর্তমান অবস্থা বর্ণনা করবেন ?

একটি উত্তরে টিক চিহ্ন দিন

- খুব ভাল ১
- ভাল ২
- মোটামুটি ৩
- খারাপ ৪
- খুব খারাপ ৫

২. মূত্র সমস্যা আপনার জীবনকে কতটুকু প্রভাবিত করেছে বলে আপনি মনে করেন ?

একটি উত্তরে টিক চিহ্ন দিন

- মোটেও না ১
- সামান্য ২
- বেশি ৩
- খুব বেশি ৪

	১	২	৩	৪
	মোটেশনা	সামান্য	বেশি	খুববেশি

৩. সীমাবদ্ধতা

ক) আপনার মূত্রসমস্যা কি গৃহস্থলি কর্মকাণ্ডকে প্রভাবিত করে ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
খ) আপনার মূত্রসমস্যা কি আপনার চাকরি অথবা বাড়ির বাইরে স্বাভাবিক কাজকর্মকে প্রভাবিত করে ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

৪) দৈহিক/ সামাজিক সীমাবদ্ধতা

ক) আপনার মূত্রসমস্যা কি আপনার শারীরিক কাজকর্মকে প্রভাবিত করে (হাঁটা, দৌড়ানো, খেলাধুলা ইত্যাদি)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
খ) মূত্রসমস্যা কি আপনার ভ্রমণের ক্ষমতাকে প্রভাবিত করেছে ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
গ) মূত্রসমস্যা কি আপনার সামাজিক জীবনকে সীমাবদ্ধ করেছে ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ঘ) মূত্রসমস্যা কি আপনার বন্ধু-বান্ধবীদের সাথে দেখা করাকে ব্যাহত করেছে?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	১	২	৩	৪
	মোটোওনা	সামান্য	বেশি	খুববেশি

৫. ব্যক্তিগত সম্পর্ক

- ক) মূত্রসমস্যা কি আপনার স্বামীর
সাথে সম্পর্ককে প্রভাবিত করেছে ?
- খ) মূত্রসমস্যা কি আপনার
যৌনজীবনকে প্রভাবিত করেছে ?
- গ) মূত্রসমস্যা কি আপনার
পারিবারিক জীবনকে প্রভাবিত করেছে ?

৬) অনুভূতি

- ক) মূত্রসমস্যা কি আপনাকে
বিষন্ন করেছে?
- খ) মূত্রসমস্যা কি আপনাকে
উদ্দিগ্ন করে ?
- গ) মূত্র সমস্যার জন্য কি
আপনার নিজের সম্পর্কে খারাপ
বোধ করেন ?

৭) ঘুম/ শক্তি

- ক) মূত্র সমস্যা কি আপনার
ঘুমকে প্রভাবিত করে ?
- খ) মূত্রসমস্যা কি আপনাকে
জরাজীর্ণ এবং ক্লান্তবোধ করায় ?

৮) আপনি নিম্নলিখিত যেকোনো একটিও করেছেন কি ? যদি করে থাকেন তাহলে কতটুকু ?

	১	২	৩	৪
	কখনওনা	মাঝেমাঝে	প্রায়ই	সবসময়
ক) শুষ্ক থাকার জন্য প্যাড পড়েন ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
খ) কতটুকু পানি পান তার জন্য কি সতর্ক থাকেন ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
গ) ভিজে যাওয়ার কারণে অন্তর্বাস পরিবর্তন করেন ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ঘ) দুর্গন্ধ বের হয় কিনা সেজন্য চিন্তিত থাকেন ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

আপনার দৈনিক প্রস্রাবের ডায়েরি

সময়	পানীয়		প্রস্রাব বিষয়ক			আকস্মিক প্রস্রাব			আপনি কি দ্রুত প্রস্রাব এ যাওয়া অনুভব করেছেন?		তখন আপনি কি করতেন/করছেন? যাঁচি, কপিশি, চুমামো ইত্যাদি
	কি খেয়েছেন?	কতটুকু? মিলি/ গ্লাস	কতবার?	কি পরিমাণ?	বের হওয়া? কি পরিমাণ?	অল্প	মধ্যম	বেশি	হ্যাঁ	না	
নমুনা	জুস	১ গ্লাস	✓✓	অল্প মধ্যম বেশি	অল্প মধ্যম বেশি				হ্যাঁ	না	
সকাল ৬-৭									হ্যাঁ	না	
৭-৮									হ্যাঁ	না	
৮-৯									হ্যাঁ	না	
৯-১০									হ্যাঁ	না	
১০-১১									হ্যাঁ	না	
১১-১২									হ্যাঁ	না	
দুপুর ১২-১									হ্যাঁ	না	
১-২									হ্যাঁ	না	
২-৩									হ্যাঁ	না	
৩-৪									হ্যাঁ	না	
৪-৫									হ্যাঁ	না	
৫-৬									হ্যাঁ	না	
৬-৭									হ্যাঁ	না	
৭-৮									হ্যাঁ	না	
৮-৯									হ্যাঁ	না	
রাত ৯-১০									হ্যাঁ	না	
১০-১১									হ্যাঁ	না	
১১-১২									হ্যাঁ	না	
১২-১									হ্যাঁ	না	
১-২									হ্যাঁ	না	
২-৩									হ্যাঁ	না	
৩-৪									হ্যাঁ	না	
৪-৫									হ্যাঁ	না	
৫-৬									হ্যাঁ	না	

আমি দৈনিক ----- প্যাড ব্যবহার করি।

Dated: 01-12-2019

The Head of the Department,
Department of Physiotherapy,
Centre for the Rehabilitation of the Paralyzed (CRP),
CRP-Chapain, Savar, Dhaka-1343.

Through: Course coordinator, MPT Program, Department of Physiotherapy, BHPI.

Subject: Prayer for seeking permission for data collection to conduct my academic thesis.

Sir,

With due respect and humble submission to state that I am Parvin Akter, student of Part-(II) M.Sc. in Physiotherapy program at Bangladesh Health Professions Institute (BHPI). The Ethical Committee has approved my thesis title on **"Effectiveness of Pelvic Floor Muscle Training on Quality of Life of Women with Urinary Incontinence: A Randomized Clinical Trial"** under the supervision of Mohammad Anwar Hossain, Associate Professor, BHPI and head of physiotherapy department, CRP. Conducting this thesis is partial fulfillment of the requirement for the degree of Part-II M.Sc. in Physiotherapy. I want to collect research data for my thesis at Musculoskeletal unit, CRP. So, I need permission in this regard. I would like to assure that, anything of my study will not be harmful for the participants.

I, therefore, pray and hope that you would be kind enough to grant my application and give me the permission for data collection and oblige thereby.

Yours faithfully

Parvin
Parvin Akter
Part-(II) M.Sc. in Physiotherapy
Session: 2018-2019
Bangladesh Health Professions Institute
(An academic Institution of CRP)
CRP- Chapain, Savar, Dhaka- 1343.

Approved
12/12/19
Concern
12/12/19

Recommended
9/12/19
Prof. Md. Obaidul Haque
Head, Department of Physiotherapy
Bangladesh Health Professions Institute (BHPI)
CRP, Savar, Dhaka- 1343

Approved
9/12/19
Firoz Arned Mamin
Associate Professor
Dept. of Rehabilitation Science
M.Sc. in Physiotherapy Program
BHPI, CRP, Savar, Dhaka-1343



Centre for the Rehabilitation of the Paralyzed (CRP) Department of Physiotherapy

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Ref: CRP/PT/2102/27/12.12.19

Date: 12.12.19

CONVENTIONAL PHYSIOTHERAPY PROTOCOL FOLLOWED BY PHYSIOTHERAPY DEPARTMENT FOR URINARY INCONTINENCE

Conventional physiotherapy treatment for urinary incontinence followed by different exercises along with home advices are practiced in clinical Department of Physiotherapy. The interventional procedure depends on patient's condition and disease progress.

✦ Abdominal strengthening exercise

✓ Abdominal drawing exercise:

This exercise is usually done for abdominal muscle strengthening mainly transverse abdominal (TA) muscle. The subjects are instructed to draw in the lower abdominal wall toward the spine, an action that specifically activates the TA. The subjects are asked to breathe in a relaxed manner. No movement of the lumbar spine was allowed.

- Instructed to do the exercise for 10 repetitions with 3 seconds hold.

✓ Ball punching with both knees:

This is also an abdominal strengthening exercise. Subjects are instructed to both hip flexion with 90 degree with knee flexion and then punch the ball by both knees. No contraction of the vagina. No movement of the spine allowed.

- Instructed to do the exercise for 10 repetitions with 3- 5 seconds hold according to patient's condition.



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Date: 12.12.19

✦ Gluteus strengthening Exercise

✓ Gluteus squeezing exercise

It is mainly applied to strengthen the gluteus muscle. Subjects are instructed to squeeze the gluteus fold. No movement of the spine and pelvic girdle allowed.

- Instructed to do this exercise for 10-12 repetitions. Hold this for 3-5 seconds according to patients' condition.

✓ Bridging exercise

Subjects are instructed to lift the pelvic and hold for maintain the stabilization of trunk muscles. Also hip and knee are flexed during the exercise.

- Performs this exercise with 10 repetitions for each set.
- Progress the exercise with one leg bridging and bridging with physioball.

✦ Kegel exercise:

Subjects are instructed to contract the muscles around the vagina "like a drawstring" and to lift them internally. No posterior tilt of the pelvis was allowed. Instructed for not to use the abdominal muscles.

- ✓ Performs the exercise for 10 repetitions for one set.



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Ref: CRP/PT/2102/27/12.12.19

Date: 12.12.19

Home advice

- ✓ The choice treatment was made by the physiotherapist based on the assessment findings.

Mohammad Anwar Hossain
Associate Professor & Head
Department of Physiotherapy
CRP, Savar, Dhaka



বাংলাদেশ হেল্থ প্রফেশন্স ইনস্টিটিউট (বিএইচপিআই)
Bangladesh Health Professions Institute (BHPI)
(The Academic Institute of CRP)

Ref:

CRP/BHPI/IRB/02/2020/1389

Date:

18/02/2020

To
Parvin Akter
Session: 2018-2019, Student ID: 111180063
BHPI, CRP, Savar, Dhaka- 1343, Bangladesh

Subject: Approval of thesis proposal "Effectiveness of Pelvic Floor Muscle training on Quality of Life of Women with Urinary Incontinence: A Randomized Clinical Trial" by ethics committee.

Dear Parvin Akter,

Congratulations.

The Institutional Review Board (IRB) of BHPI has reviewed and discussed your application to conduct the above-mentioned dissertation, with yourself, as the Principal investigator. The following documents have been reviewed and approved:

Sr. No.	Name of the Documents
1	Dissertation Proposal
2	Questionnaire (English and Bengali version)
3	Information sheet & consent form

Since the study involves questionnaire that takes maximum 40- 45 minutes and have no likelihood of any harm to the participants, the members of the Ethics committee have approved the study to be conducted in the presented form at the meeting held at 09:00 AM on September 21, 2019 at BHPI.

The institutional Ethics committee expects to be informed about the progress of the study, any changes occurring in the course of the study, any revision in the protocol and patient information or informed consent and ask to be provided a copy of the final report. This Ethics committee is working accordance to Nuremberg Code 1947, World Medical Association Declaration of Helsinki, 1964 - 2013 and other applicable regulation.

Best regards,

Muhammad Millat Hossain
Assistant Professor, Dept. of Rehabilitation Science
Member Secretary, Institutional Review Board (IRB)
BHPI, CRP, Savar, Dhaka-1343, Bangladesh

The Chairman
Institution Review Board (IRB)
Bangladesh Health Professions Institute (BHPI),
CRP, Savar, Dhaka- 1343, Bangladesh.

Subject: Application for review and ethical approval.

Dear Sir,


With due respect, I am Parvin Akter, student of part-II of M.Sc. in Physiotherapy course at the Bangladesh Health Professions Institute (BHPI), academic Institute of Center for the Rehabilitation of the Paralyzed (CRP) under the faculty of medicine of university of Dhaka. As per the course curriculum, I have to conduct a thesis entitled "**Effectiveness of Pelvic Floor Muscle training on Quality of Life of Women with Urinary Incontinence: A Randomized Clinical Trial**" under the most honorable supervisor. The purpose of the study is to determine the effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence (UI). These interventions help in improving quality of life involving personal hygiene, social life as well as sexual life, emotional and sleep problem, decreasing number of incontinence episodes.

The study involves use of urinary society defined incontinence classification questionnaire, to find the types of urinary incontinence, King's health questionnaire to find out the incontinence quality of life, 24 hours voiding diary to assess incontinence episodes. Since the study involves questionnaire that takes maximum 20-25 minutes and have no likelihood of any harm to the participant's or stakeholders. Data collector will receive informed consent from all participants and keep it confidential.

Therefore, I look forward to having your kind approval for the thesis proposal and to start data collection. I can also assure you that I will maintain all the requirements for study.

Sincerely,

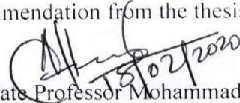
Thesis Presentation Date: 28.09.2019


.....
Parvin Akter
Class Roll no-11
Student of M.Sc. in Physiotherapy (part-II)


Course Coordinator
M.Sc. in Physiotherapy (MPT)

Firoz Ahmed Mamin
Associate Professor
Dept. of Rehabilitation Science
Coordinator
M.Sc. in Physiotherapy Program
BHPI, CRP, Savar, Dhaka-1343

Recommendation from the thesis supervisor


Associate Professor Mohammad Anwar Hossain
Head, Physiotherapy Department,
CRP, Savar, Dhaka-1343, Bangladesh

FULL DETAILS (Read-only) -> [Click Here to Create PDF for Current Dataset of Trial](#)

CTRI No	CTRI/2020/07/026729 [Registered on: 22/07/2020] Trial Registered Retrospectively	
Acknowledgement Number	REF/2020/06/034420	
Last Modified On:	21/07/2020	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Physiotherapy (Not Including YOGA)	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study Clarification(s) with Reply Modification(s)	Muscle Training for improving Quality of Life of Women with Urine problem	
Scientific Title of Study Clarification(s) with Reply Modification(s)	Effectiveness of Pelvic Floor Muscle Training on Quality of Life of Women with Urinary Incontinence: A Randomized Clinical Trial	
Trial Acronym		
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Name	PARVIN AKTER
	Designation	Clinical Physiotherapist
	Affiliation	CRP
	Address	Musculoskeletal Unit, Department of physiotherapy CRP, Savar, Dhaka, 1343
		1343 Other
	Phone	01681722303
	Fax	
	Email	parvin22303@gmail.com
Details Contact Person Scientific Query Clarification(s) with Reply Modification(s)	Name	Parvin Akter
	Designation	Clinical Physiotherapist
	Affiliation	Masters in Physiotherapy Student
	Address	Department of physiotherapy CRP, Savar, Dhaka, 1343
		1343 Other
	Phone	01681722303
	Fax	
	Email	parvin22303@gmail.com

Details Contact Person Public Query Clarification(s) with Reply Modification(s)	Name	Mohammad Anwar Hossain		
	Designation	Senior Consultant & Associate Professor		
	Affiliation	CRP		
	Address	Department of physiotherapy CRP, Savar, Dhaka, 1343 1343 Other		
	Phone	01753559949		
	Fax			
	Email	anwar_physiobd@yahoo.com		
Source of Monetary or Material Support Clarification(s) with Reply Modification(s)	Department of Physiotherapy, Centre for the Rehabilitation of the Paralyzed (CRP)			
Primary Sponsor Clarification(s) with Reply Modification(s)	Name	Parvin Akter		
	Address	CRP, Savar		
	Type of Sponsor	Other [Self]		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	Bangladesh			
Sites of Study	No of Sites = 1			
	Name of Principal Investigator	Name of Site	Site Address	Phone/ Fax/ Email
	Mohammad Anwar Hossain	Musculoskeletal Unit	Department of physiotherapy CRP, Savar, Dhaka, 1343	01753559949 anwar_physiobd@yahoo.com
Details of Ethics Committee Clarification(s) with Reply Modification(s)	No of Ethics Committees= 1			
	Name of Committee	Approval Status	Date of Approval	Approval Document
	Institutional Review Board	Approved	18/02/2020	Approval File
Regulatory Clearance Status from DCGI	Status	Date	Approval Document	
	Not Applicable	No Date Specified	No File Uploaded	
Health Condition / Problems Studied	Health Type	Condition		

	Patients	(1) ICD-10 Condition: N328 Other specified disorders of bladder,	
Intervention / Comparator Agent Clarification(s) with Reply Modification(s)	Type	Name	Details
	Intervention	McKenzie Method & Pelvic Floor Strengthening	McKenzie method Soft tissue mobilization Pelvic floor muscle training (Sustained contraction, quick contraction, Pelvic floor contraction with coughing). Treatment session- 2 sessions per week, up to 6 weeks.
	Comparator Agent	McKenzie Protocol	McKenzie method Soft tissue mobilization Abdominal muscle training Treatment session- 2 sessions per week, upto 6 weeks.
Inclusion Criteria Clarification(s) with Reply Modification(s)	Age From	40.00 Year(s)	
	Age To	60.00 Year(s)	
	Gender	Female	
	Details	Patients with LBP with urinary incontinence. Age range: 40 to 60 years. LBP ≥ 3 months.	
Exclusion Criteria	Details	Patients with any neurological involvement. Patients with hearing impairments. Patients who received treatment for pelvic organ dysfunction.	
Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc		
Method of Concealment	Sequentially numbered, sealed, opaque envelopes		
Blinding/Masking	Participant and Outcome Assessor Blinded		
Primary Outcome Clarification(s) with Reply Modification(s)	Outcome	TimePoints	
	Quality of Life	4 weeks	
Secondary Outcome Clarification(s) with Reply Modification(s)	Outcome	TimePoints	
	Episodes of Incontinence	4 weeks	
Target Sample Size	Total Sample Size="100" Sample Size from India="0" Final Enrollment numbers achieved (Total)= "Applicable only for Completed/Terminated trials" Final Enrollment numbers achieved (India)= "Applicable only for Completed/Terminated trials"		
Phase of Trial Clarification(s) with Reply Modification(s)	Phase 1/ Phase 2		
Date of First	No Date Specified		

Enrollment (India) Clarification(s) with Reply Modification(s)	
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	08/08/2020
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	Years="1" Months="0" Days="0"
Recruitment Status of Trial (Global) Clarification(s) with Reply Modification(s)	Not Yet Recruiting
Recruitment Status of Trial (India)	Not Applicable
Publication Details Clarification(s) with Reply Modification(s)	NIL
Individual Participant Data (IPD) Sharing Statement	Will individual participant data (IPD) be shared publicly (including data dictionaries)?
Brief Summary	<p>Urinary incontinence (UI) is an important public health & social problem predominantly in women (Milsom et al., 2013). According to the International Incontinence Society (ICS), UI is defined as an involuntary loss of urine which affects in all ages especially in fifth decade of life (Chang et al., 2017).The prevalence of this problem is of 25-45% all over the world. Daily incontinence affects between 5% and 15% of middle aged and older women. Prevalence estimates of urinary incontinence during pregnancy & postpartum period are even higher, as it is reported in 42% of pregnant women & 38 % of women post-partum (Morkved & Bo, 2014).</p> <p>There are three main types of UI: Stress urinary incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence (MUI). Among these the most common is Stress Urinary incontinence (SUI) and its prevalence varies at 10-39%, mixed urinary incidence (MUI) has a prevalence of 7.5-25% (Botlero, Davis, Urquhart, Shortreed, & Bell, 2009). Thus, SUI and MUI constitute nearly two-thirds of the women with urinary incontinence.</p>

Effectiveness of pelvic floor muscle training on quality of life of women with urinary incontinence

Supervised Intervention

Control Group:

Conventional Physiotherapy

- McKenzie treatment approach
- Soft tissue mobilization
- Supervised abdominal muscle strengthening exercise
 - Abdominal drawing exercise
 - Ball punching with both knees

Treatment Duration: 30 min duration

Repetition: 1. RFIL/ REIL – 10 repetitions × 1 set

2. Soft tissue mobilization- 05 minutes

3. Supervised abdominal strengthening exercise

- 10 repetitions × 2 sets × 3seconds hold

Treatment session: 2 sessions per week, 4 weeks. (Tajiri, Huo & Maruyama, 2014)

Home Advice:

1. RFIL / REIL – 10 reps× 2 hourly per day.
2. Abdominal drawing exercise & Ball punching exercise with both knees
 - 10 repetitions × 1 set for each exercise × 3 seconds hold between each repetition.

Experimental Group:

1. Conventional Therapy
2. Supervised pelvic floor Muscle Training
 - Pelvic floor muscle contractions (vaginal contraction) sustained for each participants' power (sec)
 - Pelvic Floor Muscle contractions (contract/relax) according to each participants' endurance (repetition).
 - Pelvic floor muscle contraction with coughing.

Treatment duration: 30 min duration

- Repetition:
1. RFIL/ REIL – 10 repetitions ×1 set
 2. Soft tissue mobilization- 05 minutes
 3. Abdominal strengthening exercise
 - 10 repetitions × 2 sets × 3seconds hold
 4. Supervised pelvic floor muscle training
 - 10 repetitions × 3 sets
 -

Treatment session: 2 sessions per week, up to 4 weeks.

Home Advice:

1. RFIL / REIL – 10 reps× 2 hourly per day.
2. Abdominal drawing exercise & Ball punching exercise with both knees
 - 10 repetitions × 1 set for each exercise × 3 seconds hold between each repetition.
3. Pelvic floor training
 - 10 repetitions × 3 sets × 3 times per day. (Vaz et al., 2019)