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# Assessment of the effect of *Mulabandha* yoga therapy in healthy women, stigmatized for pelvic floor dysfunctions: A randomized controlled trial

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## ABSTRACT

**Background:** In developing countries, women do not reveal their perineum related health issues because most of the time they are stigmatized by the society. Multiparity, mostly found in women of rural areas is one of the major causes of pelvic floor dysfunctions (PFDs) like pelvic organ prolapse, urinary incontinence, rectal incontinence, etc. Usually, they visit health centres in the advanced stage of diseases, and then medical treatment is not the only choice left. Many research studies show that yoga practices promote health conditions, contribute to enhancing endurance, flexibility, and muscular strength, and improving quality of life.

**Objective(s):** The study was conducted to assess the impact of *Mulabandha* yoga therapy (MYT) in healthy woman participants as a preventive measure.

**Material and methods:** The study was a prospective and randomized controlled trial. Fifty healthy woman participants were allocated in two groups viz., MYT group and No MYT group. *Mulabandha* yoga was conducted for the MYT group for 12 weeks. No MYT group was advised not to do yoga. Pelvic floor muscle strength was internally evaluated by employing the PERFECT scheme score (P = power, E = endurance, R = repetitions, F = fast contractions, ECT = every contraction timed). For eligible samples, MYT sessions were held for 12 weeks. Data interpretation was done with SPSS software 20.0 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY, USA).

**Results:** Fifty healthy woman participants were allocated for analysis. There was no statistically significant difference in between the groups comparison in terms of age, socio-economic status, occupation, education, parity and mode of delivery. PERFECT scheme score significantly improved in participants after 12 weeks of regular MYT. No statistically significant differences were observed between the groups comparison in terms of PERFECT scheme score.

**Conclusion:** The current study shows that regular practice of MYT for 12 weeks is a better means to reinforce the strength of pelvic floor muscles in women. This MYT procedure will establish evidence for women who are reluctant towards their pelvic organ-related issues. Women must incorporate the MYT practice in their routine life as a preventive measure to refrain from pelvic floor dysfunctions.

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## 1. Introduction

Women usually suffer from pelvic floor dysfunction (PFD) which involves relaxation of the pelvic floor muscles (PFM) and their associated anatomical structures. Pelvic organ prolapse (POP),

urinary incontinence and rectal incontinence are the most common disorders associated with it [1]. Women tend to avoid health issues until it worsens. This may be due to lack of knowledge, feeling distressed or embarrassed, and experiencing awkwardness in sharing their issues with someone else [2]. It is believed that women's reluctance to seek healthcare for PFDs in its early stage was due to its low awareness [3].

PFDs have an effect of 46.2% on women globally [4,5]. POP, urinary incontinence, stress incontinence, urge incontinence,

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mixed incontinence, faecal incontinence are the major classifications of PFDs [6]. The global prevalence of POP is 9%–20% (in high-income low-income countries) [7] and urinary incontinence prevalence in elderly women is 9.9% [8] while the global trend of faecal incontinence in women is 7%–15% [9]. Individual women suffer physical and mental stress due to PFD symptoms. This negatively impacts their personal and professional lives [10]. Risk factors include multiple pregnancies, vaginal deliveries, obesity, perineal tears, (H/O) previous abdominal surgery, heavy weight lifting, rigorous exercise, and loosening of the PFMs with increasing age [5,11,12]. Even though PFDs cause agitation and unpleasantness, women do not disclose their problems until the condition of the disease worsens [13]. Surgical intervention has so far been accepted as a primary option in women suffering from pelvic floor disease. Patients suffering from this disease are less interested in surgery these days due to the high prevalence rates (43.5%) for post-surgery complications (vault prolapse, postoperative haemorrhages, infections, wound dehiscence) and subsequent needs of revised surgery [14]. Although surgery is widely regarded as a definitive improvement, however, prospective surgery faces many obstacles, including the potential cost and limited availability of trained surgical hands.

Women with PFD-related symptoms may be provided with considerable and moral support with the help of MYT. In the last few years, people have increased interest in yoga and its activities. Today, yoga is proving successful in creating a different identity on the world stage. Yoga is an ancient medical practice that is used to keep the body healthy as well as to cure many types of diseases. The classical text of Yoga philosophy was first presented by Maharishi Patanjali [15]. In recent times, yoga has become an evolving option to strengthen PFMs and to treat symptoms related to pelvic floor dysfunctions [16]. The implementation of yoga continuously increases muscle strength, flexibility and increases its endurance as well as it promotes concentration and peace of mind [17]. Regular practice of MYT may provide better results in the early stages of the disease in women who are unaware of symptoms related to pelvic floor dysfunction and feel uncomfortable to disclose their problems to medical practitioners [18].

*Mulabandha* has defined as the *Mula* (root) and *bandha* (lock), which initially suggests a continuous contraction of the PFMs, based on the strength of the individual muscles and muscle strength also gradually increases with the duration of contraction [19]. MYT is a process performed between the vulva (vagina) and the *guda* (anus) i.e. the perineum [20]. The perineum is a diamond-shaped space under the pelvic diaphragm, divided into two triangular regions: the anterior urogenital triangle with vaginal and urethral sphincters, and the anal portion of the anal canal, i.e. the anal sphincter, in the posterior anal triangle [21]. The pelvic viscera and its associated sphincters (sphincter vagina, urethra and anal rhabdo sphincters) are connected with the PFMs and are conjugated to each other by the supporting connective tissues [22]. Sphincters (sphincter vagina, urethra and anal rhabdo sphincter) receive their parasympathetic innervations by sacral outflow and sympathetic innervations by spinal thoraco-lumbar outflow. The application of MYT restores the function of the muscles of the pelvic region as well as exciting the autonomic innervations in the pelvic region [23].

The purpose of this study was to assess the effect of MYT as a preventive measure in healthy woman participants. During the research, the emphasis was placed on reviewing healthy women who may suffer from the early stages of pelvic floor dysfunction but felt unaware or embarrassed to discuss this with their family and physicians [24,25].

## 2. Materials and methods

### 2.1. Study design

The study was a prospective and randomized controlled trial. Healthy woman participants as per inclusion and exclusion criteria were allocated in two groups randomly (MYT group and No MYT group) by generating a random allocation sequence. In MYT group, participants were advised for *Mulabandha* yoga procedures whereas in the other group participants were requested to maintain their usual self-care throughout the trial period. The PERFECT scheme was used as an internal assessment tool for PFM strength. Outcome measurements were performed at baseline and on completion of the intervention.

### 2.2. Sample size calculation

Assuming a larger effect size according to Cohen 1988, the sample size would be  $n = 26$  for each group ( $\alpha = 5\%$  and power = 80%) [26]. It was further assumed that 10% of participants could be lost during follow-up scores, so the required number increased to approximately  $n = 27$ . A total of 54 cases were reported for the study, but four participants were initially denied participation ( $n = 3$  participants, refused consent and  $n = 1$  participant, not meeting the inclusion criteria). Therefore, in the present study, a total of 50 woman participants were randomly divided into two identical groups of 25 cases each. To ensure the effectiveness of MYT, the present study advocates a minimum of 12 weeks (90 days) of therapy.

### 2.3. Attrition of the sample

There was no attrition of the sample in both groups as all participants completed the study.

### 2.4. Ethical clearance

The procedures for conducting the study have been assessed and approved by the institutional review board and also following the Declaration of Helsinki as revised in 2013. The study was approved by the Institutional Human Research Ethics Committee of Banaras Hindu University, IMS, Varanasi. ECR/526/Inst/UP/2014 is the protocol number. The study was conducted in the Department of *Rachana Sharira*, Faculty of Ayurveda, IMS BHU, Varanasi with keen observation.

### 2.5. Participants

Healthy woman participants belonging to 20–60 years of the age group from Varanasi zone of Uttar Pradesh were invited to participate. Inclusion criteria were healthy women aged 20–60 years of age, able and willing to follow all study requirements, women who went through vaginal or LSCS mode for delivery were also included in the study, and participants were also screened for the absence of any acute or chronic diseases after a thorough history taking to define their health status.

Exclusion criteria were participants over the age of 20 or 60, suffering from PFD such as pelvic organ prolapse, urinary incontinence or rectal prolapse, vaginal pain, thyroid diseases, any malignancy, any neuro-psychiatric illnesses, low backache, pregnant or nursing women, has undergone any other surgery except LSCS, feel uncomfortable to follow the MYT procedures, and being unable

to perform this process until the final stages of the study. All participants were assessed at baseline before starting the intervention.

## 2.6. Criteria for assessment

An evaluation was based on the change in percentage scores of the PERFECT scheme at baseline and post-study. The PERFECT scheme was developed by Laycock [27]. It is a method of evaluation for the contractility of the PFMs in both the MYT and No MYT groups. PERFECT acronym consists of:

- **Power** - Modified Oxford Grading System. This is a six-point scale: 0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate, 4 = good, and 5 = strong.
- **Endurance** - expressed as the length of contraction time (up to 10 s) until muscle fatigue occurs.
- **Repetition** - repetitions up to 10 times.
- **Fast**-evaluation phase should be limited to a maximum of 10.
- **Every Contraction Timed** - a reminder to the examiner to record the sequence of steps.

The Oxford Grading Scale was used for the measurement of power, grading from 0 to grade 5. Grade 0 was characterized for cognition without pelvic floor [28]. For effective consideration of power, the power grade must be  $> 3$  [27]. To avoid muscle fatigue, a 4-s rest was given between contractions [29].

## 2.7. Intervention (MYT) procedure

The participants were advised to take a suitable posture of *Siddhasana* [30] with closed eyes and place their hands on their knees and relax. Focus on breathing, pelvic floor area, and the sphincter of the urogenital triangle. Exhale and then take a deep breath. Shrink the sphincters and pull the PFMs up, hold it for a few seconds until they hold their breath. Relax the sphincters and release the PFMs and finally exhale and thus it completes the MYT procedure. This completes one cycle of the MYT procedure. Maximum 10 cycles should be repeated in a session [31]. The MYT performed for participants of the MYT intervention group twice a day (Morning- Evening) for 12 weeks regularly. In the first session, fundamental information and objectives were given. The anatomy of PFMs and MYT procedures were explained in detail to all participants before evaluating the ability of PFM contraction [32]. A trained researcher supervised yoga for 12 weeks through group sessions held at *Rachana Sharira*, IMS BHU, Varanasi. After a detailed explanation of MYT procedures and its significance, valid written consent was signed by individual participants. Participant's compliance with the MYT procedure was taken care of during the study. Each participant was monitored and encouraged to perform the MYT session well and with attention. Gentle care was taken to avoid any inconveniences to the participant during the MYT session. Participants in both the groups were followed at (baseline and post-study) respectively and data was collected.

## 2.8. Statistics analysis

Data interpretation was done with SPSS software 20.0 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY, USA). Baseline information for demographic profile was compared. The complete number of participants of each of these variables was calculated in percentage for both groups. A Chi-square test was done for categorical variables to study the difference between the two groups in terms of demographic profile and at the baseline, none were found statistically significant. Statistical assessment of changes in percentage score of the PERFECT scheme

was done and data interpreted at baseline and after 3 months (12 weeks). The significant value of  $p$  was set at  $p < 0.05$ .

## 3. Results

The study involved 50 participants, who were randomly allocated to each group, with 25 in MYT and No MYT group. The study design and participants allocation strategy are discussed using the CONSORT flow chart given in Fig. 1. The two groups were comparable in terms of participant's demographic profile, namely age, socio-economic status, occupation, education, parity, and mode of delivery. The baseline values of the two groups were observed by applying the Chi-square test. The results have been shown as inclusive data comparison at baseline and after 3 months (12 weeks) within each group, which shows significant improvement in the percentage score of MYT group for all the variables of the PERFECT scheme. However, when the PERFECT scheme scores of the MYT and No MYT groups were compared, they were not found statistically significant ( $<0.05$ ) as shown in Table 2. Chi-square value for both the group was found non-significant ( $<0.05$ ).

### 3.1. Demographic profile

Fifty healthy woman participants fulfilling the inclusion and exclusion criteria allocated in the study. Demographic profile of the participants is alluding to Table 1. Majority of the participants were of age group ranging from 30 to 50 years, multipara and housewives, having a vaginal mode of delivery, residing in a joint family, educated up to secondary level schools, and belonging to lower class economy group.

### 3.2. Assessment of PERFECT scheme score [Table 2]

Data interpretation of power at baseline and after 3 months showed significant improvement in percentage scores in the MYT intervention group. In the MYT group, 44% of participants at baseline had a power score of grade  $\geq 3$ , which progressively improved after each follow-up and 84% of participants moved to grade  $\geq 3$  after 3 months. This change in power grade was found to be clinically significant. However, Chi-square value for both the groups was not found significant ( $p < 0.05$ ).

In the MYT group, 64% of participants at baseline had an endurance capacity score ranging from 4 s to 10 s. After 3 months the percentage of participants for endurance capacity increased to 92%. This change in endurance percentage score is found to be clinically significant. However, Chi-square value for both the groups was not found significant ( $p < 0.05$ ).

In the MYT group, 84% of participants after 3 months showed their repetitions between grades 3, 4 and 5, compared to 32% before baseline. This change in the grade of repetition score is found to be clinically significant. However, Chi-square value for both the groups was not found significant ( $p < 0.05$ ).

In the MYT group, the Fast percentage score of participants attending grades 3, 4 and 5 gradually increased from 32 to 84%, indicating an increase in its ability to contract at its maximum speed. This change in percentage score was found to be clinically significant. However, Chi-square value for both the groups was not found significant ( $p < 0.05$ ).

## 4. Discussion

Social stigma is a major factor that puts a stop to the regular health visit of women suffering from PFDs especially in a lower economy country where literacy rate is also less. They gradually undergo distress and are despondent until they are revealing their

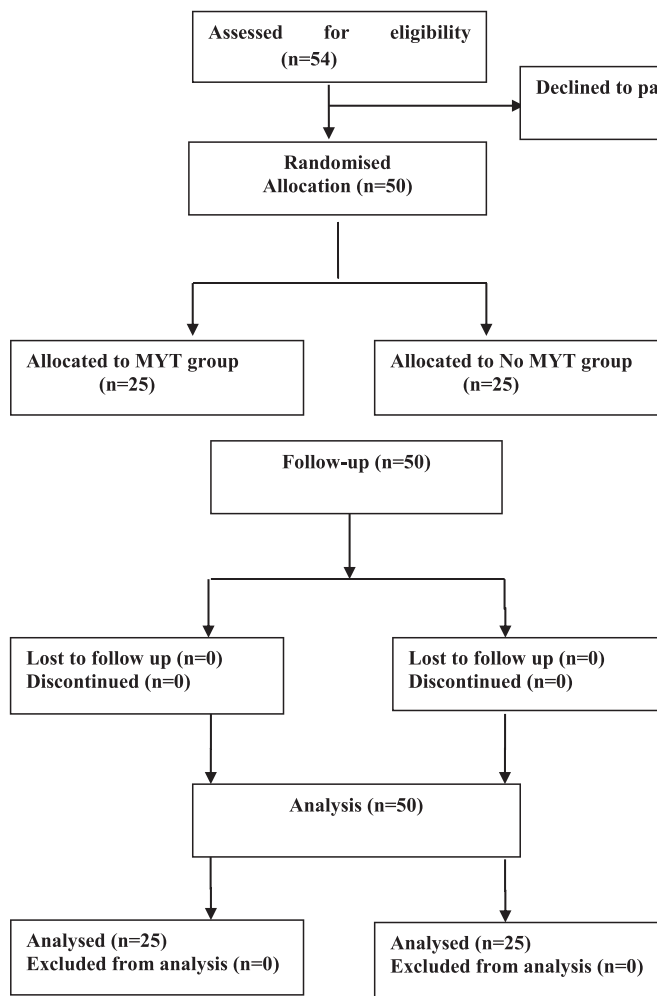


Fig. 1. Participant flow (CONSORT) chart.

problems [33]. The reporting of PFDs related diseases is less documented than actually; it persists in the current scenario especially in the rural population of India. They simply start to live with the symptoms which arise due to PFDs until it bothers them or begins to disturb their routine life. PFDs related issues explicitly or implicitly cost over the economy of a country [34]. So, being from the medical fraternity it's our responsibility to help them out of trouble at every stage of their life and for this purpose researcher's effort to implement MYT in women could be counted as a basic preventive measure and concomitantly it will overcome the economic burden.

The prevalence of pelvic floor dysfunctions in India is 21%, which is higher and not far away from the USA (25%) [35]. Risk factors for pelvic floor dysfunctions are vaginal mode of delivery [36], multiparity [37], lower-class economic group [5], progression in age [38,39], and so on.

The majority of participants in the study were of age group ranging from 30 to 50 years which were similar to the findings of a study where the mean age of respondents susceptible to PFDs was found to be 48.9 years [40]. Chen GD had elucidated in his review article that many factors are associated with the fact that an increase in age may harm the structural and functional changes in PFDs. As age increases, symptoms associated with PFDs start to affect initially, deterioration of connective tissues

with age, decrease in myographic activity, pelvic floor denervation, and neurological injuries results from surgical intervention [41]. Memon and Handa in their literary review established a direct association between multiparity and vaginal mode of delivery with the occurrence of pelvic floor dysfunctions. Repetitive stretching of pelvic floor connective tissues in multiparous and vaginal delivery causes excessive damage of levator ani muscles [11].

Lower socioeconomic status plays a significant role in the commencement of PFDs. The majority of the woman participants were housewives (agronomist) by occupation and women diligent in farming were assumed to do vigorous labour and thus subjected to the possibility of developing PFDs. This high-intensity type of workload leads to increased intra-abdominal pressure and laxity in pelvic floor connective tissues [39,42].

Twelve weeks of MYT practice showed clinically significant improvement in the percentage score of the PERFECT assessment scheme. The MYT was practised only by the MYT group. However, when the PERFECT scheme scores of the MYT and No MYT groups were compared, they were not found statistically significant (<0.05) after twelve-week of duration. The implementation of MYT by women is proposed to be highly efficient and cost-beneficial, which is easy to get into their routine life. MYT practices restore the PFM strength.

**Table 1**  
Demographic profile of the participants.

Age	MYT group	No MYT group	Chi-square test results
20–30 year	04	02	$\chi^2 = 3.5$ p = 0.31
31–40 year	12	13	
41–50 year	07	09	
51–60 year	02	01	
Socio-economic status	MYT group	No MYT group	Chi-square test results
Higher class	02	03	$\chi^2 = 0.4$ p = 0.81
Middle class	07	08	
Lower class	16	14	
Occupation	MYT group	No MYT group	Chi-square test results
Housewife	16	22	$\chi^2 = 4.2$ p = 0.1
Private job	05	01	
Government job	04	02	
Education	MYT group	No MYT group	Chi-square test results
Illiterate	04	05	$\chi^2 = 0.14$ p = 0.9
Primary	04	04	
Secondary	16	15	
Graduate & above	01	01	
Parity	MYT group	No MYT group	Chi-square test results
Primae	04	06	$\chi^2 = 0.5$ p = 0.4
Multi	21	19	
Mode of Delivery	MYT group	No MYT group	Chi-square test results
Vaginal	18	21	$\chi^2 = 1.04$ p = 0.3
LSCS*	07	04	

\*LSCS = Lower segment caesarean section.

The PERFECT scheme score was used to assess the changes in the strength of PFM before and after the study. It incorporates power, endurance, repetition, and fast score calculation. For this, digital palpation was chosen to assess this type of therapy. Power is the strength of the contraction of pelvic muscles. Endurance is the ability to retain sustained contraction. Repetition is an instance of repeating. Fast is the ability to contract at its maximum speed.

**Table 2**  
Assessment of PERFECT scheme score.

Grade	MYT group		No MYT group		Between the group comparison Chi-square test results
	Baseline (0 weeks) n (%)	Post-study (12 weeks) n (%)	Baseline (0 weeks) n (%)	Post-study (12 weeks) n (%)	
<b>Power</b>					
*Grade < 3	14 (56)	04 (16)	11 (44)	08 (32)	At Baseline $\chi^2 = 0.72$ p = 0.39 Post- study $\chi^2 = 1.75$ p = 0.18
**Grade ≥ 3	11 (44)	21 (84)	14 (56)	17 (52)	
<b>Endurance</b>					
^Grade < 3	09 (36)	02 (08)	12 (48)	07 (28)	At Baseline $\chi^2 = 0.22$ p = 0.63 Post- study $\chi^2 = 3.38$ p = 0.06
^^Grade ≥ 3	16 (64)	23 (92)	13 (52)	18 (72)	
<b>Repetition</b>					
^Grade < 3	17 (52)	04 (16)	11 (44)	06 (24)	At Baseline $\chi^2 = 2.92$ p = 0.08 Post- study $\chi^2 = 0.5$ p = 0.47
^^Grade ≥ 3	08 (32)	21 (84)	14 (56)	19 (76)	
<b>Fast</b>					
^Grade < 3	17 (52)	04 (16)	09 (36)	05 (20)	At Baseline $\chi^2 = 5.12$ p = 0.02 Post- study $\chi^2 = 0.13$ p = 0.71
^^Grade ≥ 3	08 (32)	21 (84)	16 (64)	20 (80)	

n = no. of participants, \* Grade 1, 2 \*\* grade 3, 4 & 5, ^ grade 1,2 for 1–4 s, ^^ grade 3,4 & 5 for 4–10 s.

Preponderance of grade 3,4 and 5 was observed in MYT group for power (84.0%), endurance (92.0%), repetition (84.0%), fast (84.0%) followed by No MYT group for power (44.0%), endurance (64.0%), repetition (32.0%), fast (32.0%). When both groups (MYT/No MYT) were compared for the PERFECT scheme score for PFM strength, all the four parameters (Power, Endurance, Repetition, Fast) were found clinically significant but statistically not significant.

Similar findings were proposed by Tibaek and Dehlendorf who suggested power >4 as strong muscles and power <3 as weak muscles [43]. Thus, the occurrence of PFDs is independent of the strong ability of PFMs, strong PFMs may suffer from PFDs as the anatomical structure of pelvic muscles included urethral, anal, and vaginal sphincters along with neurovascular structures [44].

MYT application potentially strengthens the PFMs [45] which were measured by assessment of PERFECT scheme score [46] evolved into an upward-lifting of pelvic muscle with effective constriction [47].

Yoga therapy is an ancient type of exercise that involves muscle training. Yogic exercise of muscles works on three basic principles i.e. overloads specificity and sensitivity. PFMs become hypergenesis and hypertrophic with yogic exercise [48].

Effect of *Mulabandha* yoga procedures simulate with the PFM training, the main objectives are an increase in muscular strength, effective regulation of urethral sphincter mechanism, and inhibition of automatic reflexes of detrusor [49,50]. Regular supervision of woman participants is the main ground for the achievement of better results in the MYT group. The probable mechanism of MYT had been narrated in Fig. 2.

MYT is suitable for implementation in both healthy as well as diseased with mild grade pelvic organ disease [18] conditions in the local community and low economical areas. It will prove to be of great benefit without costing any financial charges and decreasing the risk of adverse events; however, to avoid the adverse events, MYT must be delivered by trained instructors.

Integration of ancient yoga therapies with modern modalities is a burning issue of today's time. The government's trying to bridge the experimental wisdom of yoga with empirical modern medical science. There is a need for multiple trained yoga instructors to create public awareness about the beneficial effects of yoga therapy.

There may be some possible limitations in this study. This study was a time constraint, conducted on a small sample and randomized controlled trial was used, larger sample size and longer duration could have generated more accurate results. Participants

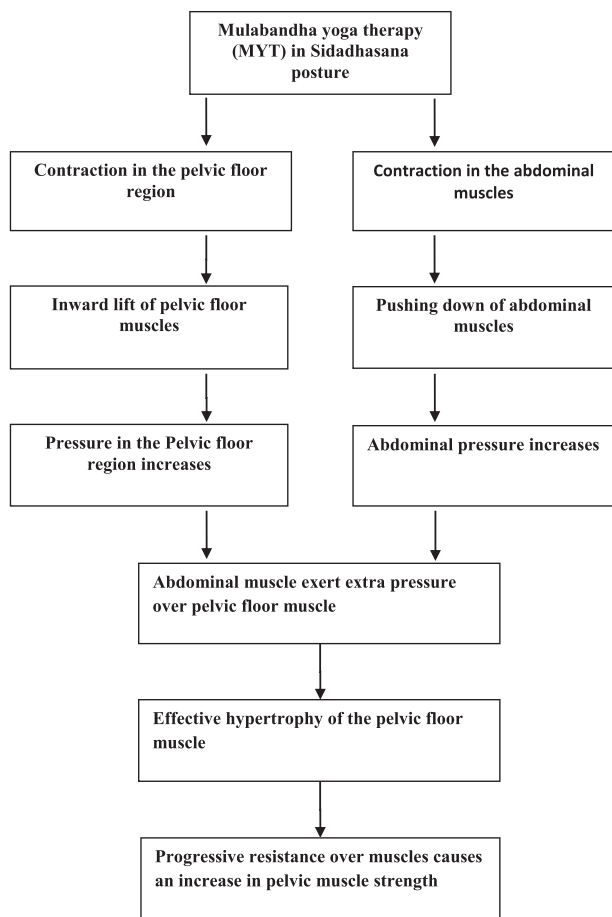


Fig. 2. Showing the probable mechanism of action of Mulabandha.

registered from rural areas of Uttar Pradesh state and hence, the generalizability of the study findings may be limited. Manual palpation of measuring PFM contractibility may be another limitation. There are other methods available to assess women's ability to contract the PFM; they are visual observation, electromyography, ultrasound and magnetic resonance imaging. Dynamometer and perineometer measures different aspects of PFM function, which may be a future valid, reliable, and responsive method of measuring PFM force. To our knowledge, this is the first study to assess the impact of MYT in healthy woman participants for conservative intervention and lack of prior research studies on the recent topic allowed for the future scope of research. To gather more data on the feasibility of non-surgical interventions, further study is required.

### 5. Conclusion

The results of the present study demonstrated that the MYT is effective to be used as a preventive measure for PFM strength. It is easy to use and cost-effective. In a clinical context, yoga, if practised regularly, would prove to be a good tool that could delay or potentially prevent the onset of a clinical diagnosis of PFDs. Conservative interventions may be an alternative approach to surgery. The present study highlights the opportunity to provide effective and safe non-surgical interventions to address the burden of pelvic floor diseases. As the women screened in this programme may represent the tip of the iceberg, further outreach and expansion of the screening programme are warranted.

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None

### Conflict of interest

None

### Author contributions

Sweta: literature search, manuscript preparation. Amrit Godbole: concepts, design, definition of intellectual content. Seema Prajapati: manuscript editing. H.H. Awasthi: manuscript review.

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