



Pelvic Floor Muscle Training in Women with Pelvic Organ Prolapse: A Randomised Controlled Trial

Binal Dave*, Keshar Choudhary and Swati Singh

Department of Women's HealthCare, University of Technology, India

*Corresponding Author: Binal Dave, Department of Women's Health, University of Technology, India.

DOI: 10.31080/ASWH.2024.06.0558

Received: January 08, 2024
Published: January 23, 2024
© All rights are reserved by Binal Dave, et al.

Abstract

Background: Pelvic organ prolapse (POP) is a condition where shortcoming of pelvic floor muscles can cause at least one organs in your pelvis (vagina, uterus, bladder and rectum) to hang. An organ may bulge onto another organ or externally in more severe cases. PPelvic organ prolapse is normal and is related post labor and with expanding age. Females with prolapse are in many cases encouraged to do pelvic floor muscle training, however proof supporting the advantages of such activities is scant. Our goal was to determine whether individually tailored pelvic floor muscle training reduced prolapse and its symptoms.

Methods: We did an equal gathering, multicentre, randomized controlled preliminary at 2 centre's in India, between July 2017 and December 2023. Female short term patients were recently analyzed, suggestive of stage I, II, or III prolapse were haphazardly relegated (1:1), by far off PC distribution with minimisation, to get an individualized program of pelvic floor muscle preparing or a prolapse, way of life pamphlet and no muscle preparing (control group). Result assessors, and agents who were gynecologists at preliminary destinations, were veiled to bunch allotment; The statistician masked the data untill analyzed. Our essential endpoint was members' self-report of prolapse effects at end of the year.

Findings: 67 eligible patients were randomised to the intervention group (n = 34) or the control group (n = 33). 34 participants completed follow-up for questionnaires at 6 months and 33 participants for questionnaires at 12 months. Women in the intervention group reported fewer prolapse symptoms (i.e., a significantly greater reduction in the pelvic organ prolapse symptom score [POP-SS]) at 12 months than those in the control group (mean reduction in POP-SS from baseline 3.77 [SD 5.62] vs 2.09 [5.39]; adjusted difference 1.52, 95% CI 0.46-2.59; p = 0.0053).

Interpretation: One-to-one pelvic floor muscle training for prolapse is effective for improvement of prolapse symptoms. Long-term benefits should be investigated, as should the effects in specific subgroups.

Funding: No source of funding.

Keywords: Pelvic Organ Prolapse; Obesity, Heavy Lifting

Introduction

Pelvic organ prolapse is a typical problem in ladies — 40% of ladies more established than 45 years have some level of prolapse on assessment [1].

Around 11% of ladies go through a medical procedure for urinary incontinence or prolapse in the course of their life, and 7% for prolapse alone [2].

The primary risk factors for prolapse are increasing age and parity, as well as a prolapse-related family history. However, obesity, heavy lifting, and constipation can also play a role [3].

One review detailed an all out populace inferable gamble for prolapse of 46%, which was related with ladies having prolapse side effects during pregnancy, a mother with prolapse, and undertaking weighty actual work [4].

Prolapse is described by suggestive plunge of the vaginal walls, peak, or vault from the typical physical position [5].

Ladies with prolapse could give vaginal, bladder, gut, back, stomach, and sexual side effects. The problem can influence day to day action and personal satisfaction. Treatment choices incorporate a medical procedure and moderate administration, of which the last option is utilized normally in the event that the prolapse is low in

seriousness or the lady isn't a contender for medical procedure. Moderate mediations incorporate actual intercessions to work on the capability and backing of the pelvic floor muscles through pelvic floor muscle preparing; mechanical mediations (eg, utilization of vaginal pessaries) to help the prolapse; furthermore, way of life mediations (eg, weight reduction and staying away from of hard work) to keep away from worsening of the prolapse by diminishing intra-stomach pressure.

Numerous physiotherapists who have practical experience in ladies' wellbeing offer ladies with prolapse individualized pelvic floor muscle preparing [6]. Muscle training aims to increase the structural support for the pelvic organs and improve the strength, endurance, and coordination of the pelvic floor muscles. A Cochrane survey [7] showed that preparation of the pelvic floor muscles was powerful for treatment of urinary incontinence. Proof for the administration of prolapse is less clear. A different Cochrane survey [8] recognized four preliminaries (counting two pilot preliminaries) contrasting people going through pelvic floor muscle preparing with control gatherings; two of which were at critical gamble of predisposition. Side effects, albeit estimated diversely in various examinations, were worked on in the transient in three preliminaries, and pooled information for seriousness from two preliminaries showed an improvement in prolapse after treatment because of muscle preparing. The audit inferred that dependable proof is required about the medium-term and long haul adequacy and cost-viability of pelvic floor muscle preparing.

We did the Pelvic Organ Prolapse Physiotherapy (POPPY) preliminary to evaluate whether balanced pelvic floor muscle preparing would lessen the side effects of prolapse and the requirement for additional prolapse treatment in ladies with stage I-III prolapse, and whether it would be a financially savvy choice, contrasted and a prolapse way of life exhortation handout.

Methods

Study design and participants

Between July 2017 and December 2023, we conducted a parallel-group, multicentre, randomized controlled trial at two locations in India. Women of any age who were eligible had prolapse as their primary presenting complaint and stage I-III prolapse of any type (anterior, posterior, apical, or a combination) as confirmed by their gynecologist during a vaginal examination using the pelvic organ prolapse quantification (POP-Q) system. We barred ladies who had gotten past treatment for prolapse, including a medical procedure; who were pregnant or under a half year post pregnancy; or on the other hand who couldn't consent to the intercession (i.e., in the event that they couldn't go to the center for meetings with the physiotherapist). Ladies who required treatment for vaginal decay were qualified in the wake of following through with a tasks of supplanting oestrogens [9]. The results of our pilot trial served as the basis for our trial procedures [10].

Patients gave marked informed assent.

Randomisation and masking

Patients were haphazardly doled out (1:1), with the remote-PC decided randomisation , to get an individualized program of pelvic floor muscle preparing or a prolapse way of life counsel pamphlet and no muscle preparing (control bunch). Randomisation utilized a minimisation way to deal with balance bunch sizes for key prognostic elements at benchmark. Factors were focus, phase of prolapse (I, II, or III), and the inspiration for prolapse a medical procedure (i.e., ladies not considering a medical procedure versus those thinking about a medical procedure). Inspiration for medical procedure is a possibly significant element influencing how disciple ladies will be to pelvic floor muscle preparing. The intercession couldn't be concealed from ladies or treating physiotherapists. Participant responses to questionnaires served as the outcome assessment, avoiding assessor bias; information passage staff were covered to bunch designation. The gynecologists taking the POP-Q test at six months, including the investigators, were not told which group they were in until after the test. The factual expert (SB) was free of the examination group and was concealed to bunch allotment until after the fundamental investigation had been attempted.

Procedures

Ladies designated to the intercession were welcome to go to five balanced arrangements for pelvic floor muscle preparing more than 16 weeks (at weeks 0, 2, 6, 11, and 16) with a ladies' wellbeing physiotherapist. Based on muscle physiology (specific muscle training for 15 weeks is required to gain muscle hypertrophy [11]) and clinical guidelines for the management of urinary incontinence, which recommend muscle training for "at least 3 months," the duration of 16 weeks was chosen [12].

Arrangement recurrence depended on present clinical rules — i.e., first arrangements near one another to permit support of right activity method and comprehension of all guidance given, later arrangements turning out to be further separated to energize free home activity.

At the primary arrangement a clarification of sorts of prolapse, life systems and capability of pelvic floor muscles was given with utilization of charts and a model pelvis. Interior evaluation of the pelvic floor muscles was finished to address practice procedure and survey muscles (utilizing the Ideal Plan) [13].

An individualized home activity program was endorsed based on assessment discoveries. Ladies were urged to advance activities, with a point of multiple times 10 s most extreme holds and up to 50 quick constrictions three times each day, and to keep all practices in a journal. Besides, ladies were shown how to precontract the pelvic floor muscles against expansions in intra-stomach

pressure (supposed the Skill work out) and were urged to utilize this method everyday. The home activity program was adjusted at every arrangement based on assessment discoveries and journal accounts. Utilization of electromyography biofeedback, pressure biofeedback, and electrical feeling were not allowed. Preliminary physiotherapists went to preparing before their contribution in mediation conveyance inside the preliminary. No extra preparation was given to physiotherapists during mediation conveyance.

Members got a prolapse way of life guidance pamphlet that offered regarding about weight reduction, clogging, evasion of hard work, hacking, and high-influence work out; ladies in the benchmark group got this handout by post, though ladies in the mediation bunch got it at their most memorable arrangement. The pamphlet contained no data about pelvic floor muscle activities or strategies. Ladies went to a survey meeting with their gynecologist a half year after preliminary passage, when they could be alluded for additional treatment whenever wanted.

We utilized postal polls to gather information at standard, and a half year and a year after preliminary passage. Our essential end-point was prolapse side effects at a year as estimated by the pelvic organ prolapse side effect score (POP-SS) [14].

An approved, patient-finished strategy with seven things connecting with recurrence of prolapse side effects in the past about a month; every thing is scored from 0 (never) to 4 (constantly), with a potential complete score going from 0 to 28. Optional results were ladies' apparent change in prolapse starting from the beginning of the review (same, better, or more regrettable); personal satisfaction, estimated as obstruction of prolapse side effects with regular daily existence (scored 0 [not at all] to 10 [a extraordinary deal]); number of days with prolapse side effects in the past about a month; take-up of additional prolapse treatment (medical procedure, pessary, reference to physiotherapy, reference to dietitian, estrogen cream or tablets, or chemical substitution treatment); seriousness of incontinence (Global Interview on Incontinence Poll — Urinary Incontinence Short Structure, scored from 0 to 21, with higher qualities showing more noteworthy seriousness) [15].

Entrail side effects (early short structure form of Global Conference on Incontinence Survey — insides module, as given by the designers); sexual symptoms (Sex Questionnaire for Pelvic Organ Prolapse and Urinary Incontinence); [16] general wellbeing (12-Thing Short Structure Wellbeing Review); [17] utilization of wellbeing administrations in essential and optional consideration; furthermore, recurrence of the act of pelvic floor muscle practices in the beyond 4 weeks (a couple of times in particular, one time each week, a couple of times each week, one time per day, a couple of times each day; and less than five contractions per day, five to ten, 11-20, 21-30, 31-60, and more than sixty). Mediation adherence was estimated as far as participation at arrangements and

how much activity ladies kept in their everyday work-out journal. Furthermore, at every arrangement, the physiotherapists conveying the mediation gathered information about ladies' adherence to the endorsed work out.

The facilities' gynecologists utilized the POP-Q framework to evaluate prolapse type and stage in all ladies before bunch portion and at the half year survey arrangement [18].

Formal POP-Q preparing was given at every preliminary place commencement visit. A verbal explanation of the POP-Q system was included in this training; POP-Q preparing DVD; data about normalization of conditions for POP-Q assessment (e.g., assessment position, bladder exhausting, and gear use); what's more, utilization of the recording structure and an interactive discussion. Each middle was given a duplicate of the DVD and the distribution portraying the POP-Q [19].

Focuses were urged to attempt further in-house preparing, and extra focus visits were offered if fundamental.

Statistical analysis Based on the results of our pilot study, we calculated an effect size of 25 (SD 8) as the mean difference between the groups in POP-SS [20].

With 67 ladies, the preliminary had 80% power at a 5% importance level to recognize a distinction of 2.5 places in the essential result measure, expecting a typical SD of 8 places [21]. This calculation allowed for a follow-up loss of 10% overall and 15% of the control group getting the full benefit of muscle training by doing exercises on their own.

Descriptive statistics were tabulated, and the baseline demographics and clinical characteristics were presented with means, standard deviations, or IQRs, as required. We utilized expectation to-get examinations look at the essential result at a year by fitting a direct blended impacts model to change from gauge in POP-SS at a half year and a year, with an irregular capture for patient inside place, and an irregular slant for time inside quiet, and adapted to pattern POP-SS score and the minimisation factors. Such models verifiably change the model evaluations when information are absent, with a suspicion that information are absent aimlessly, as per detailed values [22].

We included ladies who had perceptions at benchmark and no less than one follow-up timepoint in the model. We present the distinction between the mediation and control bunches in assessed mean change from standard for a very long time and a year with 95% CIs and p values. We likewise utilized numerous ascription to survey the presumption of information missing aimlessly and the comparing impact of missing reactions on the essential result [23].

Model suspicions were checked with remaining plots and were displayed to hold.

We looked at POP-Q stage between bunches in an ordinal re-lapse model with half year POP-Q stage as the reliant variable and standard POP-Q stage and minimisation factors as covariates. The pooled chances proportion (OR) from the ordinal model was determined with a 95% CI and p esteem. Stage II prolapse was partitioned into two gatherings reliant upon whether the prolapse was over the hymen or at the hymen or underneath. Change in POP-Q stage among benchmark and a half year was likewise introduced. Other optional results were contrasted among gatherings and the Mann-Whitney U test for ceaseless and ordinal factors and the χ^2 or Fisher’s definite test for straight out factors.

With arranged subgroup investigations we investigated the impact of prolapse stage and type, age, and inspiration for a medical procedure on the essential result, with stricter degrees of importance (two-sided $p < 0.01$) than those utilized for different examinations.

Examinations were finished by a pre-determined measurable investigation plan utilizing the R programming bundle (form 2.15.0) [24] what’s more, the mi bundle in R (form 0.09-17) 25 for post examination.

Results

The figure shows the trial profile. 67 eligible patients were randomised to the intervention group (n = 34) or the control group (n = 33). 34 participants completed follow-up for questionnaires at 6 months and 33 participants for questionnaires at 12 months, women attended for 6 month review. Non-responders at 12 months were significantly younger and had a higher body-mass index (BMI) than did responders (data not shown). We noted no evidence of differential dropout between the trial groups The mean age of participants was 56.8 years (SD 11.5). Women were on average overweight (mean BMI 27 [SD 5.1]). The most common presentation was combined anterior, posterior, and upper compartment prolapse, followed by combined anterior and posterior . Stage II prolapse was the most common type and most women had stage II prolapse at or below the hymen . Median duration of prolapse symptoms was 12 months . As expected for a trial of this size, the clinical and demographic factors at baseline were similar between groups.

When asked “how do you feel your prolapse is now compared to the start of the study?”, women in the intervention group were significantly more likely than those in the control group to report that their prolapse was “better”, both at 6 months and 12 months.

After adjustment for baseline POP-Q stage, centre, and whether the woman was motivated to have surgery, the odds of women having a low-severity of prolapse at 6 months were greater in the intervention group than in the control group, although this difference was not significant (OR 1.47, 95% CI 0.97-2.27; $p = 0.07$). A greater

	Intervention (N = 34)	Control (N = 33)
Age (years)	56.20 (11.60)	57.50 (11.39)
BMI (kg/m ²)	27.15 (4.99)	27.42 (4.57)
Parity	2 (2–3)	2 (2–3)
Stage of prolapse*		
Stage I	8	10
Stage II (above the hymen)	18	17
Stage II (at or below the hymen)	6	4
Stage III	2	2
Stage IV	0	0
Type of prolapse		
Anterior	8	10
Posterior	18	17
Anterior and posterior	4	4
Anterior and upper	4	2
Posterior and upper	0	0
Duration of prolapse symptoms in months	12 (6–24)	12 (6–24)
Baseline POP-SS †	10.04 (6.0)	9.51 (5.64)
Symptom reported in last 4 weeks		
Something coming down	33/34	31/33
Discomfort worse when standing	30/34	29/33
Abdominal pain when standing	18/34	16/33
Lower-back heaviness	12/34	18/33
Strain to empty bladder	18/34	19/33
Feel bladder not empty	19/34	22/33
Feel bowel not empty	14/34	14/33
Faecal urgency ‡	13/34	15/33
Faecal incontinence ‡	6/34	5/33
Urinary incontinence	14/34	15/33
Urinary incontinence score (ICIQ-UI SF	4 (0–7)	4 (0–7)

Table 1: Baseline characteristics.

Data are mean (SD), median (IQR), n (%), or n/N (%), unless otherwise indicated. BMI = body-mass index. POP-SS = pelvic organ prolapse symptom score. ICIQ-UI SF = International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form.

* Pelvic organ prolapse quantification (POP-Q) stage reported here was calculated at the analysis stage with a specially developed programme that used the nine individual POP-Q measurements recorded by the gynaecologist. On occasion this stage differed from that assigned by the gynaecologist that identified women’s trial eligibility.

† POP-SS: 0 = no symptoms, 28 = all seven symptoms all the time.

‡ We defined faecal urgency as a sudden, irresistible need to have a bowel movement; faecal incontinence was any involuntary loss of faecal material.

§ ICIQ-UI SF score: 0 = no incontinence, no interference with everyday life; 21 = maximum leakage and interference.

proportion of women in the intervention group than in the control group had an improvement in their prolapse stage by 6 months but this difference was not significant (risk difference 7.5%, 95% CI -1.4 to 16.4, $p = 0.10$; risk ratio 1.39, 95% CI 0.94-2.06, $p = 0.10$).

At 12 months, significantly more women in the control group than the intervention group had received further treatment risk

difference 25.5%, 14.5-36.0, $p < 0.0001$; risk ratio 2.1, 1.5-2.9, $p < 0.0001$). We noted a similar uptake of surgery, pessary, and other non-trial treatments in the study groups at 12 months, but significantly more women in the control group had had a physiotherapy referral for pelvic floor muscle training.

	Intervention (n = 34)	Control (n = 33)	p value
+2 stages	4/34	9/33	..
+1 stage	26/34	29/33	..
no change	2/34	1/33	..
-1 stage	4/34	2/33	..
-2 stages	11/34	8/33	..
Further treatment received by 12 months			
Any further treatment received	3/34	7/33	<0.0001
Surgery	6/34	4/33	0.84
Pessary	1/34	3/33	0.13
Physiotherapy referral	2/34	3/33	<0.0001
Oestrogen, drugs, or other	3/34	1/33	0.85

Table 2: Change in prolapse (pelvic organ prolapse quantification) stage at 6 months, and uptake of further prolapse treatment by 12 months.

Women were asked to report to what extent prolapse interfered with dimensions of their quality of life and about other symptoms. At 6 months, scores in women in the intervention group were significantly lower (i.e., better) than those in women in the control group for all aspects of daily life, and sexual, bladder, and bowel function (except for faecal incontinence), but this finding was not evident at 12 months .The treatment effect at 12 months was consistent for all prespecified subgroups. We recorded no significant interactions between trial group and any of the subgroup terms in the model: prolapse stage I-III ($p = 0.38$); prolapse type of most descended part anterior, posterior, or upper ($p = 0.61$); age younger than 50 years or 50 years and older ($p = 0.29$); and motivation for surgery as keen or wants to avoid ($p = 0.89$).

Data are median (IQR) or n/N (%), unless otherwise indicated. Women were asked to answer questions in relation to the last 4 weeks. ICIQ-UI SF = International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form.

- Prolapse-related interference scores range from 0 (not at all) to 10 (a great deal).
- † Mann-Whitney *U* test done on the ordinal response.
- ‡ ICIQ-UI SF score: 0 = no incontinence, no interference with everyday life; 21 = maximum leakage and interference.
- § We defined faecal urgency as sudden, irresistible need to have a bowel movement; faecal incontinence was any involuntary loss of faecal material.

Discussion

Our findings show a greater reduction in prolapse symptoms at 12 months in women who underwent pelvic floor muscle training than in the control group. This difference was both statistically significant and of a magnitude that would be important to women, because it exceeded the minimally important change for the POP-Q [26].

This finding was supported by an increase in uptake of supplementary treatments (mainly pelvic floor muscle training) in the control group after 6 months, showing a residual need; a reduced prevalence of each individual prolapse symptom, and of bladder, bowel, and sexual symptoms; and a better quality of life in the intervention group after 6 months of muscle training. Furthermore, women in the intervention group were more likely to report that their prolapse was “better” at both 6 months and 12 months. Although more women in the intervention group had improvement in prolapse stage, this result did not differ significantly between the groups. Subgroup analyses showed that these findings of effectiveness held irrespective of prolapse stage or type, or the woman’s age or attitude towards having surgery. Because of the high degree of uptake of some form of pelvic floor muscle training in the control group before the primary outcome assessment at 12 months, and the absence of evidence of differential use of other non-training interventions, the intention-to-treat treatment effect estimate could be an underestimate of the benefit associated with pelvic floor

muscle training at 12 months. Therefore, we are confident that the significant treatment effects reported represent real effects that are of importance to women and clinicians. The finding that at 12 months, women in the control group were as likely to be exercising as were those in the intervention group might partly be explained by the uptake of physiotherapy in the control group. That almost 80% of women in the intervention group were still exercising at 12 months is encouraging, because long-term adherence is an important consideration for the effectiveness of this intervention.

The main area of uncertainty is the longer-term effect of pelvic floor muscle training on the need for subsequent treatments such as pessaries, physiotherapy, and surgery; our results are based on the trial follow-up period and we cannot exclude the possibility that treatments have been delayed rather than avoided. Our sensitivity analyses showed plausible ranges around our results; however, reasons exist for believing that the increased costs are unlikely—namely that expenditure on the intervention is a once only event, as such all costs have been incurred and the benefits in terms of reduced symptoms and treatments avoided are likely to continue to accrue over time.

The main strengths of our trial were its size, rigour, and pragmatic design, with the intervention being relevant to clinical practice, and potentially to other similar health systems worldwide; furthermore, the outcomes were woman-centred. Participants' compliance with trial processes and the intervention were generally high. Unlike other trials in this specialty, our main focus was the prolapse symptoms that led women to seek treatment, and which we used to measure treatment success.

In terms of limitations, we achieved 88% of our target sample size of 67, and noted a lower rate of questionnaire response than expected at 12 months, despite postal and telephone reminders. However, because the SD of the POP-SS was smaller than originally assumed, we nevertheless had sufficient power to identify important differences. We noted no evidence of differential dropout because the response rate was similar in both groups, and results were also robust to missing data. Not all women had a prolapse assessment at 6 months; therefore there was also attrition in the POP-Q responses. This attrition might have contributed to the non-significant POP-Q finding. We noted significant crossover of women in the control group to the intervention group due to their uptake of pelvic floor muscle training after 6 months, which makes interpretation of the findings more challenging. A further limitation is the short follow-up period of 12 months. Because of natural fluctuation in prolapse symptoms and the effect of different treatment modalities, clinical and cost differences between the groups might be expected to change with time. Included women were treatment-naïve and presented for treatment for the first time. However, pelvic floor muscle training might also be effective for enhancement of surgical or pessary treatment, or for use after surgical failure, or shortly after childbirth, and these situations need further re-

search. In the economic analysis we did not estimate quality of life gained because findings from our pilot work showed that the SF-12 was insensitive to meaningful changes in prolapse symptoms in this population. Therefore, decision makers should interpret the results on the basis of a careful reading of the symptoms women suffered and the extent to which these symptoms were relieved. The paucity of other economic studies in this specialty makes comparing of results difficult; we look forward to future studies that provide comparisons for these results.

Six other randomised studies have been published to date comparing pelvic floor muscle training with a control intervention [27].

Three of these trials are pilot trials, which makes the drawing of conclusions from their findings problematic on the basis of their developmental nature and small sample sizes [28].

Three other full-sized trials have been published [29].

The Piya-Anant trial [30] had methodological limitations and a high risk of bias, and cannot reliably contribute to the evidence base. No information was provided about the processes of random sequence generation or allocation concealment, the investigators did not report about attrition and selectively reported about only a subgroup of the women randomised, and uncertainty existed as to whether the analysis was intention to treat. Of the remaining two trials, the Brækken single-centre trial [31] of pelvic floor muscle training versus control randomly assigned 109 women with stage I-III prolapse, of which a subgroup of only 69 (63%) women were symptomatic and hence similar to our population. The very intensive training regimen consisted of weekly appointments for 3 months, followed by bi-weekly appointments for 3 months—a treatment model that would not be possible to deliver in the UK and many other countries because of the restricted availability of specialist physiotherapy resource within their health services. Kashyap and colleagues [32] reported a single-centre trial in women with stage I-III prolapse, which compared taught pelvic floor muscle training plus a self-instruction manual (n = 70) with the self-instruction manual alone as the control intervention (n = 70). One person delivered the training intervention to all women. The content of the manual was not described and therefore what written instruction the control group received is unclear. More importantly, four women transferred from the control group to the training plus manual group; in which group these women were analysed is unclear. Until this point is clarified, the results have restricted use. Both Brækken and colleagues [33] and Kashyap and colleagues [34] reported symptom benefit from pelvic floor muscle training. Brækken and colleagues analysed the subgroup of women with symptoms at baseline and reported that women who had received muscle training were more likely than women in the control group to have reduced frequency of prolapse symptoms (74% vs 31%) and reduced bother of symptoms (67% vs 42%). Kashyap and colleagues reported a significantly greater mean reduction in POP-

SS score after the intervention for the muscle training plus manual group compared with the control group (2.99 vs 1.25). Neither trial sought evidence about longer term outcomes or the effect on the uptake of other treatments.

Braekken and colleagues [35] also reported that pelvic floor muscle training improved POP-Q stage: 19% of women in the intervention group had an improved stage versus 8% in the control group (11% risk difference). Our finding for POP-Q was non-significant, but of a similar size. The most likely reason for the non-significant finding in our trial is that the study was not powered to show a difference for this outcome. Data for change in the POP-Q or prolapse stage in Kashyap and colleagues' trial were not adequately reported to allow comparison [36].

We chose symptom change as our primary outcome measure. This endpoint is usually the driver for individuals seeking treatment for prolapse and is hence the most important outcome for women. That little correlation exists between stage of prolapse and the prolapse symptoms ascribed to it is increasingly recognised [37,38].

Therefore, and as we recorded, that an improvement in symptoms does not necessarily correspond to an improvement in stage is not surprising. 45% of women in the control group in our study reported that their prolapse was better at 12 months. This finding is partly because about half of these women had received further treatment for prolapse by this timepoint. Although significantly more women in the intervention group than the control group reported that their prolapse was better, the remaining participants reported no change or worse prolapse. Thus, a substantial group of women did not benefit. One potential reason for this finding is that a more intensive intervention might be needed for some women. Another reason is that some types or stages of prolapse do not respond to pelvic floor muscle training as well as do others, and hence, improved selection of women for training might be needed. Although our subgroup analyses did not support these hypotheses, the analyses were exploratory and underpowered to draw firm conclusions.

Prolapse can regress with time, which could partly explain the improvement we noted. Three studies of the epidemiology of prolapse concluded that prolapse can both progress and regress [39].

Handa and colleagues' and Bradley and colleagues' studies assessed change in severity of prolapse, but in populations older than our own. The study by Miedel and colleagues is most relevant for comparison because it examined both symptoms and stage of prolapse over time in women with a mean age of 56 years. Their findings show that 44% of stage I prolapses had regressed to stage 0, 24% of stage II showed regression, and 64% (95% CI 56-72) of women had a reduction in symptoms by 5 years. However, the study population was mainly non-consulting women identified by

a positive questionnaire response to "a feeling of a vaginal bulge", rather than women who were actively seeking treatment for prolapse. As the investigators mentioned, results cannot be automatically generalised to patients who present to health-care services. Therefore, we do not know to what extent women in our trial naturally improved. However, we would expect that any natural regression or progression would happen equally in both groups by virtue of the group allocation, and hence the noted significant differences between the groups must be due to the intervention.

Our trial is the largest, rigorous, pragmatic multicentre trial of pelvic floor muscle training for prolapse, with the longest follow-up, and as such provides the necessary evidence to support changes in clinical practice (panel). However the resource implications of implementation of these findings should be considered. The physiotherapists delivering the trial intervention were specialists in women's health; their numbers are few and their workload is large, presently consisting of mainly the management of urinary incontinence. With the establishment of an evidence-base for pelvic floor muscle training for the management of prolapse, health-care providers will need to invest in extra resources to ensure that a similar service can be provided for women with prolapse. Additionally, beyond the clinical arena, the role of pelvic floor muscle exercises for alleviation of prolapse symptoms is an important public health message that should be shared widely among women of all ages.

Conclusion

We conclude that pelvic floor muscle training should be recommended for the conservative management of prolapse. Effectiveness of such training in the long term, in women who have had previous prolapse surgery, in conjunction with pessary use, and within populations of women with different types or combinations of prolapse, should be investigated further.

Conflicts of Interest

We declare that we have no conflicts of interest.

Acknowledgments

We accept full responsibility for the research. We thank all the women who willingly participated in the POPPY trial and completed their questionnaires and attended physiotherapy and gynaecology appointments; the staff at each of our centres for recruiting, motivating and treating our participants; those who administered the trial in India (Gaye Ellis) and members of the trial steering committee and data monitoring committee for giving their time in advising the trial team throughout the work.

Bibliography

1. Hendrix SL, et al. "Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity". *American Journal of Obstetrics and Gynecology* 186 (2002): 1160-1166.

2. Olsen AL, et al. "Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence". *Obstetrics and Gynecology* 89 (1997): 501-506.

3. Health and Social Care Information Centre. Hospital episode statistics, admitted patient care—England, 2010-11.

4. Wu JM, et al. "Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050". *American Journal of Obstetrics and Gynecology* 205 (2011): 230.e1-230.e5.

5. Miedel A, et al. "Nonobstetric risk factors for symptomatic pelvic organ prolapse". *Obstetrics and Gynecology* 113 (2009): 1089-1097.

6. Slieker-ten Hove MC, et al. "Symptomatic pelvic organ prolapse and possible risk factors in a general population". *American Journal of Obstetrics and Gynecology* 200 (2009): 184.e1-184.e7o.

7. Abrams PH, et al. "Incontinence". 5th edn. Health Publication Ltd, Plymbridge, UK (2013).

8. Hagen S, et al. "A United Kingdom-wide survey of physiotherapy practice in the treatment of pelvic organ prolapse". *Physiotherapy* 90 (2004): 19-26.

9. Dumoulin C and Hay-Smith J. "Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women". *Cochrane Database of Systematic Reviews* 1 (2010): CD005654.

10. Hagen S and Stark D. "Conservative prevention and management of pelvic organ prolapse in women". *Cochrane Database of Systematic Reviews* 12 (2011): CD003882.

11. Bump RC, et al. "The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction". *American Journal of Obstetrics and Gynecology* 175 (1995): 10-17.

12. Hagen S, et al. "A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse". *International Urogynecology Journal and Pelvic Floor Dysfunction* 20 (2009): 45-51.

13. Bo K. "Pelvic floor muscle exercise for the treatment of stress urinary incontinence: an exercise physiology perspective". *International Urogynecology Journal* 6 (1995): 282-291.

14. National Institute for Health and Clinical Excellence. "Urinary incontinence: the management of urinary incontinence in women". Clinical guidance 40.NICE, London (2006).

15. Laycock J and Jerwood D. "Pelvic floor muscle assessment: the PERFECT scheme". *Physiotherapy* 87 (2001): 631-642.

16. Hagen S, et al. "Psychometric properties of the pelvic organ prolapse symptom score". *BJOG* 116 (2009): 25-31.

17. Avery K, et al. "ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence". *Neurourology and Urodynamics* 23 (2004): 322-330.

18. Rogers RG, et al. "A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)". *International Urogynecology Journal and Pelvic Floor Dysfunction* 14 (2003): 164-168.

19. Ware Jr, et al. "A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity". *Medical Care* 34 (1996): 220-233.

20. Allahdin S, et al. "A randomised controlled trial evaluating the use of polyglactin mesh, polydioxanone and polyglactin sutures for pelvic organ prolapse surgery". *Journal of Obstetrics and Gynaecology* 28 (2008): 427-431.

21. Diggle PJ, et al. "Analysis of longitudinal data". 2nd edn. Oxford University Press Inc, Clarendon (2002).

22. Rubin DB. "Multiple imputation for nonresponse in surveys". John Wiley and Sons, New York (1987).

23. R Development Core Team. "R: a language and environment for statistical computing". R Foundation for Statistical Computing, Vienna (2012).

24. Su Y-S, et al. "Multiple imputation with diagnostics (mi) in R: opening windows into the black box". *Journal of Statistical Software* 45 (2011): 1-31.

25. Curtis L. "Unit costs of health and social care 2009". University of Kent, Kent (2009).

26. Information Services Division. Scottish health service costs year ended 31 March 2010. NHS National Services Scotland, Edinburgh (2010).

27. Joint Formulary Committee. British National Formulary. 61st edn. British Medical Association and Royal Pharmaceutical Society of Great Britain, London (2011).

28. C&G Medicare. Club pessary (2010).

29. Hagen S, et al. "Further properties of the pelvic organ prolapse symptom score: minimally important change and test-retest reliability". *Neurourology and Urodynamics* 29 (2010): 1055-1056.

30. Ghroubi S, et al. "Effect of conservative treatment in the management of low-degree urogenital prolapse". *Annales de Réadaptation et de Médecine Physique* 51 (2008): 96-102.

31. Stüpp L, et al. "Pelvic floor muscle training for treatment of pelvic organ prolapse: an assessor-blinded randomized controlled trial". *International Urogynecology Journal and Pelvic Floor Dysfunction* 22 (2011): 1233-1239.

32. Piya-Anant M., *et al.* "Integrated health research program for the Thai elderly: prevalence of genital prolapse and effectiveness of pelvic floor exercise to prevent worsening of genital prolapse in elderly women". *Journal of the Medical Association of Thailand* 86 (2003): 509-515.

33. Brækken IH., *et al.* "Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial". *American Journal of Obstetrics and Gynecology* 203 (2010): 170e1-170e7.

34. Kashyap R., *et al.* "Comparative effect of 2 packages of pelvic floor muscle training on the clinical course of stage I-III pelvic organ prolapse". *International Journal of Gynecology and Obstetrics* 121 (2013): 69-73.

35. Ellerkmann RM., *et al.* "Correlation of symptoms with location and severity of pelvic organ prolapse". *American Journal of Obstetrics and Gynecology* 185 (2001): 1332-1337.

36. Mouritsen L and Larsen JP. "Symptoms, bother and POPQ in women referred with pelvic organ prolapse". *International Urogynecology Journal* 14 (2003): 122-127.

37. Handa VL., *et al.* "Progression and remission of pelvic organ prolapse: a longitudinal study of menopausal women". *American Journal of Obstetrics and Gynecology* 190 (2002): 27-32.

38. Bradley CS., *et al.* "Natural history of pelvic organ prolapse in postmenopausal women". *Obstetrics and Gynecology* 109 (2007): 848-854.

39. Miedel A., *et al.* "Short-term natural history in women with symptoms indicative of pelvic organ prolapse". *International Urogynecology Journal* 22 (2011): 461-468.