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Pelvic floor muscle function and Pelvic Organ Prolapse

DISSERTATION FROM THE NORWEGIAN SCHOOL OF SPORT SCIENCES • 2010

ISBN nr 978-82-502-0434-8

Summary

The overall high prevalence of pelvic organ prolapse (POP) and related problems indicates a need for identification of risk factors, prevention and treatment strategies. The aetiology of POP is considered to be multifactorial. Only a minority of the many proposed risk factors for POP can easily be prevented. Treatment of POP is surgery, use of a pessary or pelvic floor muscle training (PFMT). Today there is a lack of evidence for the effect of PFMT in reducing and preventing POP, and there is scant knowledge of possible changes in morphology and function of the pelvic floor muscles (PFM) following PFMT. Proposed changes in the pelvic floor include increased muscle volume, elevated positions of the pelvic organs and narrowing of the levator hiatus. Use of responsive, reliable and valid outcome measures is mandatory for evaluation of these proposed effects. 3D/ 4D perineal ultrasound is a new promising assessment tool. However, its reliability and validity must first be tested. The overall aim of this thesis was to establish intra tester reliability of the ultrasound measurements, identify risk factors for POP, evaluate the effect of PFMT in prevention and treatment of women with POP and to assess morphological changes after PFMT.

To evaluate test- retest and intra-observer repeatability of 2D, 3D and 4D perineal ultrasound assessments of PFM morphology and function, 17 participants were examined twice. Perineal ultrasound was a reliable method for measuring most of the tested parameters of morphology and function of the PFM. 4D ultrasound reliably assessed muscle length, narrowing of hiatal area, reduction of hiatal antero-posterior dimension and lift of bladder, bowel and back sling of the puborectalis muscle during a PFM contraction. Hence, it may be used in clinical trials evaluating changes in anatomical parameters after PFMT.

To investigate proposed risk factors for POP, including physical activity, clinically measured joint mobility and PFM function, 49 participants with POP were age- and parity matched with 49 controls. Univariate analyses showed no significant differences between groups in postmenopausal status, current smoking, current low intensity exercise, type of birth (cesarean, forceps, vacuum), birth weight, and presence of striae, diastasis recti abdominis and joint hypermobility. Women with POP had lower PFM strength, PFM endurance and vaginal resting pressure than controls. Body mass index (BMI), socioeconomic status, heavy occupational work, anal sphincter lacerations and PFM function were independently

associated with POP. BMI and PFM function may be of particular clinical significance in prevention of POP, since these factors can be altered by the women themselves.

The effectiveness of PFMT in reversing POP and alleviating symptoms related to POP was investigated in an assessor blinded randomised controlled trial (RCT), called the POP study. Another aim of this study was to evaluate morphological and functional changes in the PFM after PFMT. Fifty women were randomly allocated to the control group and 59 to the PFMT group. Both the PFMT and control group received written information about POP and were advised to contract their PFM prior and during increases in abdominal pressure (coughing, sneezing, heavy lifting) and they were advised not to bear down (e.g. during defecation). Women in the PFMT group were advised to do 3 sets of 8-12 close to maximum PFM contractions per day for six months. Once every week in the three first months and every second week for the last three months the PFMT was individually supervised by a physical therapist (PT). Forty-seven (79%) women in the PFMT group reached an adherence level of 80% (\geq 14 PT visits and \geq 144 days with home exercise). No adverse effects were reported. One woman in each group dropped out of the study.

At six months, 11 women (19%) in the PFMT group versus four (8%) controls improved one stage of prolapse (p=.04), measured with pelvic organ prolapse quantification system (POP-Q). Compared to the control group, women in the PFMT group reduced the frequency and bother of mechanical, bladder and bowel symptoms. The PFMT group had significantly greater improvement than the control group in PFM strength and endurance. Compared to women in the control group, women in the PFMT group increased thickness of the pubovisceral muscle, elevated position of bladder and bowel, decreased hiatus area and shortened muscle length measured by 3D ultrasound. Additionally, they reduced the levator area and muscle length at maximum valsalva indicating increased PFM stiffness.

To our knowledge the POP study is the first full-scale RCT of the effectiveness of PFMT in women with all sites of POP. The RCT demonstrated that supervised strength training of the PFM can reverse POP, reduce symptoms and create morphological and functional changes of the pelvic floor.

Acknowledgements

The project was conducted at the Norwegian School of Sport Science (NSSS), department of sports medicine, Oslo Norway in cooperation with Akershus university hospital (Ahus), department of obstetrics and gynaecology, Lørenskog, Norway in the period 2005 – 2009. The practical part was carried out at Ahus and Hans & Olaf physiotherapy, Oslo, Norway.

We gratefully acknowledge support for this research through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

I would like to express my sincere gratitude to everyone who made this thesis possible. Especially I would like to thank:

My supervisor, Kari Bø, professor, Ph.D, PT, exercise scientist at NSSS and, of course, coauthor of all the papers. You "headhunted" and introduced me to a field that was totally new for me. I feel privileged to work with one of the most internationally best known researchers in sports medicine and women's health, specialising in pelvic floor rehabilitation. You had already designed the main study when I started. I appreciate your generosity for allowing me to "run the project". You have been positive to my suggestions on expansion of the test protocol, especially regarding the ultrasound measurements. Without your interest and belief in pelvic floor muscle training this project would have never come true. Thanks for thorough, effective, and honest feedback to my questions and manuscripts. Your scientific guidance, involvement and enthusiasm in the projects, and belief in me, have been extremely valuable.

My co- supervisor, Marie Ellstrøm Engh, Ph.D. Associate professor, Consultant gynaecologist at Ahus and Faculty Division Akershus University, University of Oslo and coauthor of all the papers. You kindly opened the doors for us at Ahus and started the close collaboration between the hospital and NSSS. I really appreciate your excellent, constructive feedback on the manuscript and the valuable discussions we have had.

Memona Majida, Consultant gynaecologist, MD, PhD student at Ahus and co-author of all the papers. You stand out as one of my best collaborators. In four years we have shared many

hours with ultrasound and clinical examinations at Ahus. I am grateful for your precise work and the discussions about the ultrasound protocol, technical questions and life in general.

Ingar Morten Holme, professor and biostatistician, colleague and co-author of paper III. Thanks for your statistical counselling and patience in explaining to me the different statistical approaches needed to survive in research.

Hans Peter Dietz, associate professor, MD, Nepean Clinical School, University of Sydney, Australia, co-author of paper I, Wolfgang Umek, associate professor, MD, Medical University Vienna, Department of Obstetrics and Gynaecology co-author of paper I and Anneke B Steensma, Department of Obstetrics & Gynaecology, Erasmus Medical Center, Rotterdam, the Netherlands and Austria. Thank you for valuable help setting up the ultrasound technique and teaching us how to analyse the ultrasound images. Without your help we could never have used this new ultrasound technique.

John O. DeLancey, professor; MD, University of Michigan, Ann Arbor, USA for initial collaboration and discussions in planning the study, and for allowing me to use his figures/ drawing in this thesis. I would also like to thank James A. Ashton-Miller, professor, MD, College of Engineering, University of Michigan, Ann Arbor, USA for initial collaboration, and Richard C. Bump, M.D. Lilly Research Laboratories, Indianapolis, Indiana, USA, Michal Otcenasek, MD, PhD, Institute for the Care of Mother and Child, Podoli, Czech Republic, Renato M. Natal Jorge, Mechanical Engineering Department, Faculty of Engineering, University of Porto, Portugal and Kjersti Vardeberg at National Resource Centre for Rare Disorders, Sunnaas Rehabilitation Hospital, Nesodden, Norway for allowing me to reprint figures in this thesis.

I want to express my sincere thank to all participating women for giving your time to one or more of the three projects. It is amazing to feel the motivation of every one of you that have been training daily for six months. Needless to say, without your effort this study would never have come through.

The physical therapists Vigdis Skøld and Gudrun Agusta Brandsdottir, Ahus, for assessing and supervising the training sessions for some of the women in the POP study. You have done

an impressive job with supervising, motivating and closely following up the actual women. I know that both the treated women and the whole project group really appreciate your work. Without your motivation and persistence, the adherence rate would have dropped.

Kjersti Andersen and Guro Pauck Øglund scientific assistants, at the NSSS for helping me to transfer the data into the SPSS files, and other logistic tasks. This has saved me from an additional year's work.

My colleagues and friends at the department of Sports medicine. We have shared a lot and I appreciate the friendship we have developed. It is good to have someone with whom to share joys and frustrations. A special thanks to PhD students, "conference room-mates" Kathrine Marie Owe and Lene Anette Hagen Haakstad, who have gone trough the same PhD process and "shared" the same supervisor as me. I would also like to acknowledge my colleagues at Hans & Olaf physical therapy for sticking out with me, being supportive and offering their personal input. It has been great to spend some days at "my old job". Roar Robinson, manual therapist, Msci, you have shown generosity by providing me an office for the exercise sessions and clinical examinations. I would also like to thank Hanne Borg Finckenhagen, Women's health physiotherapist, for introducing me to the practical side of the field.

All the librarians at the NSSS for greatly helping me with articles and references.

Gill Brook MSc, MCSP, physiotherapist, Bradford Teaching Hospitals, UK for English revision of the present thesis. Helena Frawley, PhD, physical therapist, University of Melbourne, The Royal Women's Hospital, Melbourne for English revision of paper II, Dr. Patricia Neumann, PhD, at the Centre for Allied Health Evidence, University of South Australia, Adelaide for English revision of paper III, Ingrid Nygaard, professor, MD, University of Utah School of Medicine, Department of Obstetrics and Gynecology, Salt Lake City, USA for English revision of paper IV and V. Without you, the "Norwegian-English" would have been much more prominent.

To all my friends wondering what I have been doing and to those who have known exactly what I have been doing by voluntarily participating in the projects, thank you for being my friends.

A very special thank to my parents for raising me up to believe that "nothing is impossible" and for helping me out when the days had too few hours. Without you this PhD degree would have taken so much longer. You pick up Marie and Theodor at school and kinder garden, cook dinner for the whole family, and do everything to help me and my husband to "survive" the hard working periods.

Marie (8 years) and Theodor (5 years), you are the best children one can have and you have helped me to let work be work and leisure time be leisure time. To be with you is the best medicine to "unhook" the project thoughts. I dedicate this thesis to my two beautiful children.

Finally, my warmest thanks go to my husband, Kjetil, for constant support and belief in me. You have encouraged me to work hard and from time to time not work at all ⁽²⁾. I really look forward to doing more of the things we like to do; skiing, sailing, cycling, drinking wine in the garden and enjoying our life with the children.

Oslo, August 2009

Ingeborg Hoff Breeker

List of Papers

This thesis is based on the following papers, referred to in the text by their roman numerals.

- I. Brækken,I.H, Majida,M, Ellström-Engh,M, Dietz,H.P, Umek,W, and Bø,K, 2008. Testretest and intra-observer repeatability of two-, three- and four-dimensional perineal ultrasound of pelvic floor muscle anatomy and function. *Int. Urogynecol. J. Pelvic .Floor. Dysfunct.*, 19, 227-235.
- II. Braekken, I.H., Majida, M., Ellström-Engh, M. and Bø, K., 2009. Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. *Neurourol. Urodyn*, 28, 68-73.
- III. Braekken, I.H., Majida, M., Ellstrom, E.M., Holme, I.M., and Bo, K., 2009. Pelvic floor function is independently associated with pelvic organ prolapse. *BJOG.*, **116**, 1706-1714.
- IV. Braekken,I.H., Majida,M., Ellström-Engh,M. and Bø,K., Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? – An assessor blinded randomized controlled trial, accepted American Journal of Obstetrics and Gynecology 22. December 2009, Manuscript number: W09-0796R1
- V. Braekken,I.H., Majida,M., Ellström-Engh,M. and Bø,K., Morphological Changes After Pelvic Floor Muscle Training Measured By 3-Dimensional Ultrasound: A Randomized Controlled Trial. In press: Obstetric & Gynaecology, Reference: ONG-09-1094

Abbreviations

3D	Three dimensional
4D	Four dimensional
Ahus	Akershus university hospital
BMI	Body mass index
CI	Confidence interval
ICC	Intraclass correlation coefficient
MRI	Magnetic resonance imaging
NSSS	Norwegian School of Sport Science
OR	Odds ratio
PFM	Pelvic floor muscles
PFMT	Pelvic floor muscle training
POP	Pelvic organ prolapse
РТ	Physical therapist
RCT	Randomized controlled trial
SD	Standard deviation

SUI Stress urinary incontinence

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Introduction

Pelvic organ prolapse - four thousand years of treatment

Pelvic organ prolapse (POP) is defined as descent, protrusion or herniation of one or more of the pelvic organs (uterus, vagina, bladder, bowel) through the levator hiatus into or out of the vaginal canal ¹⁻³. POP was described as early as 2000 years before the birth of Christ in an Egyptian text. Wet feet, excessive exertion, fatigue and sexual excess were proposed as risk factors for developing POP by Hippocrates. Two hundred years later mental suffering, accidents, delivery trauma, heavy lifting and increasing age were listed as risk factors ⁴. A suggested treatment for POP was to lubricate the descended genitals with melted butter, bathed in hot milk and then reposition and bandage ⁴. Hippocrates recommended succussion therapy where the woman was tied to an inverted ladder for 3-5 minutes while being moved up and down quite rapidly ⁵ (Fig 1). Cleopatra describes a vaginally applied astringent solution, and others suggested insertion of a half pomegranate dipped in vinegar. Vaginal tampons made of sponge, cotton, linen, wood, bone ivory, cork or various metals have also been used to treat POP. The first vaginal hysterectomy was performed in 1521, but it was in the 19th century, after the development of anaesthesia, that a wide spread of surgical techniques were developed ⁴.



Figure 1 Hippocratic succussion as treatment for POP⁵

Background

It has been estimated that approximately 50% of women loose some of the supportive mechanisms of the pelvic floor due to childbirth leading to different degrees of POP ⁶. The prevalence of all stages and types of prolapse ranges from 3% to 94%, depending on the definition used and the target population ⁷⁻⁹. The highest prevalence of POP is found among elderly women. Therefore, in the future, incidence of prolapse may rise due to global aging ¹⁰. POP can persist with or without symptoms. Symptomatic POP can greatly affect the suffering woman's quality of life. About 11% of all women will at one point in their life undergo surgery for POP or incontinence ¹¹. In the UK, POP accounts for 20% of women on waiting lists for major gynaecological surgery ⁶, and there is a high occurrence of recurrent prolapse (58%) ¹², vaginal/graft infection (4.7% - 18.4%), granulation tissue complication (17.3%-38.8%) ¹³ and re-operations (29 %) ¹¹.

The aetiology and risk factors for developing POP are considered to be multifactorial ¹⁴. Unfortunately, only a minority of these risk factors can easily be prevented. Treatment of POP can be conservative (pelvic floor muscle training [PFMT]), mechanical (use of a pessary) or surgical ^{3;15}. Only three recent randomised controlled trials (RCTs) have investigated the effect of PFMT on POP. One trial ¹⁶ scored low on methodological quality ^{15;17}, one is a pilot study ¹⁸ and one trial published in French included only women with anterior wall POP, and assessed symptoms only ¹⁹.

To date there is scant knowledge of possible changes in morphology and function of the PFM following PFMT ²⁰. Until recently, magnetic resonance imaging (MRI) was the only imaging method capable of assessing the levator ani in vivo ²¹. Three and four- dimensional (3D/4D) ultrasound has the advantage of allowing multi planar imaging ²² and can thereby simultaneously measure the lift of the pelvic organs and the constriction (squeeze) of the PFM.

The overall high prevalence of POP and related problems indicates a need for early intervention and identification of risk factors ²³. Research aiming to treat POP conservatively and to understand modifiable risk factors for prevention of POP has been warranted ^{7;10;15}. Responsive, reliable and valid outcome measures are essential for this purpose, and reliability studies for ultrasound measurement are recommended ^{24;25}.

Definition, classification and prevalence

The different types and sites of prolapse include ^{3;26}:

- Apical compartment prolapse; defined as any descent of the uterus (uterine prolapse) or vaginal cuff scar (after hysterectomy).
- Anterior vaginal wall prolapse; defined as descent of the anterior vaginal wall, including cystocele (bladder descent), urethrocele (urethra descent) and paravaginal defect (pelvic fascia defect).
- Posterior vaginal wall prolapse; defined as any descent of the posterior vagina, including rectocele (rectum descent) and enterocele (small bowel descent).

A woman can present with prolapse of one or more of these sites.

Research in the area of POP has suffered from the lack of standardised assessment. From 1963 to 1996 at least three different systems have been used to classify POP ²⁷⁻²⁹. In 1996 the pelvic organ prolapse quantification system (POP-Q) was introduced ¹. This is now considered to be the internationally recommended classification scale ^{30;31}. The system can measure prolapse in the three compartments and classify POP in five stages. POP-Q stages refer to the most severe portion of the prolapse during maximal valsalva (straining in order to create high intra-abdominal pressure). POP-Q has been tested and found reproducible ^{32;33}.



Figure 2. Pelvic organ prolapse quantification system (POP-Q) measures six defined points around the vagina; two points measure the position of the; anterior vaginal wall (Aa, Ba), posterior vaginal wall (Ap, Bp) and uterus/apical compartment (C,D), in addition to genital hiatus (gh), perineal body (pb) and total vaginal length (tvl). From: Bump,R.C., Mattiasson,A., Bo,K., Brubaker,L.P., DeLancey,J.O., Klarskov,P., Shull,B.L., and Smith,A.R., 1996. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am.J.Obstet.Gynecol.*, 175, 10-17. With permission from R. Bump.

An international survey shows that only 40% of pelvic floor surgeons use POP-Q clinically; the main reason being that they find the system complex and time-consuming 34 .

It is the consensus view that POP should be assessed with POP-Q. However, POP can be defined in different ways. In 2002 the International Continence Society defined absence of POP as stage 0, and POP was staged from I to IV³⁰. In 2001 the National Institutes of Health (NIH) defined prolapse as POP-Q stage II or greater ³¹. There are now, therefore, two definitions from two very well-known institutions. In addition, some research groups want to include both physical findings and bothersome symptoms in the definition of the condition ³⁵.

Large population-based epidemiologic studies of pelvic organ prolapse are rare, but important when describing the prevalence of POP. One barrier is the need for physical examination (POP-Q) in order to confirm the condition. If POP is defined as stage I or more on POP-Q, the prevalence of anatomical POP is found to be 76 - 94%. However, it drops to 40 - 51% if POP is defined as stage II or more $^{7;36;37}$. The Pelvic Organ Support Study found that the prevalence distribution followed a bell-shaped curve, with most women having a milder degree of POP (stage I or II) ³⁸. The prevalence of symptomatic POP is reported to be 3-29% $^{7-9;39-41}$. The discrepancy in prevalence of the condition is most likely due to different study populations, age, race, parity and different measuring methods $^{41;42}$.

Symptoms of pelvic organ prolapse

Milder degrees of POP are often asymptomatic, and when the prolapse reaches the hymen, mechanical symptoms, like vaginal bulging and pelvic heaviness, are common ⁴³⁻⁴⁵. A report from the standardisation sub-committee of the International Continence Society states that women with POP may have a feeling of a lump ("something coming down"), low back pain, pelvic heaviness, dragging sensation, or the need to digitally replace the prolapse in order to defecate or micturate ²⁶. Symptoms of prolapse can be divided into four domains ⁴³:

- Mechanical symptoms include pelvic heaviness and vaginal bulging/introital lump. A strong correlation between a sensation of vaginal bulging with the degree of POP, measured by ultrasound, has been found ⁴⁶.
- Bladder symptoms include stress and urge incontinence, urgency, frequency, nocturia, straining to void, emptying problems and recurrent cystitis ⁴⁵. In a review by Mouritsen ⁴³ it was documented that POP was often accompanied by incontinence and

voiding difficulties. More severe stages of POP correlate with voiding difficulties and the need to digitally replace the prolapse to void. However, in 30-50 % of patients with voiding difficulties this was not correlated to anterior vaginal wall prolapse. Stress urinary incontinence (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. Urgency urinary incontinence (urge urinary incontinence), is the complaint of involuntary leakage accompanied by or immediately preceded by urgency, and urgency is the complaint of a sudden compelling desire to pass urine, which is difficult to defer ^{26;47}.

- 3) Bowel symptoms include evacuation problems, bowel motions, use of laxatives and faecal incontinence (flatus, liquid, solid). The number of women with POP complaining of faecal incontinence is 10-30% ⁴⁵. The reported prevalence of constipation varies widely (6-67%) ⁴³. An association between faecal incontinence and posterior vaginal wall prolapse has not been found ⁴³. Faecal incontinence can be graded into four. Complete continence (grade 1), incontinence of flatus (grade 2), incontinence of flatus and liquid stool (grade 3) and incontinence of flatus, liquid and solid stool (grade 4) ⁴⁸.
- 4) Sexual symptoms include reduced frequency of sexual activity due to incontinence during intercourse, dryness, soreness, low libido, psychological barriers and/or dysfunction by the partner ⁴⁵. Two studies have compared sexual function between women with POP, urinary incontinence and controls. One study did not demonstrate any association between POP and sexual problems ⁴⁹. The other study found that the frequency of intercourse was less in women with UI/POP compared to controls. The main reason for reduced sexual satisfaction was fear of incontinence ⁵⁰.

Backache and pain in the lower abdomen seems to be non-specific to POP. The most specific symptom of POP is a bulge/lump at or outside the introitus ^{43;51}. Symptoms from all four domains are frequent in women with POP. Symptoms from the bladder, bowel and sex life can also exist without having POP and they are not shown to relate very well to the specific compartment or to the stage of POP ⁴⁵.

Anatomy and function of the pelvic floor

The pelvic floor consists of the PFM, the endopelvic fascia (ligaments and fascia) and the skeletal structure to which they attach. The pelvic organs (bladder, urethra, vagina, uterus and bowel) are supported in their positions by the PFM and connective tissue.

Pelvic floor muscles

The PFM comprise muscles in the pelvic diaphragm and in the urogenital triangle. All the muscles run more or less from the pubic symphysis or pubic bone towards the coccyx. The urogenital triangle is divided into the deep perineal space, where the deep transverse perinei forms an incomplete sheet, and the superficial perineal space, where the transverse perinei, bulbospongiosus and ischiocavernosus muscles run. The floor or "outlet" of the true pelvis is formed by the muscles of levator ani ⁵².

Levator ani can be subdivided into:

- The ischiococcygeus which can be referred to as a separate muscle. It arises from the pelvic surface and tip of the ischial spine and attach at the coccygeus and fifth sacral segment ⁵².
- The iliococcygeal muscle which has its origin at the arcus tendineus levator ani (thickened band of obturator internus fascia) (Fig 3) ⁵³.
- The pubovisceral muscle (pubococcygeus) which arises from the pubic bone. It is agreed that, apart from puborectalis, the pubovisceral muscle consists of the puboperineal, pubovaginal and puboanal muscles (Fig 3) ^{53;54}. The main functions of these muscles are to close the levator hiatus, elevate the vagina and anus and to pull the perineum ventrally towards the pubic symphysis ⁵⁴. In this thesis the puborectal muscle will be defined as a part of the pubovisceral muscle, based on the fact that the rectum is one of the viscera and that it is almost impossible to distinguish the puborectal muscle from the levator ani complex by ultrasound.

Each of the muscles contributing to the PFM has its specific fibre direction, origin and attachment, thereby a unique mechanical action. Because of its location inside the pelvis the levator ani muscle is the component which contributes most to the pelvic floor, giving structural support to the pelvic organs ⁵⁵.

The levator plate is the muscle tissue between the rectum and the coccygeal bone where the back sling of the puborectal muscle runs and the left and right iliococcygeus muscles meet (iliococcygeal raphe)^{54;56}. Levator hiatus is the opening (hiatus) surrounded by the pubovisceral muscle, through which the urethra, vagina and rectum pass. It is formed superiorly by the pubic symphysis and laterally by the medial edges of the muscles ⁵⁷.



Figure 3. Levator ani muscles, arcus tendineus levator ani (ALTA), puborectal muscle (PRM), puboperineal muscle (PPM), perineal body (PB), puboanal muscle (PAM), iliococcygeal muscle (ICM). Illustration: © John O DeLancey 2003. From: Kearney,R., Sawhney,R., and DeLancey,J.O., 2004. Levator ani muscle anatomy evaluated by origin-insertion pairs. Obstet.Gynecol., 104, 168-173. With permission from J.O. DeLancey.

PFM function

It is primarily the pubovisceral muscles that support the pelvic organs (pelvic viscera). In women with good pelvic floor support the levator plate has an almost horizontal course and both uterus and vagina are situated cranially to this muscle plate, not above the levator hiatus ⁵⁸. When normal muscle function is present, it is believed that the muscles support the pelvic organs and there is almost no tension in the suspending ligaments; even during increased abdominal pressure ^{43;59}.

A voluntary PFM contraction comprises both a lift ⁶⁰⁻⁶² and a squeeze around the urethra, vagina and rectum (narrowing of levator hiatus) ⁶³. In addition, DeLancey ^{62;64} suggested that a PFM contraction may press the urethra against the pubic symphysis, further mechanically increasing urethral pressure.

The PFM has two important automatic functions. The muscles have a constant activation, even at rest and during sleep, thereby narrowing the levator hiatus and "closing the pelvis" ^{58;65;66}. Additionally, the PFM is supposed to react automatically (increase its resting activity)

to any increases in the intra abdominal pressure or ground forces, such as coughing and jumping. When normal support is present the increase in intra abdominal pressure is counteracted ^{56;65}.

Ligaments/ fascia:

The pelvic floor is supported by a complex system of ligaments known as the endopelvic fascia (Fig 4). The superior fascia of the levator ani muscle is connected to the endopelvic fascia. This fascia supports and surrounds the vagina and part of the uterine cervix and divides the pelvic floor into the anterior and posterior compartments. The anterior margin of the insertion runs from the lower part of the pubic bone and is thickened. It is often named "arcus tendineus fasciae pelvis" or "fascial white line" (ATFP, Fig 4). The posterior portion blends with the arcus tendineus levator ani or "muscle with line" (ATLA, Fig 3 and 4) ⁶⁷. The pubocervical (endopelvic) fascia forms a hammock to support the bladder and bladder neck, by providing a firm backstop against which the urethra is compressed during increases in intra abdominal pressure ^{68;69}.



Figure 4. Attachments of the pelvic fascia to the pubic bone (A), anterior perineal membrane (B), superior fascia of the levator ani muscle (C), and perineal body (D). PS, pubic symphysis; ATLA, arcus tendineus levator ani; ATFP, arcus tendineus fasciae pelvis; ATFR, arcus tendineus fasciae rectovaginalis; OIM, obturator internus muscle; LA, levator ani muscle; IS, ischial spine; PM, piriformis muscle; U, urethral outlet; V, vaginal outlet; PB, perineal body; R, rectal outlet; CM, coccygeus muscle. Illustration: © Ivan Helekal.Otcenasek. Anatomy of Endopelvic Fascia in Women. Obstet Gynecol 2008. From: Otcenasek, M., Baca, V., Krofta, L., and Feyereisl, J. : Obstet Gynecol, Volume 111(3).March 2008.622-630. With permission from M. Otcenasek.

The suspension system can be divided into three levels ^{70;71}.

- Level I supports the cranial parts of vagina and consists of the sacrouterine and cardinal ligaments (Fig 5).
- Level II consists of the arcus tendineus fasciae pelvis and the levator ani muscles covered by the pubocervical fascia anterior and rectovaginal fascia posterior and it supports the middle of vagina (Fig 5).
- Level III is a continuum of level II and supports the caudal vagina (Fig 5).



Figure 5. In level I paracolpium suspends vagina from lateral walls. Fibers of level I extends both vertically and also posteriorly towards sacrum. In level II vagina is attached to arcus tendineus fasciae of pelvis and superior fascia of levator ani muscles. Illustration: © John O DeLancey. From: DeLancey,J.O: Anatomical aspect of vaginal evasion after hysterectomy. Am J Obstet Gynecol 1992; 166:1717-28. With permission from J.O. DeLancey.

Risk factors for POP

The aetiology of POP is considered to be multifactorial ⁴³. Based on the recently published integrated life span model ¹⁴, it can be assumed that the development of POP includes predisposing factors (growth and development; genetic constitution, nutritional factors and socialization), intervening factors (age related changes, increased stresses on the pelvic floor, weakening of the support tissue and lifestyle factors) and inciting factors. The inciting factors can be divided in three; 1. Predisposing maternal-fetal factors (pelvic floor shape and size, macrosomic infant and fetal head position), 2. Effects of obstetrical interventions (forceps, prolonged second stage and occipitoposterior presentation) and 3. Mechanism of injury (muscle avulsion, connective tissue rupture, nerve avulsion and nerve compression). Figure 6 shows factors from the integrated life span model integrated in a modified multivariate model, primarily developed for sports injury ⁷². Such models can help to guide effective prevention strategies and to predict women at risk of suffering an injury or disorder.

PFM function

Initial growth and development of the PFM is influenced by predisposing factors, such as genetics, nutrition and socialization (toilet training). During life the PFM can be negatively influenced by intervening factors and inciting events. The better developed and maintained PFM function is, the more intervening factors and inciting events the pelvic floor can withstand without resulting in pelvic floor disease ¹⁴. It has been shown that women with POP have a 40% reduction in PFM strength compared to women with normal support ⁷³ and that low PFM strength ⁷³⁻⁷⁵ and low vaginal resting pressure ⁷³ are associated with POP. In addition to vaginal resting pressure and PFM strength, PFM endurance may be considered an important component of PFM function. However, as far as we have ascertained, its association with POP has not yet been investigated.



Figure 6. Modified multivariate model, primary developed for sports injury 72 and the integrated life span model of DeLancey et al 14

Predisposing factors

Genetic factors (ethnicity, family history)

It is likely that genetic factors play a role in the aetiology of POP. To our knowledge, only one study has assessed gene expression ⁷⁶. In this case-control study five women with advanced POP were compared to five controls. 12626 genes were compared, and a difference was found in gene expressions for the proteins supporting the microstructure (actin and myosin) of the pubovisceral muscle. The authors suggest that this will result in an inadequate length or quality of myofilaments in the muscle. It is unclear whether the genes are related to the cause of POP or if they have been regulated in response to the prolapse ⁷⁶.

There are differences in prevalence of POP between ethnic groups. POP is more common in Hispanic women than Africans and Asian woman ^{38;77}. In a cross sectional study on 32342 women, Africans seem to have a lower risk of POP than Hispanic women ⁷⁷. Ultrasound measurements have supported this by demonstrating less pelvic organ mobility in Asian compared to hispanic women ⁷⁸.

An increased risk of POP has been found in women with a family history of POP and/or hernias ^{76;79-83}. The familiar incidence of POP was 30% in a case-control study of women undergoing POP surgery ⁸⁰. The odds ratio (OR) for a positive family history alone has been found to be 4,3 (95% confidence interval [CI] 1.9-9.7) ⁸¹ and the OR for having a combination with hernia was 1.4 (95% CI 1.2-1.8) ⁷⁹. In studies on twins a positive family history and ethnic differences accounted for half of the variance of elbow joint mobility and bladder neck descent, measured with ultrasound ^{84;85}.

Skeletal architecture

Increased diameters of the opening of the bony pelvis may facilitate birth, but may also play a role in increasing risk of pelvic floor disorders. In a case control study on 59 women with and 39 women without pelvic floor disorders there was a significant association between pelvic floor disorders and a wider transverse inlet (OR 3.4) and shorter obstetrical conjugate (OR 0.2), measured by MRI⁸⁶. However, a recent MRI study comparing bony dimensions in women with and without POP did not support these findings⁸⁷.

Connective tissue

The mechanical stability of the genitourinary tract is based on the quality of collagen fibres in ligaments and fascia, and there is some evidence suggesting that changes in the connective tissue in the pelvic structures are associated with POP and SUI ^{88;89}. A recent review of the

current literature supports the hypothesis that POP is explained by alternations in the connective tissue, but it cannot conclude that this is the true aetiology of POP ⁹⁰. It has been suggested that joint mobility ⁹¹, varicose veins ⁹², striae ^{92;93}, diastasis recti abdominis ⁸⁰, and bruising ⁹⁴ are markers of systemic alterations in connective tissue. The latter factors have not been the focus of previous POP research, but are interesting factors to be included in future studies.

Joint hypermobility

An association between increased joint mobility and POP ^{91;95-97}, rectal prolapse ⁹⁸, and urinary incontinence ⁹⁹ has been reported. In contrast to this, a study showed no significant relationship between joint hypermobility and POP in women with Ehler-Danlos syndrome ¹⁰⁰. To define joint hypermobility, different systems have been used. Carter- Wilkinsons criteria were used by Bai et al ⁹⁵. Others ⁹⁶ have used the recommended Beightons 9 criteria for joint mobility ¹⁰¹(chapter of methods).

Inciting events

Parity, obstetric factors

Parity, and especially vaginal childbirth, is established as one of the most important risk factors for developing POP ^{38;74;77;80;83;102;103}. Parity was 75% responsible for POP among women with one child and 88% among women with 2 children ¹⁰⁴. For each vaginal delivery the risk for POP increased, but it levelled off after the second vaginal delivery ¹⁰². High maternal age is reported to be a risk factor for POP in one study ¹⁰⁵, but it is not supported by other research groups ⁷⁵. Other proposed birth-related risk factors are bearing down before full cervical dilatation and a prolonged second stage of labour ^{106;107}. However, childbirth can not alone explain the development of POP as severe POP has been found among nulliparous women ^{77;102}. Pregnancy-related factors will be described under the chapter: "intra abdominal pressure".

Type of delivery

It has been documented both in review articles and in case control studies using multiple regression that forceps delivery increases the risk for POP ^{105;107}. However, this is not supported by other research groups ^{80;83}. Ultrasound and MRI studies support instrumental delivery as a risk factor for POP by demonstrating a higher proportion of levator trauma and increased mobility of the pelvic organs after instrumental deliveries, especially forceps

delivery ^{73;108-111}. As far as we know, no studies have investigated the association between vacuum deliveries and POP or PFM damage. However, an association between vacuum delivery and anal sphincter defects is known ¹¹². Prolonged active second stage of delivery is also associated with increased mobility of the pelvic organs measured by ultrasound ¹¹⁰. Use of episiotomy is another factor that is found to associate with POP ⁸³.

Birth weight

High birth weight (>4000/ 4500 gram) is shown to have a strong association with POP ^{74;80;113}. However, one study could not confirm this ¹⁰³. The risk for getting POP almost doubles if the birth weight exceeds 3690 grams (OR 2.0; 95% CI 1.1-3.6) ⁷⁵, and it is found to increase 24% for each 450 grams increase in birth weight ¹¹³.

Surgery

Hysterectomy, prolapse and incontinence surgery increases the risk of POP ^{9;11;114}. Recurrence of POP after vaginal surgery has been reported to be 25% to 58% ^{12;115}, and as many as 10-30% of the operated women needed repeat surgery ^{11;116}.

Intervening factors

Age

It has been postulated that increasing age is one of the most significant risk factors for POP $^{38;74;102;103;117}$. A cross – sectional study of 21 449 Italian women found an increase in risk of POP with increasing age. Compared to women aged 51 years or less the OR for uterine prolapse was 1.3 (95% CI 1.1 – 1.5) in the age group 52 to 55 years, and 1.7 (95% CI 1.5 – 2.0) for those aged 56 or greater 103 . Different types of prolapse seem to have dissimilar curves of prevalence. In an observational study on 971 women, both anterior and posterior wall prolapses were positively associated with POP up to 60 years and negatively associated with higher ages 118 . These findings are in line with those of Tegerstedt et al ⁹, that is an increased prevalence of POP up to 60 years, then a levelling off. Recent research has begun to question that POP is not always as chronic and progressive as one would expect $^{119;120}$.

Intra abdominal pressure

Exposure to increased intra abdominal pressure has been associated with POP. The increased pressure on the pelvic floor may be related to obesity, chronic cough and lung disease, constipation with straining at stool, pregnancy, heavy work or vigorous physical activity.

Several research groups have found that high body mass index (BMI) has a strong correlation with prolapse ${}^{38;40;77;102;103;105}$. Overweight (BMI >25/26) has been associated with a two- to threefold increase in the chance of having POP and pelvic floor disorders ${}^{83;105}$. However, this association was not confirmed in a case control study 113 , nor in population-based studies ${}^{74;75}$.

Smoking/ lung disease and an association between POP has not been proved using multiple regression analyses ^{75;77;103;113}. The relationship between POP and respiratory disease was supported in a study showing that 14% of the women with severe POP had a history of asthma compared to 2% of the control group ⁸⁰.

Constipation has been found to be a risk factor for developing anterior ⁷⁷, apical ¹²¹, and posterior vaginal wall prolapse ^{77;122}. In a case control study constipation gave an OR of 4.0 (95% CI 1.5-11.4) for developing POP after controlling for age and insoluble dietary fibre intake ¹²³. In line with this study, straining during defecation (61% vs 4%, p < 0.001) and having a bowel frequency of less than twice per week (48% vs 8%, p < 0.001) as a young adult has been shown to be more common in women with apical compartment prolapse compared with controls ¹²¹.

During pregnancy the pelvic floor can be affected by both the increased weight of the mother and the pregnant uterus. In a prospective case control study comparing 21 nulliparous, nonpregnant and 21 nulliparous pregnant woman the POP-Q stage increased during pregnancy and did not change significantly following delivery. All of the non-pregnant women had stage 0 and I, whereas 47.6% of the pregnant women had POP-Q stage II (p<0.001)¹²⁴. However, it has been debated if it is the pregnancy or the delivery that predisposes most to POP. Based on cohort and epidemiological studies it now seems that vaginal delivery is the most significant contributory factor¹⁰⁴.

Poor education and low household income can be associated with hard physical work. It has been documented that poor education is an independent risk factor for POP ^{75;103}, but this is not supported by others ¹⁰². In a cross sectional study, an annual household income of less than 10,000 Dollars was associated with severe prolapse (POP-Q stages III and IV) ¹²⁵. Additionally, POP surgery seems to be more common among assistant nurses than among the overall female population and it is suggested that this is due to heavy lifting ¹²⁶. A study of

nulliparous women at the United States Military Academy demonstrated that women attending six weeks of paratrooper training had an increased risk of developing POP¹²⁷. Based on the association between heavy work and POP¹²⁶, it can be hypothesised that vigorous physical activity may also be a risk factor¹⁴. However, while two studies reported no association between current exercise or self report of past strenuous exercise and POP^{75;77} details of relevant data such as type of activity, frequency, duration and intensity were not described. Despite the importance of regular exercise and the fact that no studies support the hypothesis that vigorous physical activity is a risk factor for POP, women undergoing conservative treatment typically are prescribed restrictions in activity and exercise¹⁸.

Aetiology / pathophysiology

Muscular weakness/ levator trauma

Women with POP have shown to have muscular impairment ^{73;128-130}, reduced PFM thickness ^{131;132} and increased size of the levator hiatus ^{57;133-135} compared to controls. The severity of POP seems to increase with increasing PFM dysfunction ^{23;136}.

As early as 1953 it was postulated that if the size of levator hiatus increased, the levator plate would decrease its inclination resulting in the pelvic organs to "slide" down through the hiatus ^{56;58;65}. The association between a decrease in levator plate angle, increase in hiatal area and presence of POP has recently been confirmed ^{129;136;137}.

Intra-abdominal pressure affects the pelvic cavity since it is a direct continuation of the abdominal cavity ¹³⁸. The assumptive reason for increased intra abdominal pressure causing POP is that it leads to increased strain on the PFM, connective tissue and the pudendal nerve and its branches ¹³⁹. During increased intra abdominal pressure the PFM are stretched and the hiatus widens. The stretching of the PFM has been visualised as ballooning of the levator hiatus, when the woman is performing a valsalva manoeuvre ¹³⁹. From general biomechanical studies it is known that a consequence of prolonged strain on muscle fibres can be muscular weakness, due to stress in the muscle filaments resulting in disruption of the Z-lines to which the actin filaments are attached ^{140;141}.

During vaginal childbirth the PFM, especially the puborectal muscle, are stretched proportionally to the head of the fetus, so that the fetus can pass through. Based on a three-

dimensional MRI computer model of a healthy nulliparous 34-year-old woman during her second stage of labour, the length of the puborectal muscle was found to be more than doubled. This results in a great risk of stretch-related injury ¹⁴². A recent 3D simulation model shows that if the fetus neck and head are extended, instead of flexed (occipito-posterior position) during the second stage of delivery, the strain on the muscle fibres increases even more ¹⁴³ (Fig 7). Levator ani defects are common after delivery (15% - 35%) ¹⁴⁴ especially when forceps are used ^{73;108}. Recently, Franco et al ¹³⁷, demonstrated that avulsion of the pubovisceral muscle is an independent risk factor for POP. More than half of the women with POP are found to have this type of injury, while only 16% with normal support and similar age and parity have levator ani muscle defects ⁷³. The risk of anterior and apical compartment prolapse is two to three times greater if a unilateral avulsion is present compared to an intact muscle, whereas a bilateral avulsion gives a 7-fold increased risk for anterior vaginal wall prolapse ^{128 145}. A computer based 3D model found that the anterior and posterior vaginal walls were destabilized as a result of an avulsion of the puborectal muscle, and a defective muscle may alter the support to the whole endopelvic fascia ¹⁴⁶



Figure 7. Fetus model during the second stage of delivery. The influence of the degree of flexion of the fetal head on the biomechanical behaviour of the pelvic floor muscles. From: Parente, M.P., Natal Jorge, R.M., Fernandes, A.A., and Mascarenhas, T. Int.Urogynecol.J 20 (s 2), s79-80 2009. With permission from RMN Jorge.
Connective tissue weakness

Collagen properties and gene factor most likely play a role in the aetiology of POP. A variety of alterations in the connective tissue is found among women with POP, such as altered; synthesis of structural proteins (collagen and elastin); activity of enzymes ¹⁴⁵, collagen content, type I/III ratio, cross linking ⁸⁸, collagen metabolism ⁸⁸ and increased collagen turnover ⁸⁸. Connective tissue support is affected by ageing, estrogen deficiency and vitamin C deficiency ^{147;148;148}. Altered collagen processing and remodelling may weaken the pelvic floor ¹⁴⁷.

Table 1 demonstrates that different types of POP can occur due to defects in different parts of the three levelled vaginal suspension system (Fig 5) ^{43;70;106}. However, it has been claimed that the clear link between defects in the fascia and the specific type of prolapse may be true only for rectocele; not for any of the other types of POP ^{122;149}.

Cystocele	Central cystocele can be a result of a central hernia in the pubocervical
	facia. Detachment of the pubocervical fascia from the arcus tendineus is
	described as a lateral defect (lateral cystocele) (level II support failure).
Rectocele	Rectocele is herniation through the rectovaginal fascia in the middle and
	upper part (level II support failure). A defect in the posterior level III
	suspension system gives a distal rectocele.
Enterocele	Enterocele is a defect/ separation in the pubocervical fascia and rectovaginal
	fascia (level II support failure).
Uterine and	Uterine and vault prolapse are the result of a defect in the sacrouterine and
vault prolapse	cardinal ligaments (level I support failure).

Table 1. Types of pelvic organ prolapse and the association to defects in the suspension system based on the review from Marinkovic and Stanton¹⁰⁶.

Peripheral nerve injury

In 42% to 80% of vaginal deliveries denervation injuries of the PFM and anal sphincter occur ^{150;151}. Usually the neuropathy is temporary with a recovery shortly after delivery. Histological and histochemical analysis of biopsy samples of pubovisceral muscle have shown a significant increase in the number of muscle fibres with pathological damage corresponding to partial denervation in women with urinary incontinence and POP ¹⁵². This has been confirmed by EMG studies ¹⁵¹. There are some controversies regarding this hypothesis. If it is

a sustained unilateral denervation, the PFM should be thinner, less contractile and subsequently atrophic on the affected side. This however seems to be relatively rare ¹⁴⁹.

Age related changes

It has been hypothesised that age can cause POP, because of tissue atrophy and weakness related to age, disease or medications. The total number and diameter of type I and II muscle fibres in the PFM and urethral sphincter decreases with age ^{153;154}. A cadaver study demonstrated 1.5 to 4.6% muscle loss every year as women aged, measured at the bladder neck and along the dorsal wall of the urethra ¹⁵⁵. In general, aging increases the diameter of collagen fibres, strengthens the intermolecular bonds and increases the number of intermolecular cross-links. This results in altered mechanical properties with increased resistance to deformation ¹⁵⁶.

Conservative treatment

PFMT as treatment

Current treatment for POP is surgery, use of a pessary or PFMT. Generally, conservative treatment (PFMT) is considered for women with a mild degree of prolapse, women planning pregnancy or those unwilling to undergo surgery ³. Despite the lack of clinical or referral guidelines 92% of the physiotherapists working with female health problems in the United Kingdom reported that they assessed and/or treated women with POP (71% response rate) ¹¹⁵. At the time when the present study was planned and initiated, a review article evaluated the effect of PFMT on women with POP, and concluded that no studies were found on prevention of POP, while one uncontrolled study and one low-quality RCT were found on the treatment of prolapse ¹⁷. A newer Cochrane review concluded that available evidence is insufficient to understand the role PFMT may play in reducing and preventing POP¹⁵. To our knowledge only one previous RCT evaluated the effect of PFMT using the POP-Q grading system, but this was a pilot study and complete POP-Q data were missing from 27 of the 47 participants ¹⁸. One larger RCT from Thailand also demonstrated improvement on severity of POP ¹⁶. However, the trial scored low on methodological quality ^{15;17}. The size of the prolapse was subjectively evaluated and only women with anterior vaginal wall prolapse were included. The effect of PFMT on symptom relief has been evaluated by Hagen et al ¹⁸ and in a relatively small French RCT¹⁹. Both studies demonstrated improvement in mechanical symptoms after PFMT. High quality RCTs is warranted ^{15;17}.

Morphological and functional adaptations as a response to PFMT

Even though it is well established from several RCTs and systematic reviews that PFMT is effective in treatment of SUI in women ^{157;158}, the morphological and biomechanical changes that may occur as a response to this strength training have been sparsely investigated ¹⁵⁹. As early as 1952, Kegel ⁶⁰ suggested that with adequate PFMT "the woman learns to maintain the perineum, bladder and uterus in a higher position, the slack in the supportive muscles will be taken up, and the vagina will become longer and tighter". Today there are two main hypotheses of mechanisms of how PFMT may be effective in the treatment and prevention of POP ^{159;160}. 1) Women may learn to consciously contract the PFM before and during increases in abdominal pressure and thereby create a behaviour modification. 2) PFMT changes muscle morphological changes include: increased muscle volume, closing of the levator hiatus, imposed viscoelastic properties ("stiffness") of the connective tissue and altered location of the PFM at a higher level in the pelvic area ¹⁵⁹.

It is not known if the size of levator hiatus, length of the PFM or position of the posterior compartment of the pelvic floor changes following PFMT intervention ¹⁵⁹. The surface of the levator ani muscle was shown to be reduced following PFMT in an uncontrolled MRI study on five women ¹⁶¹. Another uncontrolled study demonstrated increased PFM thickness ¹⁶² and one study found elevated position of the bladder following PFMT ¹⁶³. These studies indicate that morphological changes may occur. However, this needs to be confirmed in a high quality RCT.

PFMT as prevention

Prevention can be divided into three levels. Primary prevention aims to modify risk factors prior to the onset of the condition, whereas secondary prevention strategies are treatment and identification of women in a preclinical phase (asymptomatic POP). Tertiary prevention aims to treat symptomatic women in an attempt to postpone complications ^{104;164}.

Mørkved et al ¹⁶⁵ has demonstrated that PFMT is effective in primary prevention of SUI in nulliparous pregnant women during pregnancy and after delivery. Primary prevention strategies for POP have mainly focused on cesarean delivery. Cesarean has been demonstrated to be protective against development of POP ^{83;110;124;166}. However, this is not

supported by others ^{75;103}. The lifetime risk for undergoing POP or urinary incontinence surgery is 11,1% ¹¹. If cesarean delivery was preformed at all births, as primary protection, about 9 out of 10 women would gain no benefit, and in addition increase their risk of experiencing surgery-related complications ¹⁰⁴. Other primary prevention strategies such as weight loss, reduction of heavy lifting, treatment of constipation, and modification or reduction of obstetric risk factors has not yet been investigated ¹¹⁷.

It has been suggested that a 25% prevention of pelvic floor disorders would save 90 000 American women from experiencing pelvic floor dysfunction.²³. Understanding and identification of modifiable risk factors and development of prevention strategies are highlighted priorities for future research ^{23;167}.

Summary

The overall high prevalence of POP and related problems indicates a need for identification of risk factors in addition to prevention and treatment strategies ²³. Research aiming to treat POP conservatively and to understand modifiable risk factors for prevention of POP has been warranted. Only a minority of the risk factors for POP can easily be prevented. Many of the proposed risk factors have been investigated in postal surveys, interviews and medical registers only, and physical activity, clinically measured joint mobility and PFM function have not been investigated in the same study. To evaluate the effect of PFMT in the prevention and treatment of POP, there is an urgent need for a high methodological RCT with appropriate training protocols using valid and reproducible methods to assess degree of prolapse ^{15;17}. To date there is scant knowledge of possible changes in morphology and function of the PFM following PFMT ²⁰. Proposed changes in the pelvic floor include increased muscle thickness, elevated positions of the pelvic organs, narrowing of the levator hiatus and increased stiffness in the pelvic floor ²⁰.

Aims of the thesis

The overall aim of this thesis was to establish intra tester reliability of the ultrasound measurements, identify risk factors for POP, evaluate the effect of PFMT in prevention and treatment of women with POP, and to assess morphological changes after PFMT.

The specific aims were:

- I. To evaluate test- retest and intra-observer repeatability of 2D, 3D and 4D perineal ultrasound imaging of pelvic floor muscle morphology and function, including: dimensions of the levator hiatus, thickness of the pubovisceral muscle, resting position of the bladder (bladder neck), constriction of levator hiatus during PFM contraction and pelvic organ descent during increases in intra abdominal pressure.
- II. To evaluate test-retest measurements of functional aspects of PFM contraction using 4D real time ultrasound by:
 - Measuring puborectal muscle length, levator hiatus area, antero-posterior and transverse dimensions at rest and maximal contraction in the axial plane
 - Measuring lift (displacement) of the bladder (bladder neck), cervix uteri, bowel (rectal ampulla) and back sling of the puborectal muscle in the sagittal plane
- III. To investigate proposed risk factors for POP, including physical activity, clinically measured joint mobility and PFM function.
- IV. To evaluate whether PFMT can 1) reverse and prevent further development of POP and 2) reduce symptoms related to POP.
- V. To evaluate morphological and functional changes in the pelvic floor after PFMT.

Methods

Three different designs (test-retest, case control and a RCT called the "POP study") are included in the thesis and have resulted in the five papers presented here. Seventeen participants were included in the test-retest study, published in papers I and II. In the case-control study 49 women from the POP study with POP stages II and III were age and parity matched with 49 women with normal support (POP stage 0 and I) to investigate risk factors for POP. In the POP study 109 women with POP (stage I, II and III) were included. This study resulted in papers IV and V.

Design, procedure, randomization and blinding

The test- retest intra-observer study included two test series performed with an interval of 7 to 35 days. The participants received a random identification number. The assessor was blinded to the results of test one during test two. 2D, 3D, and 4D ultrasound volumes and cine loops were de-identified and analyses were conducted offline on a laptop by one investigator (IHB), blinded to clinical and background data.

The case-control study was an individual, one-to-one matched study, as recommended by Bland and Altman¹⁶⁸. The assessments in the case-control study were the same as the baseline assessment in the POP study. The POP study was an assessor blinded and explanatory RCT with stratification on severity of POP (POP-Q values ≤ 0 , or >0). All participants first completed questionnaires (Appendix 3), followed by a semi-structured interview and clinical examination performed by one PT (IHB) at a physiotherapy clinic. At the time of the examination, the PT did not know into which group in the case-control study the woman would be classified. All POP-Q and ultrasound examinations were performed by the same gynaecologist (MM). Depending on the POP-Q value, the women were included in the POP study (stage I, II and III) and/or the case group (stage II and III) or control group (stage 0 and I) of the case-control study. Two women were immediately matched in the case control study if their POP-Q values, age (5 years interval) and parity harmonized. If the participant had POP stage I, II or III and was willing to participate in the POP study, she was stratified by severity of prolapse, and randomised (computer generated random number system with opaque sealed envelopes generated by a statistician) to either PFMT or control. Information for decoding randomisation was kept by the statistician. At six months post-test

all participants of both groups in the POP study were retested with the same outcome measures.

The PT (IHB) who performed the clinical evaluation of PFM function, measured with pressure transducer, was blinded to group allocation at baseline measurements, but not at post-test. However PFM function was not an outcome measure. The gynaecologist performing POP-Q and ultrasound assessment (MM) was blinded to clinical data and group allocation at both baseline and post-test. The ultrasound images were de-identified and all analyses were performed by one investigator (IHB) blinded to group allocation.

Ultrasound procedure

A GE Voluson 730 expert and E8 ultrasound systems (GE Healthcare, Oslo, Norway) with 4-8 MHz curved array 3D/4D ultrasound transducer (RAB 4-8 l/obstetric) were used. The probe was covered with a condom and placed on the perineum in the sagittal plane. The field of view angle was set to its maximum (70 ° X 85 °). Three 3D static ultrasound volumes were recorded in the lithotomy position while participants were resting. Subsequently the participants were asked to stand upright with their legs slightly abducted and to perform three PFM contractions, coughs and "huffs" (maximal expiration) before they performed three valsalva manoeuvres in lithotomy position. During the "huff" the peak expiration flow values were obtained with a peak flow meter (GlaxoSmithKline AS, Oslo, Norway).

Ethics

All the studies were approved by the Regional Medical Ethics Committee (S-05146) (Appendix 1) and the Norwegian Social Science Data Services (200501371 SMRH) (Appendix 2) and the RCT study was registered at www.ClinicalTrials.gov (NCT00271297). All subjects gave written informed consent to participate. The trial followed the ethical standards for human experimentation established by the Declaration of Helsinki of 1975, revised in 1982 ¹⁶⁹.

Subjects

A convenient sample of female volunteers was recruited for the test- retest study. Women attending routine gynaecological examinations were referred to the case control and POP

study from May 2006 to September 2008 by community gynaecologists working in Oslo and Akershus, Norway, and through advertisements in newspapers.

All three studies had the same inclusion criteria, which were; ability to understand instructions given in the Norwegian language and ability to contract the PFM. Additionally, participants had to be at least one year beyond their last delivery to participate in the case-control and POP study.

In the case-control the exclusion criterion were; stage 4 on POP-Q, inability to contract the PFM, breast feeding, previous POP surgery, radiating back pain, pelvic cancer, neurological disorders, psychiatric disorders and untreated urinary tract infection. Additionally, POP stage 0, planning pregnancy and to be absence for more than 4 weeks of the intervention period were exclusion criterion in the POP study.

Sample size

Test-retest study: We were not able to find any studies measuring constriction of the levator hiatus with ultrasound during voluntary PFM contraction. In line with other published reliability studies in this area we chose to include 17 participants. An a-posteriori power calculation using observed standard deviations (SD) from paper I demonstrated "a least detectable change" of 1.49 cm² for the levator area constriction and 0.92 cm² for muscle shortening (80 % power and 5 % significance level).

Case-control study: As no comparable studies evaluating PFM function in relation to POP were found, power calculation for the risk factor study was based on prevalence of joint hypermobility from the study of Al-Rawi and Al-Rawi ⁹⁶. They found a 66% prevalence of joint hypermobility among women with POP compared to 15% in the control group. We assumed a 50% prevalence of hypermobility among women with POP and 25% among controls. With 80% power and 5% significance level, at least 47 women should be included in each group. Due to possible missing data we increased this to 49.

POP study: As preliminary data on effect size of PFMT to treat POP was not found at the start of the POP study, an effect size of 0.6 was used to calculate the sample size. With a two-sided

alpha of 0.05 and a power of 80%, a sample size of 45 per group was required 168 . Due to possible drop-outs we chose to include at least 50 women in each group.

Primary outcome measures

The results of papers I and II (test-retest study) created the basis for the choice of reliable ultrasound measurements in the POP study (papers IV and V).

Stage of POP (paper IV)

The internationally recommended classification system POP-Q was used to test severity of POP¹. Women were classified as having anterior, apical and/or posterior compartment prolapse with a 5 stage severity scale for each compartment (stage 0 to IV) during maximal valsalva.

Ultrasound measurements (papers I, II, IV, V)

Analyses of 2D, 3D, and 4D ultrasound volumes and cine loops were conducted offline on a laptop by one investigator (IHB), using the software "4D View v 5.0 and 6.2" (GE Healthcare, Oslo, Norway). Each manoeuvre was recorded three times and the PFM contraction with the most cranial displacement or most narrowing of the hiatal area was analysed. Likewise, the cough and "huff" with most caudal displacement, and valsalva with most widening of the hiatal area were used. All analyses in the axial plane were conducted in the plane of minimal hiatal dimensions, identified as the minimal distance between the posterior aspect of the pubic symphysis and the back sling of the pubovisceral muscle ²².

Thickness of the pubovisceral muscle (papers I and V) was measured in the axial plane, lateral to the vagina and rectum on the right and left side perpendicular to the presumed fibre direction (Fig 8). The mean of the four measurements was used. In the test-retest study additional measurements of the muscle thickness were preformed in the plane of maximum thickness as described by Dietz et al ²². Test-test reliability of muscle thickness have shown moderate reliability (intraclass correlation coefficient [ICC] 0.52 and 0.54) ²².

Position of bladder and bowel (papers I, II, IV and V) was quantified by locating the urethrovesical junction (bladder neck) and rectal ampulla, respectively. The height of the organs were defined as the vertical distance perpendicular from the central axis of the pubic symphysis (y-axis)(paper IV), and the position of the organs was described as a vertical

(height; y-axis) and horizontal distance (x-axis) (paper V) on a rectangular coordinate system in the mid-sagittal plane, as described by Schaer et al 170 . The elevation of the pelvic organs (paper V) was calculated like the displacement of the bladder neck, as described by Peschers et al 171 .

Levator hiatus dimensions were measured in the axial plane and defined as the area bordered by the pubovisceral muscle, pubic symphysis and inferior pubic ramus in the axial plane (Fig 8). The measurement (area, anterior-posterior and transverse distance) has shown good to very good test-retest reliability ²².

Puborectal muscle length (papers II and V) was measured as the inner border of the pubovisceral muscle sling which most likely is the puborectal muscle. The length was calculated as the circumference of the levator hiatus minus the length of the right and left inferior pubic ramus (bony arch) (Fig 8). This measurement has recently been tested for validity ¹⁷².



Figure 8. Measurements in the axial plane of minimal hiatal dimensions. Levator hiatus area (LH area) is marked with lines. The puborectal muscle length is drawn as a dotted line. LH ap= Levator Hiatus antero- posterior diameter; LH rl= Levator Hiatus right-left diameter; t=muscle thickness; PS= pubic symphysis. BJOG: An International Journal of Obstetrics and Gynaecology, 116, 1706-1714, 2009.

The cough and "huff" were analysed as displacement of bladder neck in the mid-sagittal plane according to Peschers et al¹⁷¹ which expanded the method developed by Schaer et al.¹⁷⁰.

Mechanical, bladder and bowel symptoms (Papers III, IV):

Participants completed a validated questionnaire (Appendix 3) to describe frequency (daily, weekly, monthly and never/less than once per month) and bother (4-point scale) of mechanical, bladder, bowel and sexual symptoms ⁴⁵. Women were considered symptomatic if they had symptoms monthly or more often. The questionnaire has been validated in Denmark ⁴⁵. The International Consultation on Incontinence Urinary Incontinence Short Form questionnaire (ICIQ-UI SF) ¹⁷³ was used to assess urinary incontinence and its impact on quality of life (appendix 3). ICIQ-UI SF has been shown to have good construct validity, acceptable convergent validity and good reliability ¹⁷³.

PFM function (paper III, independent variable in papers IV and V)

Ability to perform a PFM contraction was assessed by visual observation and vaginal palpation ¹⁷⁴. PFM function was evaluated by a vaginal balloon catheter (balloon size 6.7 x 1.7 cm) connected to a high precision pressure transducer (Camtech AS, Sandvika, Norway) ³⁹. The pressure transducer had conventional, current electronic sensor technology. The middle of the balloon was placed 3.5 cm proximal to the vaginal introitus ¹⁷⁵ in the vaginal high pressure zone ¹⁷⁶. Muscle strength was calculated as the mean of three maximal voluntary contractions (MVC, Fig 9). The method has been found to be reliable and valid if used with simultaneous observation of inward movement of the catheter/perineum during PFM contraction ^{175;177}. Vaginal resting pressure zone at rest, without any voluntary PFM activity. PFM endurance was defined as a sustained maximal contraction ¹⁷⁸ and was quantified during the first 10 seconds as the area under the curve (cmH₂Osec) (Fig 9).



Figure 9. Vaginal squeeze pressure measurements for one woman showing vaginal resting pressure, pelvic floor muscle strength measured as maximal voluntary contractions (MVC) and pelvic floor muscle (PFM) endurance. BJOG: An International Journal of Obstetrics and Gynaecology, 116, 1706-1714, 2009.

Joint mobility tests (paper III)

The Beighton's scoring system was used to assess joint mobility, and hypermobility was defined as four or more positive tests out of nine ¹⁰¹. The nine tests are recommended by the British Society of Rheumatology and have been tested for reliability (Fig 10) ⁹².



Figure 10. Beighton's scoring system to assess joint mobility. The tests include passive extension of each 5^{th} finger past $90^{\circ}(a)$, passive apposition of each thumb to the forearm (b), hyperextension of each elbow past $190^{\circ}(c)$, hyperextension of each knee past 10° (d) and trunk flexion to allow palms flat on the floor (e). Illustration: © Annette Holth Skogan. From: TRS National Resource Centre for Rare Disorders, Sunnaas Rehabilitation Hospital 2005. "Veileder for oppfølging ved EDS – Ehlers-Danlos syndrom". Used with permission from K Vardeberg.

Markers of connective tissue weakness (paper III):

Markers of weak connective tissue other than joint hypermobility were also assessed. Varicose veins and tendency to bruise easily were assessed by questionnaire (appendix 3). Presence of striae was observed during clinical examination and diastasis recti abdominis was diagnosed by palpation (finger width measurements)¹⁷⁹.

Physical activity (paper III):

Present and past physical activity was assessed by the semi-structured interview, and included type of activity, frequency, duration and intensity ¹⁸⁰. Exercise volume was estimated by multiplying exercise duration with frequency (hours/week). Current exercise was classified as being of either high or low intensity. High intensity exercise was defined as physical activity resulting in sweating or being out of breath.

BMI (paper III):

BMI was calculated by measured weight (Tanita BWB 800, Fysiopartner, Norway) and self reported height. Women with BMI \ge 25 were classified as obese, according to WHO ¹⁸¹

Socioeconomic status (paper III):

Socioeconomic status was assessed by questionnaire (Appendix 3) and consisted of both of two factors; income and educational level ¹⁸². High socioeconomic status was defined as having an income of 350 000 NOK or more and an educational level at university level or higher.

Heavy occupational work (paper III):

To be classified as having heavy occupational work, three variables in the questionnaire (Appendix 3) had to be present; 1) self report of occupational work as physically heavy, 2) lifting more than 20 heavy lifts per week, 3) working in a standing position more than 50% of the time ¹⁸³. If one or two factors were present, work was classified as moderate.

Family history (paper III):

Family history of pelvic floor disorders was assessed by the questionnaire (Appendix 3), asking: "Have your mother or grandmothers experienced pelvic floor disorders?" (yes, do not know, no).

Obstetric factors (paper III):

A semi-structured interview addressed recall of obstetric factors. Birth weight, number and types of births (vaginal, cesarean, forceps, vacuum) were registered. Recall of anal sphincter lacerations was assessed by Mouritsen and Larsen's ⁴⁵ questionnaire (Appendix 3).

Postmenopausal status (paper III):

Women were defined as postmenopausal if it was more than 12 months since their last period.

Smoking (paper III):

Current smoking was assessed by questionnaire (Appendix 3), asking about current smoking and, if they reported being smokers, how many cigarettes they smoked per day. The question was a part of the Mouritsen and Larsen's ⁴⁵ validated questionnaire.

Intervention

In the POP study both the PFMT and control group received written information about POP and were advised to contract their PFM prior and during increases in abdominal pressure (coughing, sneezing, heavy lifting) ¹⁸⁴. In addition, they were advised to avoid straining /bearing down (e.g. during defecation). Women in the PFMT group were advised to do 3 sets of 8-12 close to maximum PFM contractions per day and to hold each contraction for 6 to 8 seconds, with three or four contractions added on the top. The protocol has been effectively used in several RCT of PFMT for SUI ^{165;185;186}. The PFMT was performed in standing, lying, sitting or kneeling with legs abducted (Fig 11).



Figure 11. Pelvic floor muscle training was performed in standing, lying, sitting or kneeling with legs abducted.

Participants were encouraged to use their preferred positions. All women received a booklet (Appendix 4) and a DVD (<u>www.nih.no</u>) showing the exercise program. Adherence was noted

in an exercise diary. Once a week in the first three months and then every 14th day the PFMT was individually supervised by a PT and PFM strength, endurance and resting pressure were monitored and registered. After the project period women in the control group were referred to a physiotherapist if they so wished.

Statistical analyses

Statistical analyses were carried out in SPSS version 15. The results are given as frequencies and percentages for categorical data and means with SD or 95% CI for continuous data. Continuous data were checked for normality by Kolmogorov-Smirnov and Shapiro-Wilk test. P values <0.05 were considered significant.

Test-retest study

All parameters were analysed three times, with the mean being used for test-retest analyses. Test-retest intra-tester reliability was analysed using intra-class correlation coefficient (ICC, repeated measures) with 95% CI, and by coefficient of variation. ICC values under 0.20 were considered poor, 0.21- 0.40 fair, 0.41-0.60 moderate, 0.61-0.80 good, and 0.81-1.00 very good ¹⁶⁸. Results in paper II are given as mean values with 95% CI for test 1 values. Wilcoxon nonparametric test was used to test the hypothesis that the two variables have the same distribution, analysed from test 1.

Case-control study

The categorisation of joint mobility and BMI was made a-priori. The strength of the PFM was termed weak, medium or strong, the PFM endurance was termed poor, medium or good and the vaginal resting pressure low, medium or high, based on division of the values into tertiles. Results are given as frequencies for categorical data and means with SD for continuous data. Differences between cases and controls were analysed with Wilcoxon rank paired test for continuous variables. McNemar's test was used for paired categorical data. A special Cox regression model was used to fit a conditional logistic regression procedure for one-to-one matched case-control studies. The results are given as OR with 95% CI ¹⁸⁷. If the univariate association between POP and a risk factor was significant, it was included in a conditional multiple logistic regression model adjusting for BMI and socioeconomic status. All OR presented were adjusted for BMI and socioeconomic status unless stated otherwise, because these two factors are well known risk factors for POP ^{38;40;75;77;102;103;125}. We did not adjust for

possible markers of connective tissue weakness or symptoms/ pain since they may not be considered to play a primary role as risk factors. In addition, due to the design of the study, all analyses are adjusted for age and parity.

POP study (RCT)

Within and between groups comparisons were tested with student t-test (normally distributed) and Mann-Whitney U test (not normally distributed). Differences between groups in baseline categorical data were analysed by Chi-square. To determine treatment effect, net proportions of improvement (difference between the groups) with 95% CI and OR with 95% CI was calculated for categorical data, whereas effect size were calculated for continuous data using the formula: "(mean of PFMT group – mean of control group)/ SD". Improvement in symptoms based on Mouritsen and Larsen's ⁴⁵ questionnaire was defined as answering that they perceived the symptom less frequent (daily, weekly, monthly or less than once per month), and that they were less bothered by the eventual problem (severe, moderate, small or not a problem). The relationship between increase in PFM strength and morphological changes was investigated using Pearson product-moment correlation (normally distributed) or Spearman's rho (not normally distributed). Interim analyses were not done, and due to low drop-out we did not perform per protocol analyses. Intentions to treat analyses were used and baseline values were carried forward for the two women who dropped out (one in each group).

Main results

Paper I

The test- retest intra-observer repeatability study involved 17 participants, the median age was 49 years (range 29-71) and median parity 2 (range 0-4). The intervals between the two tests varied between 7 to 35 days (mean 15.9 days). Measurements of levator hiatal dimensions demonstrated good and very good reliability (ICC= 0.61, 0.72, 0.86 and 0.92). Muscle thickness was assessed on six sites and was less reliable, especially on the right side. However, in the plane of minimal hiatal dimension the measurements demonstrated moderate to good reliability (ICC=0.56 and 0.61). ICC values for measurement of the position of the bladder were 0.86 and 0.82 at rest in the vertical and horizontal direction, and were classified as very good. Displacement of the bladder during PFM contraction, "huff" and cough demonstrated ICC values of 0.56, 0.59 and 0.51, respectively. The coefficient of variation was under 16.5% for all tested parameters.

Conclusion: Perineal ultrasound was a reliable method for measuring most of the tested parameters of morphology and function of the PFM. Hence, it may be used in clinical trials evaluating changes in anatomical parameters after PFMT. We recommend that muscle thickness is measured in the plane of minimal hiatal dimensions.

Paper II

The results in this paper are based on the same test- retest intra-observer repeatability study as presented in paper I. Very good and good reliability were found for measurement of; levator hiatus area, hiatal anteroposterior dimension, hiatal transverse dimension, puborectal muscle length and narrowing of levator hiatus. Shortening of hiatal transverse distance and muscle length during contraction showed poor and fair reliability, respectively. In the mid sagittal plane the displacement of bladder, bowel and back sling of the puborectal muscle measured with on-screen vector assessment demonstrated good reliability. During contraction the area of levator hiatus was reduced 25% from a resting area of 19.7 cm² (95% CI 16.8–22.7) to 14.7 cm² (95% CI 12.8–16.6). The muscle length shortened 21%, from 12.5 cm (95% CI 11.1–13.8) to 9.7 cm (95% CI 8.7–10.7). The mid urethra moved 1.1 mm (95% CI 0.1–2.2) towards the public bone during contraction. The back sling of the puborectal muscle and the bowel had a greater displacement than the bladder (P < 0.004). The displacement of the pelvic organs was two times, or more, greater in the cranial versus anterior direction.

Conclusion: 4D ultrasound can reliably assess muscle length, narrowing of hiatal area, reduction of antero-posterior hiatal dimension in the axial plane and lift of bladder, bowel and back sling of the puborectal muscle in the sagittal plane. Hence, both squeeze and lift can be quantified during PFM contraction. We recommend that PFM contraction is recorded with two image views; one scan including the whole levator hiatus, and one including the pubic symphysis to measure the lift of the bladder.

Paper III

The age and parity matched one-to one case control study comprised data from 98 participants, with mean age 47.1 years (SD \pm 10.6), BMI 24.9 kg/m² (\pm 3.8) and median parity of 2 (range 1-5). There was no significant difference in age and parity between groups, which indicates a successful matching. Univariate analyses showed that women with POP had lower PFM strength (26.6 \pm 19.5 vs. 42.7 \pm 22.6 cmH₂O, p<0.01), PFM endurance (178 \pm 151 vs. 333 ± 146 cmH₂Osec, p<0.01) and vaginal resting pressure (26.7 ± 7.1 vs. 30.9 ± 8.5 , p<0.05) than controls. No significant differences were found between groups in postmenopausal status, current smoking, current low intensity exercise, type of birth (vaginal, cesarean, forceps, vacuum), birth weight, and presence of striae, diastasis recti abdominis and joint hypermobility. An association with family history of pelvic floor disorders, present high intensity exercise participation and being a former exerciser was lost after adjustments for BMI and socioeconomic status. Multivariate analyses demonstrated that BMI (OR 5.0; 95% CI 1.1-23.0), socioeconomic status (OR 10.5; 95% CI 2.2-50.1), heavy occupational work (OR 9.6; 95% CI 1.3-70.3), anal sphincter lacerations (OR 4.5; 95% CI 1.0-20.0), PFM strength (OR 7.5; 95% CI 1.5- 36.4) and PFM endurance (OR 11.5; 95% CI 2.0- 66.9) were independently related to POP.

Conclusion: BMI, socioeconomic status, heavy occupational work, anal sphincter lacerations and PFM function were independently associated with POP, whereas joint mobility and high intensity activity were not. The present study does not support vigorous physical activity as a risk factor for POP. PFM function is a modifiable risk factor for POP and future studies should include this factor.

Paper IV

The effectiveness of PFMT in reversing POP and alleviating symptoms related to POP was investigated in this assessor blinded RCT. The mean age of the 109 participants was 48.9 (SD \pm 11.8), median parity 2 (range 1-5) and mean BMI 25.9 kg/m² (\pm 4.5). Fifty women were randomly allocated to the control group and 59 to the PFMT group (Fig 12). Nineteen out of the 109 participants were classified as POP stage I, 65 as stage II and 24 as stage III. Seven (6%) women had POP in one vaginal compartment, 30 (28%) women had POP in two compartments and 71 (65%) women had POP in all three compartments, when POP was defined as POP-Q stage I or more. Sixty-nine (63%) participants had mechanical symptoms, 87 (80%) had bladder symptoms and 65 (60%) had bowel symptoms. There were no statistical differences between groups regarding age, parity, stage of POP and outcome measures at baseline, except that 43 of 59 women in the PFMT group compared to 26 of 50 women in the control group had mechanical symptoms (p=0.025). For women in the PFMT group the mean number of days performing PFMT was $161.2 (\pm 26.8)$ out of 180 possible and mean number of visits to the PT was $15.5 (\pm 3.2)$ out of 18 possible. Forty-seven (79%) women in the PFMT group reached an adherence level of 80% (≥14 PT visits and ≥144 days with home exercise). No adverse effects were reported. Two women dropped out of the study (Fig 12).

Eleven (19%) women in the PFMT group improved one POP-Q stage versus four (8%) controls (p=0.04). At six months, women in the PFMT group had a significant greater vertical elevation of the bladder (Difference: 3.0mm; 95% CI 1.5 - 4.4; p<0.001, effect size 0.79) and bowel (5.5mm; 95% CI 1.4 - 7.3; p= 0.022, effect size 0.63) than women in the control group. Compared to controls women performing PFMT reduced frequency and bother of mechanical, bladder and most of the bowel symptoms (p \leq 0.04). The PFMT group had significantly greater improvement than the control group in PFM strength (13.1 cmH₂O; 95% CI: 10.6-15.5 versus 1.1 cmH₂O; 95% CI: 0.4 - 2.7, difference: 12.0; 95% CI 8.9 – 14.9, p<0.01) and PFM endurance (107 cmH₂Osec; 95%CI: 77-136 versus 8 cmH₂Osec; 95%CI: -7-24, difference: 99; 95% CI 64-133, p<0.01). The effect size for muscle strength and endurance was 1.21 and 0.96, respectively.

Conclusion: PFMT can improve the stage of POP, elevate the bladder and bowel and reduce mechanical, bladder and bowel symptoms in women with POP.



Figure 12 Flowchart of participants through each stage of the randomized controlled trial

Paper V

The same assessor blinded RCT study as paper IV was used to evaluate morphological and functional changes following PFMT. Compared to women in the control group (n=50), women in the PFMT group (n=59) increased thickness of the pubovisceral muscle (Difference: 1.9mm; 95% CI 1.1–2.7, p<0.001), elevated (anterior-cranial direction) the position of the bladder (4.2mm; 95% CI 2.0-6.4, p<0.001) and bowel (6.8mm; 95% CI 2.1-

11.4, p=0.007), decreased hiatus area (1.73cm²; 95% CI 0.44–3.02, p=0.025) and shortened puborectal muscle length (6.0mm; 95% CI 1.5–10.5, p=0.007). Additionally, they reduced the levator area and muscle length at maximum valsalva indicating increased PFM stiffness.

Conclusion: Supervised six months strength training of the PFM can increase muscle volume, elevate the position of the bladder and bowel, close the levator hiatus, shorten PFM length and it may build up PFM stiffness.

General discussion

Short summary

To evaluate the effect of PFMT in the prevention and treatment of POP, RCTs with high methodological quality and use of valid and reproducible assessment methods have been warranted ^{15;17}. 3D and 4D ultrasound is a new promising assessment tool to assess morphological and functional changes in the pelvic floor after PFMT. The present test-retest study found that the intra-tester reliability was good enough to be used for this purpose. The overall high prevalence of POP and related problems indicates a need for identification of risk factors and prevention and treatment strategies ²³. Our case-control study found that BMI, socioeconomic status, heavy occupational work, anal sphincter lacerations and PFM function were independently associated with POP. BMI and PFM function in particular, may be of clinical importance in preventing POP, since these factors are modifiable. To our knowledge, the POP study is the first full scale RCT of the effectiveness of PFMT in women with all sites of POP. The results of the POP study demonstrated that PFMT can improve stage of POP, elevate the bladder and bowel, reduce mechanical, bladder and bowel symptoms and can make morphological changes to the pelvic floor.

Perineal ultrasound as a new assessment tool (test-retest study)

One limitation of the test-retest study can be the selection and number of participants. This study was not designed to define values for the normal population, but rather to evaluate test-retest reliability for measurements of the action of the PFM and pelvic organ movements during PFM contraction. Most of the ultrasound measured parameters showed good reliability. However, one can question the reliability of the ultrasound measurements for position of the uterus, bowel and back sling of the puborectal muscle due to the high technical failure rate. The reasons for this may be explained by placement of the transducer too anteriorly. The larger the size of the levator hiatus the harder it is to capture both the anterior and posterior compartments with a perineal transducer. Data should be extrapolated with caution in women with pelvic floor dysfunction, since it is likely that these women may have greater variability in anatomy and biomechanics.

As a result of the relatively high technical failure of the position and displacement of the uterus rate in the test-retest study we chose not to assess this in the RCT. Another result of the test-retest study was that PFM contraction in the POP study was recorded in two different

ways; one scan included the whole hiatus and back sling of the pubovisceral muscle (squeeze), and one included the whole pubic symphysis (lift).

Measurements in the sagittal plane (Paper I)

As far as we know the test-retest study is the first study to assess position of the posterior compartments (bowel, uterus) of the pelvic floor, using a reference line through the pubic symphysis in the sagittal plane ¹⁷⁰. The results of the bladder neck position measurements in our test-retest study correspond with Schaer et al. ¹⁷⁰.

Measurements in the axial plane (Paper I)

One of the most important advantages with 4D ultrasound imaging is access to the axial plane. The pubovisceral muscle morphology can be identified in any plane within the volume, without pre-defining it. Prior to the test-retest study only two studies had used 3D ultrasound ^{22;188} and reported values of test- retest data regarding biometry of the PFM. The reliability of levator hiatus area measurements is comparable to what Dietz et al. ²² and Yang et al.¹⁸⁸ found. The test-retest study showed that 3D ultrasound is capable of reliable measure puborectal muscle length, which has never been tested before. More recently the same measurement has been used to quantify muscle strain during valsalva ¹⁷². Measurements of the pubovisceral muscle thickness showed more variable results, and the lower ICC value corresponds with the results of Dietz et al. ²² and Yang et al. ¹⁸⁸ suggesting that muscle thickness is one of the least reliable measurements. Nevertheless, moderate reliability was obtained when thickness was measured in the axial plane of minimal hiatal dimensions, and we therefore used this measurement plane in the POP study.

PFM contraction (Paper II): To investigate the chronic effect of performing 36 PFM contractions per day for six months it is necessary to know what actually happens during one single contraction. Searches on PubMed database did not reveal any other studies assessing elevation of cervix uteri, bowel or back sling of the muscle during a PFM contraction. The test retest study demonstrated that ultrasound reliably can simultaneously measure both the lift and squeeze during a PFM contraction. Surprisingly, measurements in the axial plane (squeeze) produced better results than measurement in the sagittal plane (lift).

Lift: In the past, lift of the bladder (bladder neck) has mainly been investigated ^{61;189}. Our test-retest study did not achieve test-retest values as good as presented by those research groups.

On the other hand, we measured the lift of the pelvic organs (bladder, bowel, uterus and back sling of the muscle) using another method developed by Reddy et al ¹⁹⁰, so the studies cannot be directly compared. The values for bladder displacement during contraction previously found by Bø et al.¹⁹¹, Dietz ¹⁹², and the present values are higher than those found by other research groups ^{61;190;193}. The differences may be due to different populations, or strong verbal encouragement to achieve maximal voluntary contraction. The pelvic organs moved twice as much, or more, in the cranial direction compared to the anterior direction. During PFM contraction the back sling of the muscle rotated 13 degrees upwards around the pubic symphysis, like a windscreen wiper. This means that the organs positioned at the furthest distance from the pubic symphysis (back sling of the muscle, bowel) moved more than closer organs (bladder).

Squeeze: In ultrasound and MRI assessments, the squeezing function of the PFM has been much less in focus than the lifting function. The reason for this may be limited access to the axial plane. Additionally, MRI does not normally assess women in an upright position and the sampling time may be too slow. Many MRI machines require pre-selection of the plane of assessment, therefore such a machine cannot be used, since the plane of minimal dimension changes during a contraction. Paper II showed that during a PFM contraction the hiatal area was reduced by 25%, and puborectal muscle length shortened 21% during a single contraction. This is in line with what happens in the general skeletal muscles¹⁹⁴.

Risk factors for POP (case-control study)

The strengths of the case -control study were that PFM function was measured with a method found to have good reliability and validity ^{175;177}, and that validated questionnaires and clinical assessment tools were used ^{45;173}. We also followed the recommendation of Bland and Altman to use a matched pair design with small samples ¹⁹⁵. Possible limitations are a relatively small sample size, that women in the POP group had a relatively mild degree of POP (63% with stage II), a risk of overestimation of self reported height, a risk of recall bias (obstetric history, family history and physical activity as adolescent) and that measurement of vaginal squeeze pressure has not been validated in women with POP. Due to wide confidence intervals and the fact that the study was powered to assess joint mobility, this lack of association between POP and most of the obstetric factors may be due to a small sample size, and further studies with larger sample size are warranted.

Considering validation of the squeeze pressure transducer, presence of POP was not assessed in the reliability and validity study of Bø et al in 1990 ^{175;177} and in a RCT of women with SUI ¹⁹⁶. Due to the high prevalence of POP it is likely that many of the participants in the previously reported studies had POP in addition to SUI. In severe cases of POP, the prolapsed tissue may fill up the levator hiatus and it may theoretically influence the measurements of PFM function. Dynamometers have an advantage over pressure transducers, measuring force directly ¹⁹⁷. However, these devices are not yet commercially available, and so far there is no report on how POP affects their measurements.

The case-control study had a successful matching regarding age and parity, and all other proposed risk factors have been adjusted for these two variables, in addition to BMI and socioeconomic status. Women with POP were more likely to experience mechanical and bowel symptoms than controls, but not bladder symptoms. This corresponds with previously published studies showing that pelvic floor related symptoms may not predict stage or anatomic location of POP ^{45;198}. As expected, results from the case-control study found higher occurrence of low back, pelvic floor and lower abdominal pain among women with POP. This corresponds with results from other research groups ⁹⁶.

Except for joint hypermobility, markers for weak connective tissue (varicose veins, striae, diastasis of the rectus abdominis, and bruising) have not been the focus of previous POP research. The case-control study showed differences among POP women and controls for bruising and varicose veins, the latter being strongly associated with POP. Surprisingly, the case-control study did not support previous studies showing that general joint mobility is a predictor of POP ^{91;95-97}. The discrepancy in results may be due to ethnicity. In a previously reported study, women with POP-Q stages III and IV demonstrated higher prevalence of joint hypermobility than women with stage I and II ⁹⁵. The majority of the women with POP in the case-control study had POP stage II. Hence, our results may not be generalisible to women with more severe POP. On the other hand, our findings correspond with a study showing no significant relationship between joint hypermobility and POP in women with Ehler-Danlos syndrome ¹⁰⁰. Based on our case-control study we suggest that bruising and presence of varicose veins may in future be meaningful clinical markers to predict women with increased risk of POP.

The case-control study failed to demonstrate any independent association between POP and postmenopausal status, current smoking, family history of pelvic floor disorders and most of the obstetrics factors. In the case-control study, recall of anal sphincter lacerations was the only obstetric factor associated with POP, with more than four times elevated odds. High BMI ^{38;77;102;103} and low education ^{75;103} have been found to be associated with prolapse, and our results are in accordance with these findings. The results of our study are also in agreement with other studies finding an association between heavy occupational work and low income and POP ^{75;103;125;126}. Vigorous physical activity is considered a risk factor for POP ¹⁴, most likely due to the above mentioned factors. However, in our study the women with POP had participated not more, but less in exercise as adolescents compared to control women, suggesting that being a former exerciser is not associated with POP. The lower occurrence of current high intensity exercisers among women with POP compared with controls may be explained by a possible withdrawal from physical activity because of symptoms ¹⁹⁹. On the other hand, a higher occurrence of high intensity exercisers among women without indicates that vigorous activity alone is not enough to predispose women to POP. The results of the case-control study do not, therefore, support the hypothesis that either previous or current vigorous physical activity is a risk factor for POP.

Approximately 30% fewer women with strong PFM, good PFM endurance and high vaginal resting pressure were found in the POP group compared to the controls in the presented case-control study. Our findings contradict the results of Nygaard et al ⁷⁵, who did not find reduced PFM strength in POP women. Discrepancy in results may be due to different assessment methodology. They used vaginal palpation which has shown to have lower responsiveness, validity and reliability than vaginal squeeze pressure measurements ²⁰⁰. The poorer PFM function among women with POP indicates that these woman may have muscular impairment/ levator trauma, as found by other research groups ^{73;128-130;137}. However, the fact that about 20% of the women with POP had good PFM function, suggests that the POP process must also include factors other than PFM injury or weakness.

Effects of PFMT (POP study - RCT)

Strengths of the POP study include the use of a training protocol based on strength training recommendations ²⁰¹ and previously shown to be effective in RCTs on women with SUI ^{165;185;186}, a six month training period, high adherence to the training protocol, low dropout

rate, a randomized design, blinding of outcome assessors and use of POP-Q, ultrasound imaging and validated questionnaires ^{45;173}. Possible limitations are differences between groups in mechanical symptoms at baseline, different amount of time spent with the PT between groups, non-blinded measurement of PFM function (independent variable) and a relatively small sample size.

Blinding of the assessing PT could have reduced possible bias of PFM function measurements. However, due to practical reasons it was not possible to pay another PT to perform these assessments. Additionally, PFM function was not a part of the outcome measures, which were all assessed blinded. During measurements of PFM strength and endurance the standardised test protocol, including instructions, was carefully followed, which meant that placement of the balloon catheter, participant's body position, and verbal encouragement were attempted equal with all participants. The differences in mechanical symptoms at baseline between groups may overestimate the subjective improvement rate in the PFMT group due to the "regression to the mean"²⁰². However, all analyses of improvement in the mechanical symptom have been adjusted for baseline values. The difference in mechanical symptoms between groups was present even though we had a successful randomisation in the two factors on which we did stratify (not statistically significant different distribution severity of POP and age between the two groups). Another possible limitation is the difference between groups in time spent with the PT, but this is unlikely to affect objective anatomical measures. This is supported by a previous RCT controlling for the attention effect, by giving the control group back massage. There was no effect on SUI in the control group in spite of the treatment they received, only on quality of life²⁰³.

Depending on the definition used, women found on examination to have POP-Q stage I can be defined as having a mild degree of POP ³⁰ or not having POP ³¹. The reasons for including POP stage I and asymptomatic women in the POP study was the wish to assess the effect of PFMT as a prevention strategy ¹⁶⁴. However, a relatively small sample size limited our possibility to do sub-group analyses between groups of women with different stages of POP. With a larger sample size sub-group analyses could have been performed and the p-value for improving stage of POP would most likely have been lowered. However, the sample size is statistically explained and based on the effect of PFMT on women with SUI, since no data was available on women with POP. Additionally, most of the primary outcome measures were significantly better in the PFMT group compared to the control group. This indicates that the sample size was adequate.

Only 22% of the participants had POP stage III. Hence, the results may therefore not be generalisible to women with more severe POP. We believe that the same, or even better effects, may occur in women with SUI alone and in asymptomatic women due to the fact that a higher proportion of women with POP may have muscular defects ^{73;128;129}, reduced muscle volume ^{131;132} and increased size of the levator hiatus compared to women with SUI ¹³³ and healthy controls ^{57;133-135}.

PFMT protocol

General strength training programmes for all striated muscles demonstrate an increase in strength due to neurological and morphological factors ²⁰⁴. The present study did not assess neurological changes after PFMT. Increased cross-sectional muscle area is the best wellknown factor related to increase in strength, but changes in muscle architecture and structure of connective tissue and tendons also contribute ²⁰⁴. There is good evidence that strength training slows down, but does not halt, age-associated atrophy, weakness and fatigability ²⁰⁵. The standardised PFMT programme was carefully designed following recommendations from exercise science ^{178;201}. The protocol has been shown to be effective in previous RCTs in women with SUI ^{185;186;206} and in prevention and treatment of SUI during pregnancy and after childbirth ¹⁶⁵. "Overload" is mandatory for achieving muscular hypertrophy and thereby increased strength of the PFM. High intensity of each PFM contraction is considered to be the most important element to achieve "overload" ²⁰⁷. The rationale for a supervised, long duration, high frequency and high intensity training program is that women with POP often have lower PFM strength and more muscular defects than women without POP 73;74;136. It can be assumed that rehabilitation of muscular defects are more time consuming and require even more close follow-up than is needed for a well functioning pelvic floor. Results from other trials support the assertion that close follow-up and supervised training are important ^{165;186;196}. In addition, studies have found that more than 30% of women are unable to contract the PFM properly at the first consultation, even after thorough individual instruction ^{208;209}. Bump et al showed that 25% were pushing downwards instead of lifting up and inwards ²⁰⁸. Other common mistakes are to use muscle groups outside the pelvic area, such as hip abductors, adductors and gluteal muscles, instead of the PFM ²⁰⁹. Thorough instruction, feedback, close follow-up and high adherence are important factors for the training to give

results ^{157;158}. Most women seem to learn to contract their PFM correctly, but a few women seem to be unable to perform a correct contraction (especially those who push down instead of lifting in and up) ¹⁸⁵.

Change in severity of POP (paper IV)

To our knowledge the POP study is the first full-scale randomized trial using validated objective outcome measures evaluating whether PFMT can improve prolapse, and as far as we have ascertained no study has previously evaluated the effect of PFMT using imaging. Only one previous study has used the POP-Q grading system. Nevertheless, this was a pilot study and complete POP-Q data were missing from 27 of the 47 participants ¹⁸. Our data support the result of a study that found greater improvement after PFMT among elderly Thai women with severe compared to milder anterior vaginal wall prolapse ¹⁶. However, the latter trial had major methodological limitations, and POP-Q was not used ^{15;17}.

It can be questioned as to whether 19% is a satisfactory improvement rate for POP-Q. POP-Q is the recommended gold standard for assessing severity of POP ^{1;26}. Nevertheless, POP-Q involves strenuous valsalva that produces high increased intra-abdominal pressure. Increased intra-abdominal pressure is considered a risk factor for developing prolapse, and women are generally recommended to avoid straining ¹⁴. During this manoeuvre the PFM are stretched and the muscles and organs are pushed in a caudal direction ¹³⁹, opposite of the action during a PFM contraction and hence, an improvement in POP-Q may not be expected after PFMT. Nevertheless it was found in our study, and it may indicate automatic increased resistance to stretch. This hypothesis needs to be elucidated in a new study. Women performing PFMT elevated the bladder and bowel measured at rest in standing position. Ultrasound assessment may be a more valid test to describe the position of the pelvic organs during activity of daily living.

The position of the bladder and bowel can describe the severity of anterior and posterior compartment prolapse. Two uncontrolled studies have previously demonstrated an elevated position of the bladder after PFMT in women with SUI ^{163;210}, the present RCT has now confirmed this treatment effect. Additionally, we also demonstrated elevation of the bowel. The bowel was elevated relatively more than the bladder, mirroring the action during a single contraction. It can be questioned if 3.0-5.5 mm elevation of the pelvic organs makes an important morphologic change. POP seems to progress with increasing age ⁷, at least up to a

certain age ⁹, but it is not known how many millimetres per year the pelvic organs normally descend.

Change in symptoms (paper IV)

In addition to improving pelvic support, we found that PFMT reduced the frequency and bother of pelvic heaviness and vaginal bulging. A previous pilot study ¹⁸ and a RCT of anterior wall prolapse only ¹⁹ also demonstrated improvement in mechanical symptoms after PFMT. While women in our study also showed improvement in all the bladder symptoms and some of the bowel symptoms, it should be noted that bladder and bowel symptoms can exist without POP ⁴³, and are considered by most research groups as coexisting symptoms, rather than symptoms of POP.

Pelvic heaviness and bulging have been shown to be the most discriminatory symptoms in women with POP ⁴³. Of the symptomatic women in the PFMT group 74% reported reduced frequency of vaginal bulging/ pelvic heaviness at six month post test. Hence, the reduction in mechanical symptoms may be considered the most important treatment effect since these subjective symptoms are the main indication for surgery ²¹¹.

Morphological adaptations to PFMT (paper V)

The POP study demonstrated that intensive and supervised PFMT can build up muscle volume and change the morphology and function of the PFM. The chronic effect in muscle morphology after performing daily PFMT for six months were increased muscle thickness, reduced muscle length and narrowed hiatal area. Previous research has shown increase in muscle thickness ¹⁶² and reduction of the levator ani muscle surface ¹⁶¹. However, these two studies were uncontrolled with few participants, and it was not possible to rule whether this was a true effect of the intervention. Our assessor blinded RCT can elaborate such cause-effect.

We found a 44% increase in muscle strength which is in agreement with previously published studies showing increased strength after PFMT ^{165;185}. The primary morphological adaptation to general strength training is hypertrophy (whole-muscle growth) ²⁰⁴. A 15% increase in muscle thickness and a correlation between muscle thickness and muscle strength was found in the POP study. This is in concordance with results for strength training of the upper and lower limb $(4-33\%)^{204}$, and higher than what was found for the PFM in a previously published

uncontrolled study (8%)¹⁶². The discrepancy in measured hypertrophy can be explained by the different PFMT dosages including length of the training period, ultrasound assessment methods and different muscles that were measured ²¹². As emphasized from sport science, chronic exposure to "overload" in six months is important for achieving maximum morphological adaptations to strength training ²⁰⁴.

One major finding in the POP study was that PFMT led to shortening of the PFM, and thereby closing of the levator hiatus. In other words PFMT has the potential to "tighten up" the pelvic floor, as suggested in 1948 by Kegel ²¹³. By narrowing the levator hiatus the levator plate may increase its inclination resulting in prevention of the pelvic organs tendency to "slide" down through the hiatus, as postulated in 1953, and shown in 2006 ^{58;129}.

Functional adaptations to PFMT (paper V)

In addition to morphological changes, the POP study demonstrated functional changes such as; elevated resting position of the bladder and bowel and a reduction of the pubovisceral muscle length and hiatus size at maximum valsalva. These findings may be explained by increased "stiffness" in the muscle- connective tissue complex. It is likely that muscle mass and connective tissue (surrounding the muscle fibres, bundles and the whole muscle) have increased in amount, as this follows general strength training ²⁰⁴. In addition to increased amount of connective tissue, the architecture of muscle and connective tissue may have been altered ²⁰⁴. The result of the present RCT study thereby confirms the hypothesis that PFMT changes muscle morphology and thereby improves the structural support for the pelvic organs, as first described by Bø in 2004 ^{17;20}. The morphological and functional changes found after PFMT can directly affect possible underlying anatomical and pathophysiological mechanisms such as decreased muscle strength, opening of the hiatus and descended pelvic organs. Hence, rectification of pelvic floor dysfunction by PFMT may be possible.

Effect of PFMT versus Lifestyle modifications

Women may have two different strategies to minimize urine loss and prevent downward movement of the pelvic organs. "The Knack", which is timing a PFM pre-contraction with the moment of expected leakage, has been shown to have an immediate effect on cough related stress urine incontinence and downward displacement of the bladder ^{184;214;215}. However, to date it is not known 1) how strong the PFM needs to be to counteract the increase in intra-abdominal pressure, 2) whether such pre-contractions improves PFMT strength and 3) whether it becomes an automatic function ²¹⁶. The present study showed that instruction to

perform "the Knack" did not improve PFM strength nor contribute to morphological adaptations, and is in agreement with the theoretical explanations proposed by the authors of "the Knack"²¹⁴. The POP study also demonstrated that the effect on mechanical, bladder and bowel symptoms and on severity of prolapse is significantly better after PFMT compared to women receiving only lifestyle advices, including "the Knack".

Prevention of POP

As presented in Figure 6 the risk factors for POP can be organised in a multivariate model based on sport injuries ⁷². Recently this model has been modified and it is now suitable for looking at both risk factors, prevention strategies and treatment/recovery in a more dynamic, recursive way (Fig 12) ²¹⁷. The model is recursive in that one exposure can alter the total risk of a woman. If we modify the new model to fit POP, it highlights the importance of examining all possible predisposing, intervening and inciting factors, reducing the impact of interacting factors and improving modifiable risk factors to reduce POP.



Figure 12. Modified dynamic, recursive model of aetiology and development of POP. The model is based on Meeuwisse et al ²¹⁷ and the risk factors described and organised by DeLancey et al ¹⁴

Predisposing risk factors: Each woman has her own set of predisposing risk factors. PFM function was an independent and modifiable risk factor in paper III. If a woman improves her PFM strength, she may be less predisposed to POP according to the model. It can be hypothesized that the increased focus on the pelvic floor when performing PFMT may also result in more awareness about contracting the PFM before and during lifting or jumping. Increased PFM strength may even improve the automatic contraction response to increases in intra abdominal pressure (e.g. lifting, high impact aerobics, coughing). This needs further investigation. It is otherwise suggested that lifting, jumping and coughing can incite POP, but with a precontraction these tasks could further strengthen the PFM, thereby lowering overall risk.

Intervening factors: Figure 12 shows different intervening factors. "Behaviour" modifications/ strategies, such as parents teaching children not to strain during defecation, personal trainers informing women to pre-contract the PFM before heavy lifting, "lifting courses" in the workplace, and weight loss for obese women might lower the negative impact of the intervening factors. During increases in intra abdominal pressure the levator hiatus opens or "balloons"¹³⁹. A possible negative effect of this can be lengthening and microtrauma of the muscles and adjacent connective tissue. Based on the POP study the behaviour modifications will probably not result in any morphological changes of the pelvic floor, but may prevent development of muscular defects by reducing repeated stretching of the PFM.

Inciting events: If an inciting event such as childbirth results in POP, it is suggested that this is due to the combination of predisposing and intervening factors as part of the cause, based on the present model. Another scenario is that a disposed woman may not develop POP in spite of childbirth. A maladaptation may instead occur to the tissue (e.g. pubovisceral muscle avulsion resulting in lower PFM strength), resulting in altered PFM anatomy. This can make her more predisposed to future intervening or inciting factors, and her risk of developing POP increases. This may be the reason for an increased odd ratio for each child born vaginally ¹⁰².

When repeated exposure to risk factors (e.g. straining, obesity) comes together with other risk factors (poor connective tissue and reduced PFM function), it may be sufficient to cause POP without any inciting event. Knowing as many risk factors as possible, especially the modifiable risk factors, and having strategies to reduce them, may prevent women from

developing POP. As we have demonstrated in the POP study, prolapse may not be a permanent condition, or a finite end point; the condition can recover. Our data demonstrate that PFMT can help women to improve the stage of POP, reduce pelvic floor symptoms and alter PFM anatomy by strengthening the PFM. Consequently, their overall risk may be reduced, and they might be less vulnerable to the next intervening or inciting factor.

Conclusions

Our study confirms the proposal of Dietz et al ^{22;218}, that ultrasound can be used to increase knowledge about the mechanisms of PFMT. The test-retest study demonstrated that both the squeeze and lift of a PFM contraction can be measured reliably. The case-control study showed that PFM function, BMI, socioeconomic status, heavy occupational work and anal sphincter laceration were factors most associated with POP. From the perspective of prevention and treatment, BMI and PFM function are two of the few modifiable factors. Women with poor PFM function were four to 11 times more likely to experience POP than women with good PFM function. Presence of varicose veins was the only factor independently related to POP out of six possible markers of connective tissue weakness (varicose veins, bruising, striae, diastasis recti abdominis and joint hypermobility).

The POP study is the first full-scale RCT using validated objective outcome measures to evaluate whether supervised PFMT can improve prolapse, reduce mechanical, bladder and bowel symptoms and alter morphology and function in the pelvic floor. Improvement in stage of POP, elevation of the bladder and bowel, reduction in mechanical, bladder and bowel symptoms, increased muscle thickness, reduction in muscle length, and narrowing of the hiatal area can be achieved by performing 36 PFM contractions per day for six months in women with POP. Therefore, the results of this RCT demonstrate that it is possible to improve the stage of POP, alleviate symptoms and probably reduce the risk of potential pelvic floor dysfunctions, by PFMT.

Further research

Further studies are needed to compare measurement of PFM function in women with and without POP. The relationship between the strength of the PFM and the degree of narrowing of the levator hiatus and lift of the pelvic organs also requires further investigation. Likewise the relationship between PFM strength and automatic response to increases in intra-abdominal pressure. A matched- one to one case- control study design with larger sample size could be useful in investigating the association between POP and mode of delivery (cesarean, forceps, vacuum), birth weight and short or prolonged second stage of labour. PFM function is an important clinical associate of POP and future studies should include this factor. Longitudinal studies are needed to answer whether, and to what extent, mild forms of POP progress. The results of the POP study demonstrate that it is possible to correct the actual dysfunction of the pelvic floor by PFMT in some women. Further studies are needed to explore responders and non-responders. Longer follow-up studies are additionally needed to determine if these changes are sustainable. The morphologic effect of PFMT in women with SUI and in women who have normal pelvic floor support needs to be evaluated in a RCT. Finally, evaluation of PFMT as a primary prevention strategy for POP is maybe one of the most important objectives for future research. However, this demands a huge budget over many years.
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Paper I-V and appendix

Paper I

Brækken, I.H, Majida,M, Ellström-Engh,M, Dietz,H.P, Umek,W, and Bø,K, 2008. Test-retest and intra-observer repeatability of two-, three- and fourdimensional perineal ultrasound of pelvic floor muscle anatomy and function. Int.Uregynecol.J.Pelvic.Floor.Dysfunct., 19, 227-235

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Paper II

Brækken, I.H, Majida,M, Ellström-Engh,M, and Bø,K, 2009. Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. Neurourol.Urodyn., 28, 68-73 Denne artikkelen ble tatt ut av den elektroniske versjonen av doktoravhandlingen i Brage på grunn av copyright-restriksjoner. Artikkelen er tilgjengelig på: http://dx.doi.org/10.1002/nau.20618

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Paper III

Brækken, I.H, Majida,M, Ellström-Engh,M, and Bø,K, 2009. Pelvic floor function is independently associated with pelvic organ prolapse. Br.J.Obst.Gynecol., 19, 227-235

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Paper IV

CAN PELVIC FLOOR MUSCLE TRAINING REVERSE PELVIC ORGAN PROLAPSE AND REDUCE PROLAPSE SYMPTOMS? –AN ASSESSOR BLINDED RANDOMIZED CONTROLLED TRIAL.

Ingeborg Hoff BRÆKKEN PhD student¹, Memona MAJIDA MD², Marie ELLSTRÖM ENGH MD^{2,3}, Kari BØ PhD¹

The study was conducted in Oslo/Akershus in Norway

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- Presentation information: An abstract and a presentation of this manuscript has been accepted by the Scientific Committee (Abstract # 76) at 39th Annual Meeting of the International Continence Society (ICS), San Francisco, September 29th –October 3rd, 2009
- Sources of financial support: Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association
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- Word count- Abstract: 150
- Word count-text: 3252

Condensation

Pelvic floor muscle training can improve stage of pelvic organ prolapse, elevate bladder and rectum and reduce symptoms in women with prolapse.

CAN PELVIC FLOOR MUSCLE TRAINING REVERSE PELVIC ORGAN PROLAPSE AND REDUCE PROLAPSE SYMPTOMS? –AN ASSESSOR BLINDED RANDOMIZED CONTROLLED TRIAL.

Ingeborg Hoff BRÆKKEN, Memona MAJIDA, Marie ELLSTRÔM ENGH, Kari BØ

Abstract

Objective: To investigate the effectiveness of pelvic floor muscle training (PFMT) in reversing pelvic organ prolapse and alleviating symptoms.

Study Design: This assessor blinded parallel group randomized controlled trial conducted at a university hospital and a physical therapy clinic randomized 109 women with prolapse stage I, II and III to PFMT (n=59) or control (n=50). Both groups received lifestyle advices and learned "the Knack". Additionally, PFMT comprised individual physical therapy sessions and home exercise. Student's t-test, Mann-Whitney U-test, odds ratio and effect size were used to compare groups.

Results: Eleven (19%) women in the PFMT group improved one POP-Q stage versus four (8%) controls (p=.035). Compared to controls the PFMT group elevated the bladder (difference: 3.0mm; 95% confidence interval 1.5-4.4; p<.001) and rectum (5.5mm; 1.4-7.3; p=.022), and reduced frequency and bother of symptoms compared to controls. Conclusion: PFMT is without adverse effects and can be used as treatment for prolapse.

Key words: conservative treatment; pelvic floor muscle training; pelvic organ prolapse; prolapse symptoms; stage of prolapse

Introduction

It has been estimated that approximately 50% of women loose some of the supportive mechanisms of the pelvic floor due to childbirth leading to different degrees of POP.¹ The prevalence of symptomatic POP is reported to be 3-28%²⁻⁴ with prolapse symptoms such as vaginal bulging and heaviness being the most specific symptoms.^{2;5} These symptoms can greatly impair a woman's quality of life, and are the main indication for surgery.⁶ POP accounts for 20% of women on waiting lists for major gynecological surgery.¹ However, prolapse recurs in up to 58% of women after surgery, and about one-third of operated women undergo at least one more surgery for prolapse.^{7;8} This highlights the need for prevention measures that could reduce the impact of POP.

Activity in the pelvic floor muscles (PFM) plays a critical role in supporting the pelvic organs.⁹ Women with POP have reduced PFM strength^{10;11} and the severity of POP seems to increase with increasing PFM dysfunction.^{12;13} Pelvic floor muscle training (PFMT) is without adverse effects, and anatomical understanding of PFM function provides a theoretical basis for strength training of the PFM to be effective in prevention and treatment of POP.¹⁴ A survey revealed that 92% of women's health physical therapists (PT) assessed or treated women with POP despite a poor evidence base and lack of clinical referral guidelines.¹⁵ To date, only three randomized controlled trials (RCTs) have investigated the effect of PFMT on POP. One trial¹⁶ scored low on methodological quality,¹⁷ one is a small pilot study¹⁸ and one small trial, published in French, assessed symptoms only.¹⁹ A recent Cochrane review concluded that available evidence is insufficient to understand the role PFMT may play in reducing POP, and recommends RCTs with high methodological quality.¹⁷ The aim of the present study was to evaluate whether PFMT can 1) reverse and prevent further development of POP.

Materials and Methods

Design

This explanatory study is an assessor blinded randomized controlled parallel group trial with stratification on severity of POP. Participants were women with POP stages I, II and III as determined by the Pelvic Organ Prolapse Quantification System (POP-Q).²⁰ Women with POP, regardless of symptoms, were enrolled by community gynecologists and advertisement in newspapers. The study was approved by the Regional Medical Ethics Committee (S-05146), Norwegian Social Science Data Services (200501371 SMRH) and registered at ClinicalTrials.gov (NCT00271297). All subjects gave written informed consent. Participants were at least one year beyond their last delivery. Exclusion criteria included POP stage 0 or IV, inability to contract the PFM, breastfeeding, previous POP surgery, radiating back pain, pelvic cancer, neurological disorders, psychiatric disorders, untreated urinary tract infection, planning to become pregnant during the next 6 months or to be away for more than 4 weeks of the intervention period.

As preliminary data on effect size of PFMT to treat POP was not available at the start of study, we used an effect size of 0.6 to calculate the sample size. This was found in a multi center RCT evaluating the effect of PFMT for stress urinary incontinence (SUI)²¹. With a two-sided alpha of 0.05 and a power of 80%, a sample size of 45 per group was required.²² Due to possible drop-outs we chose to include at least 50 women in each group.

Intervention

Women in both the PFMT and the control group were advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack").²³

The controls were asked not to change frequency of, or to start, PFMT during the intervention period. Women in the PFMT group were advised to do 3 sets of 8-12 close to maximum PFM contractions per day and to record home training adherence in an exercise diary.^{21;24} Each woman was individually supervised by a PT once a week during the first three months and every second week during the last three months. All women in the PFMT group also received a booklet and a DVD showing the exercise program. We defined adequate adherence as completing at least 80% of exercise sessions (\geq 144 days' home exercise and \geq 14 PT sessions). This program has been successfully used in several RCTs on women with SUI.^{21;24}

Primary outcome measures

Stage of POP – The internationally recommended classification system POP-Q was used to test severity of POP.^{20;25}

Position of bladder and rectum – The participants emptied their bladder and a bladder volume of <50 ml was confirmed by ultrasound. The women stood with legs slightly apart during the ultrasound examination. A GE Voluson 730 expert and a E8 ultrasound system (GE Healthcare, Oslo, Norway) was used with a 4-8 MHz curved array 3D/4D ultrasound transducer (RAB 4-8 l/obstetric) placed on the perineum in the sagittal plane. The women were told to relax their PFM, while recording three-dimensional (3D) volumes. Position of the bladder and rectum was quantified by locating the urethrovesical junction (bladder neck)²⁶ and rectal ampulla²⁷, respectively. The height of the organs were defined as the vertical distance perpendicular from the central axis of the symphysis pubis on a rectangular coordinate system in the mid-sagittal plane, as described by Schaer et al²⁶ and found to be reliabe.^{27;28} *Frequency and bother of prolapse symptoms*– Participants completed a validated questionnaire²⁹ to describe frequency (daily, weekly, monthly or less than once per month) and bother (4-point scale) of prolapse symptoms (feeling of vaginal bulging and/or heaviness). Women were considered symptomatic if they had monthly symptoms or more often. Improvement was present if the women reported less frequent symptoms or less bother on the four point scale at six months post test compared to baseline answers.

Secondary outcome measures

Frequency and bother of bladder and bowel symptoms– The same validated questionnaire²⁹ were used to describe frequency and bother of bladder symptoms (SUI, urge urinary incontinence) and bowel symptoms (flatus, loose and solid fecal incontinence, problems with emptying bowel). In addition, the International Consultation on Incontinence Urinary Incontinence Short Form questionnaire (ICIQ-UI SF)³⁰ was used to assess urinary incontinence and its impact on quality of life.

Independent variable

PFM function was evaluated by a vaginal balloon catheter (ballon size 6.7 x 1.7 cm) connected to a high precision pressure transducer (Camtech AS, Sandvika, Norway).³¹ Muscle strength was calculated as the mean of three maximal voluntary contractions. This method has been found to be reliable and valid if used with simultaneous observation of inward movement of the catheter and perineum during PFM contraction.^{31;32} Vaginal resting pressure was measured as the difference between atmospheric pressure and the vaginal high pressure zone at rest, without any voluntary PFM activity. PFM endurance was defined as a sustained maximal contraction and was quantified during the first 10 seconds as the area under the curve (cmH2Osec).

Procedure, randomization and blinding

The participants answered the postal questionnaires prior to baseline assessment. A PT (IHB) examined ability to contract the PFM and measured PFM function. Assessment was done in a physical therapy clinic. All POP-Q and ultrasound examinations were performed by a gynecologist (MM) at a university hospital. Thereafter, women were stratified into two groups by severity of prolapse; 1) maximal vaginal descent at or above the hymen, and 2) maximal vaginal descent below the hymen. Within each strata a computer generated random number system with concealed envelopes, generated by a statistician, randomized the women to either PFMT or control. The participants opened opaque sealed envelopes with their group assignment. The gynecologist (MM) performing all the POP-Q and ultrasound examinations was blinded to group allocation, clinical and background data. Prior to the six months post test all participants of both groups completed the postal questionnaire and were retested with the same outcome measures as baseline. The PT (IHB) was blinded for all outcome measures, but not the independent variable (PFM function). The ultrasound images were stored by de identified code numbers and analyzed offline (4D View v 5.0 and 6.3; GE Healthcare, Oslo, Norway) by one investigator (IHB) blinded to group allocation, clinical and background data.

Statistical analysis

Statistical analyses were carried out in SPSS version 15. The results are given as frequencies and percentages for categorical data and means with 95% confidence intervals (CI) for continuous data. Continuous data were checked for normality by Kolmogorov-Smirnov and Shapiro-Wilk test. Between and within groups comparisons were tested with Student's t-test (normally distributed data), Wilcoxon Signed Rank Test and Mann-Whitney U test (not normally distributed data). Differences between groups in baseline categorical data were analyzed by Chi-square. To determine treatment effect, differences between groups with 95%

CI and odds ratios (OR) with 95% CI was calculated for categorical data, whereas effect sizes were calculated for continuous data using the formula: "(mean of PFMT group – mean of control group)/ SD". The one variable that significantly differed between groups at baseline (prolapse symptoms) were additionally analyzed with ordinal logistic regression analyses using the final values as the dependent and baseline as the independent variable together with group as exposure variable. The relationship between increase in PFM strength and changes in position of bladder and rectum, improvement in POP-Q and subjective improvements were analysed with Pearson product-moment correlation (r) for normally distributed data and Spearman rho (rho) for not normally distributed data. Interim analyses were not done, and due to low drop-out we did not perform per protocol analyses. Intentions to treat analyses were used and baseline values were carried forward for the one woman who dropped out in each group. P-values <.05 were considered statistically significant.

Results

One hundred forty-five women with POP were recruited to the trial from November 2005 to April 2008. The flow chart (Fig 1) presents the numbers and reasons for exclusion. Of the 109 participants 59 were randomly allocated to intensive PFMT and 50 to the control group. One woman in each group dropped out due to motivation problems (PFMT group) and urinary incontinence surgery offered at another hospital (control group).

Baseline

The mean age of the 109 participants was 48.9 years (SD \pm 11.8) and 19 were classified as POP stage I, 65 as stage II and 24 as stage III. One was not classified as she was not able to perform a Valsalva maneuver during POP-Q. However, her POP-Q values at rest and the ultrasound imaging confirmed that she had POP stage I or greater. Table 1 presents

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background variables. There were no statistical differences between groups regarding age, parity, stage of POP, proportion of women with positive values for any POP-Q measure or outcome measures at baseline, except that 43 of 59 women in the PFMT group compared to 26 of 50 women in the control group had prolapse symptoms (p=.024). Twelve of the 44 postmenopausal women received hormone/estrogen replacement therapy.

Adherence, adverse effects

Women in the PFMT group performed the training 161.2 (SD \pm 26.8) out of 180 possible days, and attended 15.5 (SD \pm 3.2) out of 18 possible PT training sessions. Forty-seven of the 58 (79%) women in the PFMT group reached an adherence level of 80%. Five (10%) of the women in the control group reported that they had performed more PFMT than they did before baseline. No adverse effects were reported.

POP stage

Table 2 shows the change in POP stages between groups and within each stage of POP. Significantly more women in the PFMT compared to control group improved one POP-Q stage (11 (19%) versus 4 (8%), p=.035). Within the PFMT group the number of women improving one stage on POP-Q increased with increasing degree of POP (0% for stage I POP, 16.7% for stage II POP, 35.7% for stage III POP) (p=.034). Subgroup analyses of the 40 women with prolapse below the hymen (positive values for one or more POP-Q measure) demonstrated no statistically significant differences between groups in changing stage of POP (p=.406). Five of the 25 women in the PFMT group with prolapse below the hymen versus three of the 15 controls improved one stage of POP, and 0% versus 20% worsened one stage of POP. The same subgroup analyses showed that 7 of the 25 women in the PFMT group, elevated the most depending organ to or above the hymen.
Position of bladder and rectum

The number of paired ultrasound volumes (pre- and post test) was 94 (47 PFMT, 47 controls) for position of the bladder (bladder neck) and 74 (36 PFMT, 38 controls) for position of the rectum (rectal ampulla). The main reason for exclusion of ultrasound images was poor image quality. At six months, women in the PFMT group had a significant greater cranial elevation of the bladder (2.3mm vs. -0.6mm; difference: 3.0mm; 95%CI 1.5 - 4.4; p< .001) and rectum (4.4mm vs. -1.1mm; difference: 5.5mm; 95%CI 1.4 - 7.3; p= .022) compared to women in the control group. The calculated effect size was 0.79 for elevation of the bladder and 0.63 for the rectum.

Symptoms

Table 3 shows improvement in prolapse-, bladder- and bowel- symptoms and bother for women who had this symptom at baseline. All women except the two drop-outs filled out the six months post test questionnaires. Also after adjusting for baseline values, women in the PFMT group had significantly reduced frequency (p=.015) and bother (p=.04) of prolapse symptoms, compared to women in the control group. Urinary symptoms based on the ICIQ-UI-SF (n=102) gave an effect size of 0.62 in favor of the PFMT group (difference: 2.40; 95% CI: 0.90-3.80, p=.002). Subgroup analyses of the 40 women with prolapse below the hymen demonstrated a reduction in frequency of prolapse symptoms in 56% (14 of 25) of the PFMT group compared to 15% in the control group (p=.008; Chi-square).

PFM function

The PFMT group had significantly greater improvement than the control group in PFM strength (13.1 cmH2O, 95%CI: 10.6-15.5 vs. 1.1 cmH2O, 95%CI: 0.4-2.7; p<.001) and

endurance (107 cmH2Osec, 95%CI: 77.0-36.4 versus 8 cmH2Osec 95%CI: -7.4-24.1;

p<.001). The effect size for muscle strength and endurance was 1.21 and 0.96, respectively. There were no differences in change of vaginal resting pressure between groups (p=.122). There were positive correlations between increased PFM strength and a cranial elevation of the bladder (r=0.23, n=94, p=0.024) and rectum (r=0.27, n=74, p=0.019). No significant correlations between increase in PFM strength and change in POP-Q values or prolapse symptoms were found.

Comment

This is a full-scale RCT using validated outcome measures to demonstrate that PFMT can improve severity of prolapse and reduce prolapse (vaginal bulging and/or heaviness), bladder (SUI, urge urinary incontinence) and bowel symptoms (flatus, loose fecal incontinence). No significant changes between groups were demonstrated for problems with emptying bowel and solid fecal incontinence.

A major strength of the present study is that all the primary outcomes are consistent in favor of PFMT. Other strengths are inclusion of women with all types of POP, stages I, II and III prolapse, randomization, blinding of primary outcome assessors, use of POP-Q, ultrasound imaging and validated questionnaires, standardized training protocol, low dropout rate and high adherence to the training protocol. Possible limitations are differences between groups in prolapse symptoms at baseline, different amount of time spent by the PT between groups, and a relatively small sample size.

The differences in prolapse symptoms at baseline between groups, may overestimate the subjectively improvement rate due to the "regression to the mean".³³ However, improvement in POP symptoms has been adjusted for baseline values. The difference between groups in

time spent with the PT, is unlikely to affect objective anatomic measures. Additionally, in another RCT controlling for a possible attention effect in physical therapy, there was no effect on measured urinary leakage in the control group who received back massage.³⁴ Only 22% of the participants had POP stage III. Hence, the results may therefore not be generalisible to women with more severe POP. Research in the area of POP has suffered from the lack of a standardized definition of POP, and POP can be defined as stage \geq I or stage \geq II. In addition, some research groups suggest including both physical findings and bothersome symptoms in the definition of POP. The reasons for including POP stage I and asymptomatic women was that they per definition had POP^{20;35,} and the wish to assess the effect of PFMT as a secondary prevention strategy (treat asymptomatic women with POP).³⁶ The study was not powered to do sub-group analyses and caution must be taken to the results of such analyses. 109 participants in a RCT may by some be considered as a small sample size. However, the present trial was based on an a-priory power calculation.

To our knowledge only one previous study evaluated the effect of PFMT using the POP-Q grading system, but this was a pilot study and complete POP-Q data were missing from 27 of the 47 participants.¹⁸ Our data support a study that found greater improvement in prolapse after PFMT in elderly Thai women with severe compared to milder anterior vaginal wall prolapse.¹⁶ However, this larger trial had major methodological limitations,¹⁷ and POP-Q was not used.

In addition to improving pelvic support, we found that PFMT reduced the frequency and bother of vaginal bulging and heaviness. A previous pilot study¹⁸ and an RCT of anterior wall prolapse only¹⁹ also demonstrated improvement in prolapse symptoms after PFMT. While women in our study also showed improvement in all of the bladder symptoms and some of the bowel symptoms, it should be noted that bladder and bowel symptoms can exist without POP,⁵ and are considered by most research group as coexisting symptoms, rather than symptoms of POP.

In addition to POP-Q, ultrasound was used to assess severity of prolapse. The bladder neck and rectal ampulla are markers of the position of the bladder and rectum, and thus indicate the severity of anterior and posterior compartment prolapse. POP-Q is the recommended gold standard for assessing severity of POP.^{20;35} However, POP-Q involves a strenuous Valsalva maneuver not being a normal part of activity of daily living. On the contrary, increased intraabdominal pressure is considered a risk factor for developing prolapse, and women are generally recommended to avoid straining.³⁷ Hence, ultrasound measurement of the resting position of the bladder and rectum in standing position may be a better way of assessing the effect of PFMT on POP. In the present study 19% of the PFMT and 8% of the control group improved one POP stage. However, only women in the PFMT group significantly elevated the bladder and rectum, the controls did not.

POP seems to progress with increasing age,² but it is not known how many millimeters per year the pelvic organs normally descent, and we do not know the long term effect of this program. The present study demonstrated elevation of the pelvic organs after PFMT, and it is likely to assume that PFMT can be used in prevention of POP. One research group¹² has estimated that 90 000 of American women could be saved from experiencing pelvic floor dysfunction with a 25% prevention rate. Vaginal bulging and heaviness have been shown to be the most discriminatory symptoms in women with POP.⁵ Of the symptomatic women in the PFMT group 74% reported reduced frequency of vaginal bulging and/or heaviness at six month post test. Hence, the reduction in prolapse symptoms may be considered the most

important treatment effect since these subjective symptoms are the main indication for surgery.⁶

We chose to conduct an explanatory study with an individually supervised training program following evidence based strength training prescriptions and former PFMT protocols showing positive effect on SUI. Future pragmatic trials are warranted based on the same protocol and longer follow-up studies are needed to determine if the improvement of prolapse severity and reduced symptoms are sustainable.

Acknowledgements

We thank the physical therapists Vigdis Skøld and Guðrún Ágústa Brandsdóttir, Akershus university hospital, for excellent help in training some of the participants, Ingar Morten Holme, professor and biostatistician, Norwegian School of Sport Sciences, Department of Sports Medicine, Oslo, Norway for statistical assistance, Roar Robinson, manual therapist, Msci, Oslo, Norway for providing an office for the exercise sessions and clinical examinations and Professor, MD Ingrid Nygaard, Department of Obstetrics and Gynecology, University of Utah School of Medicine, Salt Lake City, USA, for important English revision of the manuscript. We also gratefully acknowledge financial support through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

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Figure legends

Figure1. Flowchart of participants through each stage of the randomized controlled trial.

Table 1. Background and outcome variables in the pelvic floor muscle training (PFMT, n=59) and control group (n=50) before treatment. Means with standard deviation (SD) are given unless stated otherwise.

Detail	PFMT	Control
Background variables		
Age (years)	49.4 (12.2)	48.3 (11.4)
No (%) postmenopausal	26 (44.1%)	18 (36.0%)
Body mass index (kg/m2)	25.8 (3.8)	26.18 (5.3)
Parity	2.4 (0.8)	2.4 (0.7)
No (%) with anterior wall POP	54 (93.1%)	49 (98.0%)
No (%) with posterior wall POP	46 (79.3%)	42 (84.0%)
No (%) with apical POP	47 (81.0%)	41 (82.0%)
Stage of POP (POP-Q)		
No (%) with stage I POP	8 (13.8%)	11 (22.0%)
No (%) with stage II POP	36 (63.8%)	29 (58.0%)
No (%) with stage III POP	14 (22.4%)	10 (20.0%)
No (%) with positive POP-Q value	25 (41.3%)	15 (30.0%)
Ultrasound measurements, vertical resting position	n of:	
Bladder Neck (mm)	16.7 (9.2)	19.3 (7.2)
Rectal Ampulla (mm)	10.2 (11.1)	10.9 (12.5)
Symptoms		
No. (%) with prolapse symptoms	43 (72.9%)	26 (52.0%)
No. (%) with bladder symptoms	51 (86.4%)	36 (72.0%)
ICIQ-UI_SF	7.4 (5.9)	5.4 (4.7)
No. (%) with bowel symptoms	38 (64.4%)	27 (54.0%)

PFM	function
-----	----------

PFM strength (cmH ₂ O)	29.8 (18.6)	30.8 (20.2)
PFM endurance (cmH ₂ Osec)	212 (151)	209 (152)
Vaginal resting pressure (cmH ₂ O)	27.0 (7.5)	30.3 (12.1)

 Table 2. Change in stage of pelvic organ prolapse measured with pelvic organ prolapse

 quantification (POP-Q). Numbers with percentages are presented.

	PFMT	Control
Overall improvement	11/58 (19.0%)	4/50 (8.0%)
Stage I	0/8 (0%)	0/11 (0%)
Stage II	6/36 (16.7%)	1/29 (3.4%)
Stage III	5/14 (35.7%)	3/10 (30.0%)

Table 3. Improvement in frequency and bother of prolapse-, bladder- and bowel- symptoms for women who had the actual problem, based on the questionnaire.²⁹

Difference	(%)
------------	-----

	PFMT	Control	with 95% CI	P*	OR (95% CI)
Improvement in prolapse sympto	oms; vaginal b	oulging and	/or heaviness		
Reduced frequency	32 (74%)	8 (31%)	43.6 (21.6 - 65.7)	$.000^{\delta}$	6.55 (2.23 – 19.24)
Reduced bother	29 (67%)	11 (42%)	25.1 (1.5 - 48.7)	$.000^{\delta}$	2.82 (1.03 - 7.73)
Improvement in bladder sympton	ms				
SUI: Reduced frequency	29 (74%)	8 (30%)	44.7 (22.7 – 66.7)	<.001	6.89 (2.30 - 20.59)
SUI: Reduced bother	27 (69%)	8 (30%)	39.6 (17.1 – 62.1)	.003	5.34 (1.83 - 15.58)
UUI: Reduced frequency	16 (59%)	4 (33%)	25.9 (-6.6 - 58.4)	.042	2.91 (0.70 - 12.09)
UUI: Reduced bother	15 (56%)	3 (25%)	30.6 (-0.3 – 61.4)	.075	3.75 (0.83 - 16.99)
Improvement in bowel symptom	S				
Empty: Reduced frequency	15 (60%)	6 (40%)	20.0 (-11.4 - 51.4)	.083	2.25 (0.61 - 8.31)
Empty: Reduced bother	14 (56%)	8 (53%)	2.7 (-29.2 - 34.5)	.700	1.11 (0.31 – 4.03)
Flatus: Reduced frequency	18 (53%)	5 (22%)	31.2 (0.7 - 55.0)	.002	4.05 (1.22 – 13.42)
Flatus: Reduced bother	16 (47%)	5 (22%)	25.3 (1.5 - 49.1)	.002	3.20 (0.97 - 10.60)
LFI: Reduced frequency	11 (79%)	1 (10%)	68.6 (40.2 - 97.0)	.006	#
LFI: Reduced bother	9 (64%)	0	64.3 (39.2 - 89.4)	.007	#
SFI: Reduced frequency	2 (68%)	2(100%)	-33.3 (-86.7- 20.0)	1.00	#
SFI: Reduced bothering	2 (68%)	1 (50%)	16.7 (-70.8- 104.1)	.800	#

* Analyzed with Mann-Whitney U test (four category scales) unless otherwise specified.

^δ Analyzed with ordinal logistic regression analyses. # Odds ratios are not performed due to low number having actual problem. CI: confidence interval; Empty: Difficult emptying bowel; Flatus: flatus leakage; LFI: Loose fecal incontinence; SFI: Solid fecal incontinence.

Paper V

Brækken, I.H, Majida,M, Ellström-Engh,M, and Bø,K, 2009. Morphological changes after pelvic floor muscle training measured by 3D ultrasound. Obstetr.Gynecol., 115, 317-324

Denne artikkelen ble tatt ut av den elektroniske versjonen av doktoravhandlingen i Brage på grunn av copyright-restriksjoner. Artikkelen er tilgjengelig på: http://dx.doi.org/10.1097/AOG.0b013e3181cbd35f

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Appendix 1

Approval from the Regional Medical Ethics Committee



UNIVERSITETET I OSLO Det medisinske fakultet

Stipendiat Cand.scient Ingeborg Hoff Brekken Norges idrettshøgskole Postboks 4014 Ullevål Stadion 0806 Oslo Regional komité for medisinsk forskningsetikk Sør- Norge (REK Sør) Postboks 1130 Blindern NO-0318 Oslo

Dato: 23.08.2005 Deres ref.: Vår ref.: S-05146 Telefon: 228 44 666 Telefaks: 228 44 661 E-post: <u>rek-2@medisin.uio.no</u> Nettadresse: www.etikkom.no

S-05146 Effekt av styrketrening på bekkenbunnsmusklene i forebygging og behandling av underlivsprolaps hos kvinner

Vi viser til e-post av 01.07.05 med vedlegg: reviderte informasjonsskriv og samtykkeerklæringer.

Komiteen tar svar på merknader til etterretning.

Komiteen har ingen merknader til revidert informasjonsskriv.

Komiteen tilrår at prosjektet gjennomføres.

Vi ønsker lykke til med prosjektet!

Med vennlig hilsen

Annetine Staff (sign) Overlege dr.med. Leder

ionet Tone Haug Rådgiver

Sekretær

Appendix 2

Approval from the Norwegian Social Science Data Services

Norsk samfunnsvitenskapelig datatjeneste AS

NORWEGIAN SOCIAL SCIENCE DATA SERVICES

Ingeborg Hoff Brækken Seksjon for idrettsmedisinske fag Norges idrettshøgskole Postboks 4014 Ullevål Stadion 0806 OSLO



Norway Tel: +47/ 55 58 21 17 Fax: +47/ 55 58 96 50 nsd@nsd.uib.no www.nsd.uib.no Org.nr. 985 321 884

Vår dato: 12.09.2005

Vår ref: 200501371 SM /RH

Deres dato:

Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 30.08.2005. Meldingen gjelder prosjekt:

13212	Effekt av styrketrening på bekkenbunnsmusklene i forebygging og behandling av underlivsprolaps hos kvinner
Behandlingsansvarlig	Norges idrettshøgskole, ved institusjonens øverste leder
Daglig ansvarlig	Ingeborg Hoff Brækken

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres slik det er beskrevet i vedlagt prosjektvurdering. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/register/

Personvernombudet vil ved prosjektets avslutning, 31.12.2005, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Re H-

Bjørn Henrichsen

mathursd

Siv Midthassel

Kontaktperson: Siv Midthassel tlf: 55 58 83 34

Avdelingskontorer / District Offices:

OSLO: NSD. Universitetet i Oslo, Postboks 1055 Blindern, 0316 Oslo. Tel: +47/ 22 85 52 11. nsd@uio.no TRONDHEIM: NSD. Norges teknisk-naturvitenskapelige universitet, 7491 Trondheim. Tel: +47/ 73 59 19 07. kyrre.svarva@svt.ntnu.no TROMSØ: NSD. SVF, Universitetet i Tromsø, 9037 Tromsø. Tel: +47/ 77 64 43 36. nsdmaa@sv.uit.no

Prosjektvurdering

Daglig ansvarlig

Ingeborg Hoff Brækken Seksjon for idrettsmedisinske fag Norges idrettshøgskole Postboks 4014 Ullevål Stadion 0806 OSLO

13212 Effekt av styrketrening på bekkenbunnsmusklene i forebygging og behandling av underlivsprolaps hos kvinner

Prosjektet er todelt og omfatter en hovedstudie (RCT) og en delstudie, reproduserbarhetstesting av ultralyd.

FORMÅL

Formålet med hovedstudien (RCT) er å undersøke effekten av bekkenbunnstrening i forebygging og behandling av underlivsprolaps hos kvinner. I tillegg vil det gjøres en klinisk case- kontroll studie for å undersøke mulige risikofaktorer og bakgrunnsvariabler hos kvinner med og uten tilstanden.

UTVALG-TREKKING-FØRSTEGANGSKONTAKT

1) Hovedstudien omfatter 100 kvinner i alderen 30-70 år som har født barn og som har underlivsprolaps med eller uten symptomer. 50 av disse vil motta behandling. For delstudie 1 (casekontroll) inkluderes 50 kvinner uten underlivsprolaps (kontroll), matchet for alder og antall barnefødsler, der kvinnene i hovedstudien (RCT) utgjør casene. I delstudie 2 reproduserbarhetsstudien inngår 12-20 kvinner med helsefaglig bakgrunn, herunder fysioterapikollegaer, fysioterapistudenter og medisinstudenter.

Utvalget til hovedstudien og delstudie 1 rekrutteres gjennom allmennpraktiserende leger/gynekologer i Oslo og Akershus, ved opphenging av en plakat på venterommet. I tillegg utgår forespørsel per e-post til kvinner i prosjektgruppens nettverk (privat og jobbsammenheng). Kvinnene som mottar e-post må selv vurdere om dette er aktuelt for dem. Kvinnene blir bedt om å videreformidle e-posten til andre kvinner i aktuell alder, jf. snøballsmetoden. Utvalget for delstudie 2 rekrutteres også fra prosjektgruppens nettverk.

INFORMASJON OG SAMTYKKE

Det gis skriftlig informasjon og innhentes skriftlig samtykke fra samtlige deltakere. Personvernombudet finner informasjonsskriv av 09.09.2005 tilfredsstillende.

DATAINNSAMLING

Hovedstudie og delstudie 1

Opplysninger samles inn gjennom spørreskjema, intervju og kliniske undersøkelser, inkludert ultralyd. Opplysninger samles inn i flere omganger.

Det innhentes opplysninger om demografi, sosioøkonomiske forhold, symptomer, kartlegging av årsaker og risikofaktorer, aktivitetsnivå, sykehistorie, endring av livsstil. Undersøkelse hos fysioterapeut omfatter måling av styrke og morfologi på bekkenbunnsmuskulaturen, måling av leddbevegelighet. Gynekologisk undersøkelse omfatter gradering av underlivsprolaps, måling av størrelse, funksjon og posisjon på bekkenbunnsmuskulaturen.

Det samles inn og registreres sensitive personopplysninger, jf. personopplysningsloven § 2 8 a) og c).

Delstudie 2

Opplysninger samles inn gjennom tilsvarende kliniske tester/målemetoder som hovedstudien. Målingene foretas to ganger med en ukes mellomrom.

REGISTRERING OG OPPBEVARING

Opplysningene føres på standardisert arbeidsdokument og registreres på pc i nettverkverkssystem tilknyttet Internett tilhørende virksomheten.

Manuelle skjema/rådata oppbevares i låsbart brannsikkert skap fysisk atskilt fra koblingsnøkkelen. Ved elektronisk registrering vil direkte personidentifiserende opplysninger erstattes med et referansenummer som viser til en navneliste. Listen oppbevares atskilt fra det øvrige materialet, på en lokal pc på harddisk på et eget passordbeskyttet område. En kopi av listen vil bli skrevet ut og oppbevart i en låsbar skuff på Norges idrettshøgskole.

Digitale ultralydbilder vil kun bli lagret på referansenummer.

Delstudie 2 avsluttes 31.12.2005. Datamaterialet vil da anonymiseres ved at verken direkte eller indirekte personidentifiserbare opplysninger fremgår, navneliste slettes.

Prosjektslutt i sin helhelt (hovedstudie og delstudie 1) er satt til 31.12.2008. Ved prosjektslutt vil navneliste/kodingsnøkkel for hovedstudien og delstudie 1 overføres til NSD for videre oppbevaring. Listen oppbevares fram til 31.12.2019 med tanke på en evt. oppfølgingsstudie.

Ombudet legger til grunn at utvalget er informert om dette. Ombudet forutsetter at en evt. oppfølgingsstudie meldes i god tid før utvalget kontaktes. Dersom ikke nytt samtykke foreligger vil datamaterialet anonymiseres innen 31.12.2019. Anonymisering innebærer at verken direkte eller indirekte personidentifiserbare opplysninger fremgår og navneliste/kodingsnøkkel slettes.

Personvernombudet legger til grunn at prosjektet er tilrådd av Regional komité for medisinsk forskningsetikk.

Prosjektet er støttet av Norske Kvinners Sanitetsforening og Helse og Rehabilitering.



Questionnaire used in the case-control and POP study



- Akershus Universitetssykehus

POPstudien

Spørreskjema til kvinner som deltar i studien:

Effekt av bekkenbunnstrening i forebygging og behandling av underlivsprolaps hos kvinner

Med underlivsprolaps mener vi nedfall/fremfall av underlivsorganer, slik som livmor, urinblære og endetarm.

Besvar spørsmålene ved å krysse av for det alternativet du synes passer best. Er du usikker kan du spørre fysioterapeuten som skal undersøke deg.

Skjemaet er optisk lesbart, det er derfor viktig at du skriver tydelig og at du er nøye med hvordan du krysser av i boksene. Der er viktig at krysset kommer på innsiden av boksen (firkanten). Hvis deler av krysset kommer på utsiden av boksen vil ikke skjemaet bli lest automatisk. Sett kun **ett LITE kryss** for hvert spørsmål, hvis ikke noe annet er spesifisert. Skiv med blokkbokstaver (STORE BOKSTAVER) der dette er aktuelt.

Opplysningene i skjemaet er fortrolige, og er underlagt taushetsplikten.

Tusen takk for at du støtter forskning på kvinnehelse! Lykke til med utfyllingen!

Vi vil be deg fylle ut dette skjemaet og ta det med til undersøkelsen hos fysioterapeuten sammen med samtykkeerklæringen (bak på informasjonsskrivet).

Du har fått time hos fysioterapeut Ingeborg Hoff Brækken:

Oppmøte: Hans og Olaf fysioterapi, Torggata 16, o181 Oslo (3 etg). Tlf resepsjon: 22993140

Norske Kvinners Sanitetsforening

	Fylles ut av terapeut
Dato:	Kodenr
Navn:	
Adresse:	
The privat: The mobil:	
E-postadr:	
	Treningsgruppe (A)
Fødselsnummer (11 siffer):	_ Alder: ar Kontroll POP (B)
Høyde cm	Kontroll frisk (CC)
Genetisk opprinnelse. Hvilket opphav har dine fore	eldre? (Flere kryss hvis din mor og far har ulikt opphav)
🗌 Europeisk (hvit/amerikaner med opphav fra Europ	pa)
Amerikansk urbefolkning (indianere, inuitter)	
Afrikansk	
Asiatisk (Kina, Japan, Korea, Mongolia)	
Øygruppene i Stillehavet inkl. urbefolkning i Aust	ralia
Usikker Høveste utdennelse (kun ett knyss)	Dersonlig instakt
	200.000 - 249.000
	250.000 - 299.000 over 550.000
Vrke/profesion (STORE BOKSTAVER)	Stillingsprosent (%) (ikke i arbeid
Hvor ofte opplever/ opplevde du belastende løft på	arbeidsplassen?
Sjelden eller aldri	
Mindre enn 20 ganger ukentlig	
🗌 Mer enn 20 ganger ukentlig	
10-20 ganger daglig	
Mer enn 20 ganger daglig	
Arbeider/ arbeidet du stående og/ eller gående?	Vil du klassifisere arbeidet ditt som fysisk krevende
Sjelden eller aldri	Ja
🗌 Av og til, men ikke daglig	
🗌 Ja, mindre enn 50% av tiden	
Ja, mer enn 50% av tiden	Nei
Tror du selv at du har underlivsprolaps? Har e	en lege fortalt deg at du har underlivsprolaps?



PROLAPS – ÅRSAKER OG SYMPTOMER

 \langle

Dette er et standardisert spørreskjema for underlivsprolaps som brukes blant annet i Danmark.

Har du fått en avrivning/ rift til endetarmens lukkemuskel/ ringmuskel?	
2hølsi	
Har du kronisk bronkitt eller astma? Får du østrogen behandling?	Nei Ja Nei Ja type Tabletter/ plast
Røyker du?	Nei Ja sigaretter pr dag
Spørsr	nål 3
Hvor lenge har du eventuelt hatt symptomer på undelivsprolaps (utbuling i skjedeåpning og/eller tyngdefornemmelse)?	Har ikke symptomer Mindre enn 0,5 år 0,5 til 1 år 1-2 år Mer enn 2 år
Hvor raskt har eventuelt symptomene endret seg?	Har ikke symptomer Forbedring siste år Forværring siste år
Hvordan endrer eventuelle symptomer seg i løpet av dagen?	 Har ikke symptomer Verst på mogenen Verst på dagen Verst på ettermiddagen Verst på kvelden
Spørsr	nål 4
Hommor at eventualt underliverralans dag	Huis In or dat day (att aller flore syar)
i det daglige liv?	Ved arbeid i hjemmet
🗌 Nei, eller mindre enn en gang i måneden	Ved arbeid på arbeidsplassen
🗌 Ja, 1 til 3 ganger i måneden	Ved fysiske utfoldelser (sport_daps)
🗌 Ja, en til flere ganger i uken	Inder selskaneligheter
🗌 Ja, en til flere ganger om dagen	Begrenser muligheter til å reise
Spørsr	nål 5
Føler du at noe buler ut fra, eller inn i skjeden?	Hvis Ja, er det et problem for deg?
Ja, 1 til 3 ganger i måneden	Moderat problem
La en til flere ganger om dagen	Stort problem
Spørsr	nål 6
Har du følelse av trykk eller tyngde mot underlivet?	Hvis Ja, er det et problem for deg?
Nei, eller mindre enn en gang i måneden	
Nei, eller mindre enn en gang i måneden	Lite problem
 Nei, eller mindre enn en gang i måneden Ja, 1 til 3 ganger i måneden Ja en til flere ganger i uken 	Lite problem

Vannlatingssy	mptomer	
Spørsmål 7		
Lekker du urin ved hoste, nysing eller fysisk aktivitet, slik som sport eller rask gange? Nei, eller mindre enn en gang i måneden Ja, 1 til 3 ganger i måneden Ja, en til flere ganger i uken Ja, en til flere ganger om dagen	Hvis Ja, er det et problem for deg?	
Spørsmå	ål 8	
ekker du urin ved sterk vannlatingstrang? Rekker ikke frem til toalettet) Nei, eller mindre enn en gang i måneden Ja, 1 til 3 ganger i måneden Ja, en til flere ganger i uken Ja, en til flere ganger om dagen	Hvis Ja, er det et problem for deg? Ikke noe problem Lite problem Moderat problem Stort problem	
Spørsmå	§ 9	
Må du skynde deg til toalettet pga sterk vannlatingstrang (UTEN urinlekkasje) Nei, eller mindre enn en gang i måneden Ja, 1 til 3 ganger i måneden Ja, en til flere ganger i uken Ja, en til flere ganger om dagen	Hvis Ja, er det et problem for deg? Ikke noe problem Lite problem Moderat problem Stort problem	
Spørsmå	l 10	
Har du vanskeligheter med å tømme blæren? Nei, eller mindre enn en gang i måneden Ja, 1 til 3 ganger i måneden Ja, en til flere ganger i uken Ja, en til flere ganger om dagen Hvor ofte løfter du opp fremre skjedevegg (trykke mot underlivet) for å tømme blæren? Ofte Iblant Noen ganger Aldri	Hvis Ja, er det et problem for deg?	
Spørsmå		
Har du blitt behandlet for urinveisinfeksjon det SISTE ÅRET? Dei Ja, 1 til 2 ganger Ja, 3 til 4 ganger Ja, 5 eller flere ganger	Hvis Ja, er det et problem for deg? Ikke noe problem Lite problem Moderat problem Stort problem	

Avføringss	ymptomer
12838 Spørsr	năl 12
Lider du av forstoppelse /avføringen er hard og	Hvis Ja, er det et problem for deg?
vansklig å få ut?	Ikke noe problem
🗌 Nei, eller mindre enn en gang i måneden	
🔄 Ja, 1 til 3 ganger i måneden	Moderat problem
🗌 Ja, en til flere ganger i uken	Stort problem
la, en til flere ganger om dagen	
	nål 12
Brukor du avføringsmidlor?	Hvis Ia, or dat at problem for dag?
Nei, eller mindre enn en gang i måneden	
	Lite problem
🔄 Ja, 1 til 3 ganger i maneden	Moderat problem
🔄 Ja, en til flere ganger i uken	
🗌 Ja. en til flere ganger om dagen	Stort problem
Spørsr	nål 14
Har du vanskeligheter med å tømme tarmen?	Hvis Ja, er det et problem for deg?
🗌 Nei eller mindre enn en gang i måneden	lkke noe problem
	Lite problem
🗌 Ja, 1 til 3 ganger i måneden	
🗌 la en til flere ganger i uken	
\Box is on til flore ganger om dagen	Stort problem
Hvor ofte løfter du opp bakre skiedevegg (trykke	
mot underlivet) for å tømme tarmen?	
mot undernvety for a tømme tarmen:	🔄 🗋 Iblant
	Noen ganger
Spørsr	năl 15
Har du vanskeligheter med å holde på luft?	Hvis Ja, er det et problem for deg?
Nei, eller mindre enn en gang i måneden	lkke noe problem
	Lite problem
🔄 Ja, 1 til 3 ganger i maneden	Moderat problem
🔄 Ja, en til flere ganger i uken	
🗌 Ja, en til flere ganger om dagen	Stort problem
Spørsr	nål 16
Har du vanskeligheter med å holde på tynn/	Hvis Ja, er det et problem for deg?
flytende avføring?	
Nei, eller mindre enn en gang i måneden	L Ikke noe problem
	Lite problem
🗌 Ja, 1 til 3 ganger i måneden	Moderat problem
Ja. en til flere ganger i uken	
la en til flere ganger om dagen	Stort problem
Spørst	Ndi 17
nai uu valiskeligileter meu a noide pa normal/fast	nvis Ja, ei uet et problem for deg?
aviøring:	🗌 Ikke noe problem
📃 Nei, eller mindre enn en gang i måneden	
🔄 Ja, 1 til 3 ganger i måneden	Moderat problem
🔲 Ja, en til flere ganger i uken	Stort problem
Ja, en til flere ganger om dagen	
Spørsr	nål 18
Hvor ofte har du avføring?	Er dette et problem for deg?
Elere ganger daglig	lkke noe problem
	Lite problem
□ nver eller river annen dag	
🔄 1 til 2 ganger i uken	Moderat problem
Sjeldnere enn en gang i uken	Stort problem
Bruker du bukpressen (trukker du) ved pufering?	Hvis la hvor ofto trukker du?
Biukei uu bukpiesseli (liykkei uu) ved avtøring?	
🔄 Nei, jeg trykker ikke	🔄 Mindre enn en gang i måneden
🗍 Ja. relativt lett	🗌 🗌 En til flere ganger i måneden
\Box is relative moderat	
	En til flere ganger i uken
🔄 Ja, relativt hardt	5 Ved hver avføring
	, <u> </u>

Seksuelle symptomer		
Spørsmål 19		
Har du hatt samleie det siste halve året?	Hvis du ikke har hatt samleie, er det da pga: (ett eller flere svar) Ubehag fra underlivsprolaps Smerter ved samleie Tørrhet og svie i skjeden Urinlekkasje ved samleie Du har mistet lysten Du har ingen partner Partner har mistet lysten/ impotent	
Spørsmål	20	
Hvor ofte har du samleie? Mindre enn en gang i måneden En til 3 ganger i måneden En til flere ganger i uken En til flere ganger om dagen Spørsmål Mar du seksuelle vanskeligheter/problemer? Nei, eller mindre enn en gang i måneden Ja, nesten hver gang (besvar spørsmålene til høyre)	Er du tilfreds med hyppigheten? Ja Nei, det er for ofte Nei, der er for sjeldent 21 Hvis du har svart Ja og har problemer, er det pga: (ett eller flere svar) Ubehag fra underlivsprolapset Smerter ved samleie Tørrhet og svie i skjeden Urinlekkasje ved samleie Du har mistet lysten Du er redd for å forverre prolapset Partner har mistet lysten/ impotent	
	lngen av overstående	
Spørsmål	22	
Hvis du har svart Ja på spørsmål 21 angående seksuell vanskeligheter	Er det et problem for deg?	
╴┣╴ _┫		

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🗌 Nei, gå til grått felt 🗌 Ja, mekaniske symptom (trykk, tyngde, utbuling, sårhet), angi hovedproble 🗌 Ja, vannlatingssymptom (lekkasje, økt trang, tømning), angi hovedbroblem ☐ Ja, avføringssymptom (luft, lekkasje, tømning), angi hovedproblem:

m:					
:					

Hvis du svarte ja på både mekaniske- og vannlatingssymptomer, hva kom først?

Symptom fra urinveiene kom først	🗌 Mekaniske symptom kom først
----------------------------------	-------------------------------

Hvis du har mekaniske symptom, hvordan blir disse/dette påvirket av anstrengelser (ex: tunge løft)?

🗌 Uforandret 🔄 Bedre 🗌 Verre	
Vi vil be deg om å fylle ut disse spørsmålene tidligere. Dett er standardiserte spørsmål so	, selv om vi har spurt om deler av dette m bli benyttet innen forsknig.
Når lekker du urin? (Ett eller flere svar) Aldri, har ikke urinlekkasje Før du kan komme deg på toalettet Når du hoster eller nyser Når du sover Når du er fysisk aktiv eller trener Når du er ferdig på toalettet/ kler på deg Uten spesiell grunn Hele tiden	Hvor ofte opplever du urinlekkasje? Aldri, har ikke urinlekkasje Ca en gang i uken, eller mindre 2 - 3 ganger i uken Ca en gang per dag Flere ganger daglig Hele tiden Hvor store mengder tror du at du lekker om gangen? Har ikke urinlekkasje - lekker ikke noe Dråper - små mengder Små skvetter - moderate mengder Større mengder
Hvor mye påvirker en eventuell urinlekkasje deg i Sett en ring rundt et tall mellom o (ikke i det hele 0 1 2 3 4 5 6 7 8 9	ditt hverdagsliv? e tatt) og 10 (svært mye) 10
Hvor ofte har du de siste seks månedene hatt smerte underlivet? nedre deler av i Aldri (siste 6 mnd) Mindre sens av soms inder som som inder som	r fra: magen? nedre deler av ryggen? mnd) Aldri (siste 6 mnd)

🗌 Mindre enn en gang i uken	🗌 Mindre enn en gang i uken	🗌 Mindre enn en gang i uken
🗌 1 – 2 ganger i uken	🗌 1 – 2 ganger i uken	🗌 1 – 2 ganger i uken
🗌 Hver eller hver annen dag	🗌 Hver eller hver annen dag	🗌 Hver eller hver annen dag
Flere ganger daglig	Flere ganger daglig	🗌 Flere ganger daglig
1		
	7	

12838 G	enerelt
Har du i løpet av de siste 2 månedene hatt smerte	r fra (ett eller flere kryss):
🗌 Rygg 🗌 Hofte 🗌 Kne 🗌 Nakke	🗌 Skulder 🔄 Hånd/ fot 🔄 Andre ledd
Har du fått skulderen din ut av ledd noen gang?	Er du født med hofteleddsdysplasi?
🗌 Ja 📄 Nei 📄 Vet ikke	🗌 Ja 📄 Nei 📄 Vet ikke
Har du hatt eller har du strekkmerker i huden?	Har du hatt, eller har du åreknuter?
🗌 Ja 🔄 Nei 🔄 Vet ikke	🗌 Ja 📄 Nei 📄 Vet ikke
Har din mor/ bestemødre hatt plager fra underlive	t ? Får du lett "blåmerker"?
Har du kunnet gå ut i spagat/splitt?	Gror sår i huden lett?
🗌 Vet ikke 🗌 Nei 🗌 Ja, tidligere 🗌 Ja	, også nå 🗌 Normalt 🗌 Ja 🗌 Nei
Но	monstatus
Hvordan har din menstruasjon vært de siste tre m	ånedene?
🗌 Regelmessig 📄 Uregelmessig 📄 Ingen r	nenstruasjon, alder ved siste menstruasjon var 📃 år
Har du svettetokter? Tar du hormo	onpreparat?
🗌 Ja 🔄 Nei 🔄 Usikker 🔄 Ja, navn:	
Tilta	ak/ trening
Hvilke tiltak har du iverksatt for dine eventuelle s	ymptomer? Fylles ut av de som trener bekkenbunnen!
Har ikke symptomer Kirurgi	Antall repetisjoner hver gang (totalt):
Bekkenbunnstrening Bind, truseinnlegg	
Elektrostinulering Hyppige dobesøk	
Annet, spesifiser:	Antall sekunder per sammentrekning:
Føler du at du klarer å løfte bekkenbunnen opp og	g inn i bekkenet?
JaNeiVetikke	Hvor har du lært øvelsene? (Ett kryss)
Har du trent bekkenbunnstrening hos fysioteraper	It tidligere?
🗌 Ja 🔄 Nei 🔄 Vet ikke	Lege
Trekker du sammen bekkenbunnsmusklene før du	hoster og nyser?
]Ja]Nei]Usikker	Avis, brosjyre, ukeblad e.l.
Trener du bekkenbunnsmusklene nå?	øler du at du kan stoppe strålen ved slutten av en vannlating? –
Ja, periodevis når jeg føler at jeg trenger det	Ja Nei Usikker
Ja, minst 1 gang per uke	øler du at du kan stoppe strålen midt i en vannlating?
L Ja, 1-2 ganger i uken	סי <u>הואו הואוגא</u> ו
Ja, hver dag	
Tusen takk for at du tok	deg tid til å fylle ut skjemaet!
Det setter	vi stor pris pa: 8



Booklet to the women in the PFMT group of the POP study

POP studien

(pelvic organe prolapse)



Registrering av daglig hjemmetrening

Takk for at du støtter forskning på kvinnehelse. Din innsats vil kunne hjelpe andre kvinner og deg selv!



Bekkenbunnsmusklene

Bekkenbunnsmusklene ligger nederst i bekkenet og danner "gulvet" i kroppen. Musklene gir støtte til bekkenorganene (blære, urinrør, skjede, livmor og endetarm), og skal automatisk trekke seg sammen ved alle økninger i trykk ovenifra. På denne måten holdes organene på plass og åpningene i det lille bekken stenges slik at lekkasje fra urinveier og tarmsystem hindres.

Underlivsprolaps (POP) defineres som nedfall av en eller flere deler av: fremre vaginalvegg (blære, urinrør), bakre vaginalvegg (tarm) og livmorhals eller hele livmoren. Det er rapportert at så mange som over 30% av alle kvinner har en eller annen form for underlivsprolaps. De fleste av disse har ikke symptomer.

Test på riktig bekkenbunnstrening

Sitt på armlene eller bordkant. Kjenn at underlivet løftes litt opp fra underlaget når du trekker sammen bekkenbunnsmusklene. Ta i så hardt at du kjenner at det skjelver litt innvendig i skjeden. Musklene i sete og lår skal ikke strammes, men hvis du tar i hardt vil nedre deler av magen trekkes litt inn. Slipp sammentrekningen uten å presse nedover. Forsøk å kjenne forskjell på når du har avslappet bekkenbunn og når du strammer.

Forsøk å stanse strålen når du tisser. Er du litt svak i disse musklene kan det være vanskelig å stanse strålen når et renner som verst. Forsøk derfor på slutten av en vannlating, når det bare drypper litt. Bruk dette som en test og ikke som trening, da dette kan forstyrre evnen til å tømme blæren helt.



Viktig INFORMASJON!

Trekk alltid sammen bekkenbunnsmuskulaturen før tunge løft, hosting og nysing.

Ikke utsett toalettbesøk, men gå på toalettet når du føler trang til det. Bruk god tid, og la tarmene få arbeide.

Forsøk å unngå å trykke nedover. Dette skaper press på muskulaturen.



Tenk deg at skipet illustrerer bekkenorganene (livmor, blære, urinrør, endetarm), fortøyningene er leddbånd og vannet er bekkenbunnsmuskulaturen. Ved å fylle vann i havna (bekkenbunnstrening) vil skipet kunne flyte og draget i fortøyningene reduseres!



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Når du trener skal du sammentrekninger dı	ı gjennor ı utfører	nfør i hv	e3: erav	serie / sei	er (A rien€	,B,C e un), f) der	∕ll in rikti	n ar g da	ntall ito ([.]	1,2,5	3,4	÷													almH	Į	T	-	2	2	-	licki Licki	rørets cemuskel	
Husk at det er bedre gjøre mange svake s	å gjøre f ammenti	ærri rekr	e sa inge	۳۳. ۲	entre	ekni	ngei	r me	ш ра	aksi	mal	krat	ft en	۵ ۵												End	letarm		Skjede		Clines		Sym Bek	fryse kenbunns- kler	

Treningsprogram

Trekk sammen rundt alle åpninger (urinrør, skjede og endetarm), løft opp og inn. Ta i så hardt du kan. Forsøk å holde i 6-8 sekunder før du slipper rolig ned, ikke press ned. Gjenta 8-12 repetisjoner i 3 serier (A,B, og C). Start med færre repetisjoner om du synes dette er for hardt.

Det er bedre å gjøre færre sammentrekninger opp mot maksimal kraft enn å gjøre mange svake sammentrekninger. Når du klarer 12 kraftige sammentrekninger i 3 serier kan du gjerne på toppen av "holdet" utføre 3-4 hurtige sammentrekninger, pass på å ikke "slippe holdet" mellom hver av disse.

Velg en eller flere av disse utgangstillingene. Du kan gjerne notere datoen for når du bytter øvelse ved siden av hvert bilde:

1. Ligg på magen med ett ben ut til siden



2. Knelende: Sitt på knærne med bena fra hverandre. føttene sammen og albuene i gulvet.



3. Sitt på stol/bord med bena godt fra hverandre. Hold armene på knærne



5. Stå med bena fra hverandre. Hold på setemusklene og kjenn at de er helt slappe. Det kan være lettere å kjenne hvor du skal ta i hvis du legger en hånd under bekkenet.

4. Sitt i skredderstilling





Vi i prosjektgruppen ønsker deg lykke til med treningen!

Vennlig hilsen prosjektgruppen:

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