DISSERTATION FROM THE
NORWEGIAN SCHOOL OF
SPORT SCIENCES
2017

Merete Kolberg Tennfjord

Pelvic floor muscle function, vaginal symptoms and symptoms of sexual dysfunction in first time mothers:

a cohort and a randomised controlled trial

NIH NORWEGIAN SCHOOL OF SPORT SCIENCES

nih.no

Merete Kolberg Tennfjord

Pelvic floor muscle function, vaginal symptoms and symptoms of sexual dysfunction in first time mothers:

a cohort and a randomised controlled trial

DISSERTATION FROM THE NORWEGIAN SCHOOL OF SPORT SCIENCES • 2017

ISBN 978-82-502-0544-4

Contents

Acknowledgements

Over three years of work has come to an end and it is time to move on. I must admit, I have truly stepped out of the comfort zone doing this research. But hopefully by bringing more attention to this field of women's health, more openness around common problems during pregnancy and after childbirth could be achieved.

This project was carried out in cooperation with the Norwegian School of Sport Sciences at Akershus University Hospital (Ahus) in the period 2009-2014. We gratefully acknowledge funding through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

My sincere gratitude goes to all of you who made this dissertation possible, especially to all the women participating in this project.

Especially I would like to thank

My main supervisor Kari Bø you gave me the opportunity to start as a research assistant and apply for funding for what was going to be this PhD. You believed in me and gave me opportunities to co-author several other research articles and to write a book-chapter. I am forever thankful. You have encouraged me to work hard, deliver in time and to be critical. Your knowledge, wisdom and passion for this field have truly inspired me. Thank-you for sharing your great knowledge and for introducing me to this new world. I hope we will continue to work together in the future.

My co-supervisor Marie Ellström Engh and co-author of all papers. Your clinical expertise and knowledge into the field of women's health has been of huge impact to this work. Getting to know you and work with you has been a privilege. Your kindness, support and comfort have meant everything. Thank-you so much for your excellent and constructive feedback and for always keeping in mind the clinical aspects of this research. I would love continue working with you in the future.

Jette Stær-Jensen and co-author of paper I-III, Franziska Siafarikas and co-author of paper II-III, and Gunvor Hilde and co-author of paper I-III. I feel so lucky being part of this excellent research team. Together with Kristin Gjestland and Tone Breines Simonsen you had done most of the data collection when I started and I am truly impressed on the enormous amount of work you have put through. You have my deepest respect and I have tried my very best to carry

forward what was "given" to me. Thank-you for fruitful discussions, laughter, support and friendship. Thank-you for putting your own busy work aside for answering all questions I have had throughout this period. A special thanks to Gunvor Hilde for introducing to this project and for taking care of me when I started the project, despite your own deadlines. You have been my extra set of eyes and ears and I am grateful for your valuable feedback, discussions and friendship.

Vigdis Skøld and Ingvild Sandholt at the Physical Therapy department at Ahus; thank-you for supervising the training participants in the RCT. Your work is impressive and most valuable. A special thanks to Vigdis Skøld for participating in the data collection of Paper IV and for being a fantastic colleague at the Physical Therapy department.

Natalie Michelle Evensen for kindly providing room for data collection for paper IV and for recruiting patients. Your help was outstanding.

Ingar Holme and Morten Wang Fagerland at the Norwegian School of Sport Sciences. Thank-you for your statistical advice and guidance and for your patience when discussing statistical approaches for my papers.

Haldor Husby, Ishtiaq Khushi and Bjørg Merete Rørvik at the Health Services Research Unit (HØKH) at Ahus: Thank you for all your work and help handling data gathered from the electronic questionnaires, getting access to delivery data, and ensuring safe storage of data.

Ingeborg Hoff Brækken; thank-you for all your work in preparation of this study and for supervising the training participants in the RCT.

Cathrine Reimers and Tuva Kristine Halle. I truly appreciate us working together. Tuva, I look forward the follow-up project and to continue working with you.

I would also express my gratitude to

Department of Obstetrics and Gynaecology at Ahus: Special thanks to all the staff at the out-patient clinic. Your great collaboration, support and patience have been most valuable.

The Physical Therapy Department at Ahus and Kolbotn Fysikalske Institutt: thanks for kindly providing room for the exercise classes. Also sincere thanks to Ellen Haug for assistance during the exercise classes at Ahus, babysitting the babies when needed.

Midwifes working in the community primary health care: thank-you for your help with recruiting patients.

My colleagues and friends at the Department of Sport Medicine, Norwegian School of Sport Sciences. I have seen my-self as very fortunate being part of this unique and excellent working environment. Thanks for all the support and help, fruitful discussion and for shearing everyday work and life in general. You are all very much appreciated and I am sad now that my time as a PhD student at SIM3 is over.

Catherine Planke at Bekkensenteret and Helle Aasgaard at the Physical Therapy department, both at Ahus: thank-you for the opportunities to work in the clinic and participate in the multidisciplinary team at Ahus. It has truly been enriching.

Hilde Løset Myrvang and Elisabeth Gløersen Prøsch: I am so grateful for being part of a fantastic working environment at Sandvika Aktiv. Thank-you for your kindness and for "allowing" me to work as much and as little as I can. A special thanks to Hilde for organizing the patient recruitment in Paper IV and for being a really good friend.

Researches at the Department of Obstetrics and Gynaecology at Ahus, led by Anne Eskild and Marie Ellström Engh: thanks for including me in your group and believing in me. The meeting at "the Villa" has been truly enriching, both scientific but also on a personal level. Sincere thanks to my fellow PhD students, sharing office at "the Villa", for your kindness and for bringing me up when I was down.

The administrative staff, Nina Viksløkken Ødegård, Karin Anne Vassbakk and Reidun Skårerhøgda at HØKH, Ahus, and Solveig Sunde and Tone Øritsland at Department of Sport Medicine, Norwegian School of Sport Sciences: thank-you for your valuable help when needed. Especially thanks to Solveig and Tone for taking care of everything at all times.

Librarians at Ahus and Norwegian School of Sport Sciences: thank-you for helping out with articles and references.

My dear friends: thank you for your sincere care, encouragement and friendship along the way. I see my-self fortunate having you as my friends.

My parents, and family on my side and on Tor-Erik's side: A huge thanks for your interest and support along the way and for helping out with the children when needed. It has been of most importance.

Lastly, my husband Tor-Erik and our two beautiful children Kristian and Sigrid. Tor-Erik you are a solid rock and you keep my feet to the ground when I am lost from time to time. Your support during hard times and good times has meant the world to me. Kristian and Sigrid, words cannot

express how proud I am of being your mother. Thank-you both for coming along on endless meetings, courses and seminars and for bringing so much happiness and joy into my life.

Thank you all!!!!

Oslo, June 2017

Merete Kolberg Tennfjord

List of papers

This thesis is based on the following original papers, which are referred to in the text by their Roman numerals:

I. Tennfjord, M.K., Hilde, G., Stær-Jensen, J. et al. Int Urogynecol J (2014) 25: 1227. doi:10.1007/s00192-014-2373-2. Dyspareunia and pelvic floor muscle function before and during pregnancy and after childbirth.

II. Tennfjord MK, Hilde G, Stær-Jensen J, Siafarikas F, Engh ME, and Bø K. Coital incontinence and vaginal symptoms and the relationship to pelvic floor muscle function in primiparous women at 12 months postpartum: A cross-sectional study. J Sex Med 2015;12:994–1003.

III. Kolberg Tennfjord M, Hilde G, Stær-Jensen J, Siafarikas F, Ellström Engh M, Bø K. Effect of postpartum pelvic floor muscle training on vaginal symptoms and sexual dysfunction—secondary analysis of a randomised trial. BJOG 2016;123:634–642.

IV. Tennfjord, M.K., Engh, M.E. & Bø, K. Int Urogynecol J (2017). doi:10.1007/s00192-017-3290-y. An intra –and interrater reliability and agreement study of vaginal resting pressure, pelvic floor muscle strength and muscular endurance using manometer.

Abbreviations

3D	three dimensional
4D	four dimensional
BMI	body mass index
CI	confidence interval
EMG	electromyography
ICC	intraclass correlation coefficient
ICIQ-VS	International Consultation on Incontinence Questionnaire Vaginal Symptoms
ICIQ-FLUTSsex	International Consultation on Incontinence Questionnaire FLUTSsex
MRI	magnetic resonance imaging
MVC	maximal voluntary contraction
N	Newton
PFD	pelvic floor dysfunction
PFM	pelvic floor muscle
PFMT	pelvic floor muscle training
RCT	randomized controlled trial
RR	relative risk
SD	standard deviation

Note regarding references in background chapter:

In general, references are updated throughout this dissertation. References related to our research area (vaginal symptoms and symptoms of sexual dysfunction during and after pregnancy) reflect our knowledge of the field before project start (January 2010) in the background chapter. Literature related to our research area published during the project period will be included in the discussion chapter in light of the findings from this dissertation.

Summary

Number of women reporting dyspareunia at each time point from pre-pregnancy until 12 months after delivery was 27.8% at pre-pregnancy, 30.5% at gestational 22, 41.4% at gestational week 37, 44.6% at six months and 33.1 % at 12 months after delivery. The majority reported severity of dyspareunia as "a little". There was no difference between women with and without dyspareunia in relation to PFM variables or delivery variables. Longitudinal data showed new cases of dyspareunia during pregnancy and after delivery, but total prevalence of dyspareunia declined throughout the study. Most women with dyspareunia prior to pregnancy and those with new symptoms during pregnancy were symptom free by 12 months after delivery. Other vaginal symptoms were prevalent (73.4%) 12 months after delivery, but few of the symptoms were severe, and 34.5% reported the symptoms to interfere with their sexual life. Overall bother of the vaginal symptoms were low (mean 1.4 out of 10). The women reporting "vagina feels loose or lax" had lower vaginal resting pressure, PFM strength and muscular endurance than women without the symptom; mean difference: 3.6 cmH_2O (95%CI 0.7, 6.6), 9.0 cmH_2O (95%CI 2.6, 15.4) and 80.0 cmH_2Osec (95%CI 32.6, 127.5), respectively. Six months postpartum no significant difference in outcome variables between groups for the total study sample (n=175) or in the stratum with no defects (n=120) were found. In the stratum with major defects of the levator ani muscle (n=55) at post intervention significantly fewer women in the training group had symptoms of "vagina feels loose or lax" than the control group; RR: 0.55 (95% CI: 0.31, 0.95, p=0.03). The results indicate that PFMT may have a preventative effect of "vagina feels loose or lax" in women with major levator ani defects. Bias and minimal detectable change for Camtech AS was found to be -2.44 ±8.7 cmH_2O for vaginal resting pressure, -0.22 ±7.6 cmH_2O for PFM strength and 0.75 ±59.49 cmH_2Osec for muscular endurance (intrarater). Bias and minimal detectable change was 1.36 ±9.0 cmH_2O for vaginal resting pressure, 2.24 ±9.0 cmH_2O for PFM strength and 15.89 ±69.7 cmH_2Osec for muscular endurance (interrater). Camtech AS seems less accurate for the strongest women. A statistically significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement.

Sammendrag

Dyspareuni er vanlig både før, under og etter graviditet og forekomst var 27.8% før graviditet, 30.5% ved gestasjonsuke 22, 41.4% ved gestasjonsuke 37, 44.6% ved seks måneder og 33.1 % ved 12 måneder etter fødsel. De fleste kvinnene rapporterte graden av dyspareuni som "liten". Ingen statistisk signifikant forskjell mellom bekkenbunnsvariabler og fødselsvariabler mellom kvinner med og uten dyspareuni ble funnet. Longitudinelle analyser viste nye tilfeller av dyspareuni under graviditet og etter fødsel, men den totale forekomsten ble redusert gjennom studiet. 73.4% (130) av kvinnene rapporterte minst et vaginalt symptom, mens 34.5% (61) rapporterte minst et vaginalt symptom som påvirket seksuallivet. Symptomene «ødela» i liten grad seksuallivet. Kvinner som rapporterte "skjede føles romslig/slapp" hadde lavere vaginalt hviletrykk, bekkenbunnsstyrke og muskulær utholdenhet enn kvinner uten symptomet; gjennomsnittforskjell 3.6 cmH_2O (95 % KI 0.7, 6.6), 9.0 cmH_2O (95 % KI 2.6, 15.4) og 80.0 cmH_2Osek (95 % KI 32.6, 127.5), respektivt. Seks måneder etter fødsel var det ingen signifikant forskjell på utfallsvariabler mellom trening og kontroll i den totale gruppen (n=175) eller i stratum uten skade (n=120). I stratum med skade av levator ani muskelen (n=55) ved post intervensjon var det signifikant færre kvinner i treningsgruppen som hadde symptomet "skjede føles romslig/slapp" sammenlignet med kontroll gruppen; RR: 0.55 (95% KI: 0.31, 0.95, p=0.03). Bekkenbunnstrening kan ha en mulig forebyggende effekt på "skjede føles romslig/slapp" hos kvinner med levator ani skade. Bias og minste reelle endring med Camtech AS var for vaginalt hviletrykk: -2.44 ±8.7 cmH_2O, for bekkenbunnsstyrke -0.22 ±7.6 cmH_2O og for muskulær utholdenhet 0.75 ±59.49 cmH_2Osek (intrarater). Bias og minste reelle endring for vaginalt hviletrykk var 1.36 ±9.0 cmH_2O, for bekkenbunnsstyrke 2.24 ±9.0 cmH_2O og for muskulær utholdenhet 15.89 ±69.7 cmH_2Osek (interrater). Camtech AS virker mindre sikkert for de sterkeste kvinnene. En statistisk signifikant forbedring i bekkenbunnsvariabler må overstige den minste reelle forskjell.

Introduction

In 2015, 59 901 deliveries took place in Norway [1]. Pregnancy and childbirth are potential risk periods for developing pelvic floor dysfunctions (PFD), including symptoms of sexual dysfunction [2], which are highly prevalent during this period of life [3]. The pelvic floor muscles (PFM) is thought to be of importance for aspects of female sexual function [4], but this relationship is poorly understood, especially during pregnancy and after childbirth. Several theories exist with lack of supporting evidence leading to hypothesis and "expert advice" about what to do and what not to do [4-7].

As health professionals we see women seeking help with a desire to "get back to normal" after giving birth. There is also an increasing focus into sexual health in media. The need for preventative and treatment alternatives is therefore of most importance. Physiotherapists working in this area, has in-depth knowledge into the pelvic floor and the PFM, with the aim to prevent and treat pain and dysfunctions, and to optimize physical activity and training [8]. Based on current guidelines, pregnant women are encouraged to stay physically active throughout pregnancy and participate in exercises that strengthen and maintain good physical health [9]. In addition, pelvic floor muscle training (PFMT) is recommended as treatment for women with urinary incontinence after childbirth [10]. There are however lack of studies investigating effect of PFMT on symptoms of sexual dysfunction after childbirth.

Background

Anatomy of the female pelvic floor

The term pelvic floor is related to the compound structure, which closes the bony pelvic outlet. The term PFM is related to the muscular layer of the pelvic floor [11]. The pelvic organs (bladder, vagina, urethra, uterus and bowel) are supported by the pelvic floor structures consisting of the vaginal wall, the endopelvic fascia, the arcus tendineus fascia pelvic and the levator ani muscle, and skeletal structure where they attach [12, 13].

Bony pelvis

The bony pelvis consists of the ischium, ilium, sacrum, pubis and the coccyx. These parts are connected by three main joints; the symphysis pubis and the two sacroiliac joints. The bony pelvis is further held together by ligaments; the sacrospinous, sacrotuberous, sacrococcygeal and the sacroiliac ligaments [14]. The pelvis has two basins: the major (greater) pelvic and the minor (lesser) pelvis. The abdominal viscera fill the major pelvis, while the minor pelvis is the narrow continuation of the major pelvis inferiorly and is closed by the pelvic floor [15].

Pelvic floor muscles

The PFM are regular skeletal muscles [16]. There are some literature claiming that the PFM consists predominantly of type I (slow twitch) fibers together with a small number of type II (fast twitch) fibers [13, 17, 18]. However, the literature is controversial. The PFM comprise a superficial layer including: ischiocavernosus, bulbospongiosus and the transverse perineal muscles and a deep layer including the levator ani muscles [12]. The levator ani muscle consists of three parts: the pubococcygeus, the puborectalis, and the iliococcygeus muscles [19]. The pubococcygeus muscle can further be divided into the puboanal, puboperineal and the pubovaginal muscle [19]. Some authors are in favour of the term puboviseralis for this portion of the muscle [20-22] (Figure 1). Different muscle fibre directions, origins and insertions makes up the subdivisions of the levator ani muscle [21, 22]. The puboviseralis and the puborectalis muscles form a U-shape as they originate from the pubic bone on either side of the midline and pass behind the rectum to form a sling. The iliococcygeus muscle arises laterally from the arcus tendineus levator ani and forms a horizontal sheet that spans the opening in the posterior region of the pelvis, thereby providing support which the pelvic organs rest [21, 23, 24]. The connective tissue (fascia) covering the superior and the inferior surfaces of the levator ani muscle and the levator ani muscles make up the pelvic

diaphragm [24]. The anterior-posterior midline cleft of these muscles is called the levator hiatus, and is the location of which the urethra, vagina and rectum pass [25].

Innervation

The levator ani -and coccygeus muscles are innervated through direct branches coming from spinal level S3 to S4 [26] (S5) [27]. The pudendal nerve originates from S2 to S4 and includes sensory and motor fibres and innervates the external urethral -and anal sphincters, the superficial perineal muscles, labial skin and clitoris [26-28]. The structures responsible for the sexual arousal responses are largely a product of spinal cord reflex mechanisms. The afferent reflex arm is primarily through the pudendal nerve, whereas the efferent reflex arm is a coordinated somatic and autonomic activity [29].

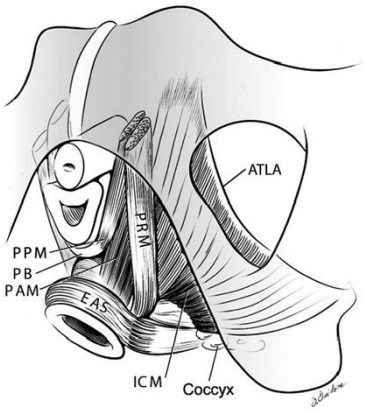

Figure 1*. The levator ani muscles from below showing the arcus tendineus levator ani (ATLA); puboanal muscle (PAM); perineal body (PB); puboperineal muscle (PPM); iliococcygeal muscle (ICM); puborectal muscle (PRM). Copyright © DeLancey 2003.*

From: Kearney,R.; Sawhney,R.; Delancey,J.O. 2004. Levator ani muscle anatomy evaluated by origin-insertion pairs. Obstet.Gynecol., 104,168-173.

With permission from J.O. DeLancey

Pelvic floor muscle function

The PFM together with the supportive ligaments and fascia contribute to maintain continence for urine, flatus and faces while allowing voiding, defecation, sexual intercourse and childbirth, in addition to the overall function to support the abdominal and the pelvic viscera [23, 30-33].
The function of the PFM is performed by contraction and relaxation. In its resting state, the pelvic floor gives support to the pelvic organs [11]. A normal PFM is a situation in which the PFM can voluntarily and involuntary contract and relax. Voluntary contraction will be normal or strong and voluntary relaxation complete (back to or below the resting line after contraction) [11]. Both contraction and relaxation must be present and are needed to allow adequate function of the PFM [11]. A voluntary PFM contraction can be described as an inward lift and a squeeze

around the urethra, vagina and the rectum, resulting in urethral closure, stabilization, and resistance to downward movement. It is the levator ani muscles (the puboviseral muscle and the puborectal muscle) that are primarily responsible for this squeeze and lift function [13, 24, 34-38]. Using transperineal ultrasound and during a PFM contraction, the displacement of the bladder neck was recorded in the cranio-anterior directions [39]. The iliococcygeus muscle acts in a similar manner as the puboviseral muscle [13, 37, 38].

The levator ani adapts to changes in posture and activity when needed; during rest, during voluntary and involuntary contractions and during defecation [32]. The mean inward lift of the PFM during maximum contraction in a magnetic resonance imaging (MRI) study of 16 continent and incontinent women has shown to be 10.8 mm (SD 6.0). During straining, the mean movement among the same women was 19.1mm (SD 7.4) [35]. During a PFM contraction it has also been shown that mean incremental increase in maximum urethral closure pressure may range from 8 [40] to 23.2 (SD 8.4) [41] to 47.3 cmH_2O [42].

A PFM contraction of the levator ani has been found upon clitoral and cervical stimulation [6]. This contraction is thought to be mediated through the vaginolevator reflex [6]. During contraction ballooning of the upper vagina and a drop in vaginal pressure is seen, while the lower two-thirds of the vagina narrow with a pressure increase. These changes are thought to enhance the sexual response and prepare for the reproductive process [6]. Both involuntary and voluntary contractions of the PFM (levator ani, bulbocavernosus and ischicavernosus) has been said to contribute to and intensify sexual arousal and orgasm [5]. The involuntary contractions has been described as a product of spinal cord reflex mechanisms [6, 29], but if and how a voluntary PFM contraction may contribute to further arousal or intensify orgasm is not clear. One theory is that during a strong voluntary PFM contraction, the bulbocavernosus may further exacerbate erection of the clitoris [6] equivalent to the penile erection [19], intensifying orgasm. The increased blood flow to the clitoris, vagina and labia leads to engorgement of these organs [6, 29, 43].

Examination of pelvic floor muscle function

Vaginal resting pressure is the resting condition of the muscle with no voluntary muscle contraction [11]. PFM strength is the force-generating capacity of a muscle and is often expressed as maximal voluntary contraction (MVC). MVC is the attempt of a muscle to recruit as many muscle fibers as possible in order of developing force [44]. Local muscular endurance is twofold; the ability of a muscle to sustain near maximal or maximal force, assessed by the time a person is

able to maintain a maximal static or isometric contraction, and the ability to repeatedly develop near maximal or maximal force determined by the number of repetitions [45]. Vaginal resting pressure, PFM strength and muscular endurance may be assessed in several ways; visual observation and palpation, electromyography (EMG), dynamometry, imaging, such as MRI and ultrasonography, and vaginal pressure measurements (manometry). It is difficult to measure and no gold standard exists [11, 46].

Visual observation and palpation

A correct PFM contraction has been described as an inward lift and a squeeze around the urethra, vagina and rectum that could be observed at the perineum and felt by vaginal examination of the PFM [34, 47]. Palpation of the PFM is relatively easy to perform and may be used to assess the PFM and surrounding areas at rest, during contraction and relaxation [11], but inter-observer variability has reported to be high [48]. The modified Oxford 6 point scale is commonly used amongst physiotherapists to quantify PFM strength [49]. However, the ability to discriminate between weak, moderate, good or strong contractions has been questioned [50, 51], although contradictory findings have been reported [52, 53]. Visual observation and vaginal palpation has been recommended to qualitatively determine if a contraction is present or not, rather than to quantify degree of PFM strength [46, 50, 51].

Electromyography

EMG has shown to be reasonable reliable, responsive, sensitive and specific to differentiate between normal, denervated and reinnervated and myopathic muscles, but its validity is questioned [54]. It is a measure of recruitments of motor units and not PFM strength [55]. The use of vaginal probes with electrodes embedded on their surfaces has been used as a convenient way to measure surface EMG from the PFM [56]. Reliability studies show conflicting results [56, 57].

Dynamometry

Dynamometry measures forces produced by a muscle contraction, and consists of an upper fixed speculum branch with an adjustable lower branch. It measures PFM strength, endurance, speed of contraction and passive forces expressed as newton (N). There are several dynamometers being developed [58], the first being the Michigan dynamometer [59]. Reliability studies on different dynamometers has concluded good reliability for maximum strength; Intraclass correlation coefficient (ICC)>0.80) [60] [61-63]. The Montreal dynamometer has shown acceptable intrarater reliability for the passive properties of the PFM (dependability indices of 0.75-0.93) [64] and

promising construct and convergent validity [51, 65]. Poorer intrarater reliability has been found for muscular endurance (dependability indices of 0.10) [62]. However, the device is not commercially available and its use is restricted to research purposes [58].

Imaging

MRI is capable of providing anatomical details of the pelvic floor, both normal anatomy and levator trauma [24], but due to cost, access and contraindications the adoption into clinical practice has been difficult [66]. The use of ultrasound has therefore emerged and three dimensional (D) ultrasound has shown to be well suited for pelvic floor imaging and biometric measurements [66, 67]. 3D/4D ultrasound gives real-time imaging of maneuvers such as a PFM contraction in any user-definable plane and gives access to the plane of the levator hiatus [68]. The method has been tested showing good reliability for assessment of pelvic floor anatomy and function [69-71], and for diagnosis of major levator ani muscle defects [72, 73]. It has also shown to be able to quantify squeeze and lift during a PFM contraction [39] and may be used as biofeedback during teaching and training and as an outcome measure after PFMT and rehabilitation [68, 74].

Manometer

In physiotherapy practices, manometer is the most common method of assessing PFM function; vaginal resting pressure, PFM strength and muscular endurance [46, 75]. There is a variety of devices in use, but they all measure squeeze pressure in either mmHg, hPa or cmH_2O. In general manometer has been established as a reliable assessment method for PFM strength [76-79] if there is a simultaneous inward movement of the perineum seen by observation and palpation [80]. Measurement of vaginal resting pressure using Peritron has also shown good reliability (ICC 0.74-0.77), while muscular endurance measured as multiple repeated muscle contractions (20 fast contractions) concluded poor reliability (ICC 0.05-0.42) [77]. Due to different manometers being tested with different measurement properties, comparing results across studies are difficult [81]. While good reliability and validity for PFM strength has been concluded using Camtech AS [78, 80], the reliability and agreement of vaginal resting pressure and muscular endurance has not been assessed, nor has interrater reliability and agreement for PFM strength.

Female pelvic floor dysfunction

PFD are listed as urinary incontinence symptoms, bladder storage and sensory symptoms of the bladder, voiding and post micturition symptoms, pelvic organ prolapse symptoms, symptoms of sexual dysfunction and anorectal dysfunction, lower urinary tract pain and/or other pelvic pain, and lower urinary tract infection [82]. However, some authors do not acknowledge symptoms of

sexual dysfunction and pelvic pain as part of PFD [83, 84]. Most common in clinical practice and clinically definable conditions are urinary incontinence, anal incontinence and pelvic organ prolapse [85].

The understanding of the cause of the above PFD is far from complete, probably due to the complexity of their multifactorial nature and the overlapping of symptoms [86]. Rather than a single underlying factor, it is more probable a combination of anatomical, physiological, genetic, lifestyle, and reproductive factors that interact throughout a woman's life span to contribute to PFDs [85, 86]. The underlying factors have been described as a three phased model: (Figure 2)

Predisposing factors (e.g. growth and development, genetics, nutritional factors).

Inciting factors (e.g. birth induced changes, surgery)

Intervening factors (e.g. age-related changes, occupational lifting, obesity, medications) [86].

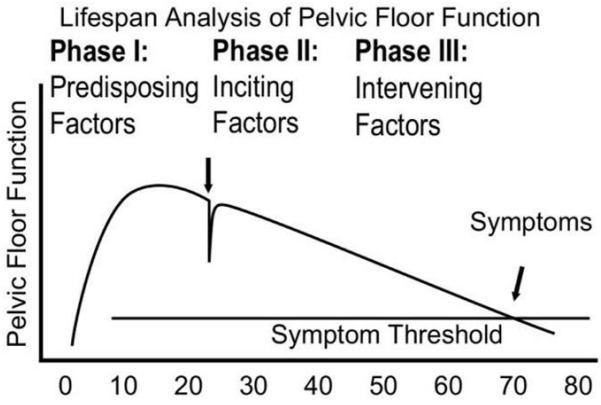

Figure 2. *Integrated lifespan analysis of pelvic floor function*

This graphical display of the abstract concept of pelvic floor function tracks the functional reserve throughout different phases of a woman's lifespan. Initially, pelvic floor structure growth in late teens leads to a fully developed pelvic floor. Vaginal birth affects pelvic floor function. Finally, age-related deterioration occurs until a symptom threshold is reached where the functional reserve present earlier in life is lost. (© DeLancey 2007)

From: DeLancey,J.O; Kane,Low L.; Miller,J.M.; Patel,D.A.; Tumbarello,J.A. 2008. Graphic integration of causal factors of pelvic floor disorders: an integrated life span model. Am.J.Obstet.Gynecol, 199,610-61.
With permission from J.O.DeLancey

Diagnosis

The use of validated questionnaires assures that data are responsive, reliable and quantifiable. Validated questionnaires utilized to assess female sexual function may be generalized or condition-specific [87]. Generalized questionnaires focuses on evaluating sexual function in a general population and not specifically in women with PFD. These types of questionnaires may not be sensitive enough to detect differences in sexual function due to e.g. incontinence and pelvic organ prolapse. There are several general questionnaires focusing on sexual function [88-90]. Sexual History Form 12 (SHF-12) is a short version of a 24 item questionnaire [89]. The Female Sexual Function Index (FSFI) is a validated 19-item self-report measure of female sexual function, which gives scores on six domains and measures sexual desire, arousal, lubrication, orgasm, satisfaction and pain [88, 91, 92]. The GRISS-questionnaire is a self-administered questionnaire covering sexual satisfaction, pain, interest in and satisfaction with sex, arousal, ability to orgasm, adequacy of vaginal tone and general feeling [90]. Prior to project start, we were not aware of any studies undertaken to validate generalized questionnaires during pregnancy or in women after childbirth.

There are several condition-specific questionnaires focusing on sexual function for use in women with PFDs [93-98]. The questionnaires differ in type of questions and focus on sexual function. The International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) has shown good validity, reliability and is sensitivity to change and includes 14 items on vaginal symptoms and the impact of vaginal symptoms on quality of life and sexual life [94]. International Consultation on Incontinence Questionnaire FLUTSsex (ICIQ-FLUTSsex) has been established as a reliable, valid and responsive assessment tool to address sexual issues in women with urinary symptoms/incontinence [96]. Questionnaires assessing sexual function and pelvic organ prolapse are that developed by Mouritsen et al [97], the original long form of the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ) [95] and the validated short form of the PISQ (PISQ-12) [99]. The Australian Pelvic floor questionnaire is an interviewer-administered pelvic floor questionnaire that integrates bladder, bowel and sexual function, pelvic organ prolapse, severity, bothersomeness and condition-specific quality of life in an urogynecologic population [93]. Prior to project start, we were not aware of any studies undertaken to validate the condition specific questionnaires during pregnancy or in women after childbirth. ICIQ-FLUTSex has been translated and validated into Norwegian language [100].

Definition and classification

The symptoms addressed in this thesis are listed below as defined in current terminology papers [82, 101].

Prolapse symptoms: "A departure from normal sensation, structure or function, experienced by the woman in reference to the position of her pelvic organs" [101].

More specific terminology:

Vaginal bulging: "complaint of a bulge or something coming down towards or through the vaginal introitus. The woman may state she can either feel the bulge by direct palpation or see it aided with a mirror" [101].

Pelvic pressure: "complaint of increased heaviness or dragging in the suprapubic area and/or pelvis" [101].

Urinary incontinence symptoms:

More specific terminology:

Coital incontinence: "complaint of involuntary loss of urine with coitus" [101]. This present thesis does not separate coital incontinence during penetration or during orgasm.

Symptoms of sexual dysfunction

"A departure from normal sensation and/or function experienced by a woman during sexual activity" [101].

More specific terminology:

Dyspareunia: "complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration" [101].

Vaginal laxity: "complaint of excessive vaginal laxity" [101].

Other vaginal symptoms that may influence sexual function [94]

- Dragging pain in lower abdomen [94]
- Vaginal soreness [94]
- Reduced sensation in or around the vagina [94]

- Vaginal dryness [94]
- Vagina feeling tight [94]

Prevalence

There are several large population based studies on PFD and sexual disorders with prevalence rates up to 40% in women of all ages [84, 102, 103]. Most common reported symptoms have been urinary incontinence, followed by faecal incontinence and pelvic organ prolapse, of which proportion of women reporting symptoms have shown to increase with parity [84] and age [84, 103].

Other PFD and symptoms of sexual dysfunction have been dyspareunia with a prevalence between 3.9-7% [102, 103], and vaginal laxity (5.2%) [103]. Coital incontinence in incontinent women has been reported to range between 10% and 27% [104, 105]. However, it has been suggested that the numbers of women with PFD and symptoms of sexual dysfunction might be underreported as women seldom report symptoms of sexual dysfunction or that women have less often sex due to problems [106, 107].

Vaginal symptoms and symptoms of sexual dysfunction during pregnancy and after childbirth

PFD, including symptoms of sexual dysfunction, are prevalent among women after delivery [3, 108-113], ranging from 30-60% in the first three months [108, 110, 111, 113]. Six months after delivery, symptoms have shown to gradually decline, with numbers ranging from 17-27% [3, 108-111]. Studies performed in primiparous women report dyspareunia as most common with similar rates [108, 110, 111]. Despite the high prevalence rates, few studies address bother of those symptoms [3, 114]. Overall impression from published research prior to project start in 2010 was that symptoms of sexual dysfunction, especially dyspareunia, is most common six months after delivery before it gradually declines [3, 114]. Few studies have confirmed this [109], whereas women seven months after delivery reported high pain levels as compared to early pregnancy (p-value <0.01) [115]. Other symptoms reported have been lack of vaginal lubrication, vaginal tightness and lack of muscle tone with prevalence of 26, 20, 12% six months after delivery, respectively [108]. Coital incontinence has been reported between 1-7% in pregnant and postpartum women [109, 116, 117], with a risk of underreported numbers [105, 107, 117].

There is reason to believe that symptoms of sexual dysfunction at pre-pregnancy and pregnancy may influence the situation after childbirth, but yet there are few longitudinal studies investigating

this relationship [3]. Serati et al [109] investigated de novo PFD six and 12 months after delivery in women with mixed parity, were almost half (46%) were excluded due to incontinence and sexual dysfunction.

Etiology and pathophysiology

PFD, especially urinary incontinence and pelvic organ prolapse seem to increase with age, parity and obesity [84, 103, 118]. Symptoms of sexual dysfunction, however, have found to decrease with increasing age [102] and the aetiology is often more diverse and complex than that of urinary incontinence and pelvic organ prolapse [4]. Further, having one or more PFD [29, 107, 119], not being in a relationship and having lower education have increased odds of experiencing symptoms of sexual dysfunction, such as dyspareunia [102, 119]. Symptoms of sexual dysfunction may be an end-product of a vicious circle and reveal little about the cause or pathophysiology [43, 107, 120].

Vaginal symptoms and symptoms of sexual dysfunction during pregnancy

Increases in PFM resting state and a reduction in PFM activity on straining, indicative of alterations in the contractile power of the muscle, has been found as a possible mechanism of the increasing weight and size of the uterus during pregnancy [121]. Further, hormones (relaxin, progesterone and estrogen) affect the biochemical composition of the pelvic floor tissue and leads to changes in the organization, orientation, and diameter of the collagen fibers, affecting the viscoelastic properties of the vaginal wall, the levator ani and the perineal body [122-124]. Physiological changes with increases in hiatal dimensions and bladder neck mobility has also been demonstrated by our study group [125].

A review on female sexual function during pregnancy concluded that sexual function had a significant global decline during pregnancy, particularly in the third trimester [114]. Of symptoms studied, vaginal pain was a barrier to sexual activity during the 3rd trimester ($p<0.001$), while symptoms of vaginal looseness and dryness was not [115]. Vaginal discomfort and dryness were significantly higher at the 3rd trimester compared to earlier in pregnancy in another study [126]. Closely linked factors studied have been sexual desire, frequency of intercourse and sexual satisfaction which have found to be influenced by fatigue and depression during pregnancy ($p<0.05$) [127].

Vaginal symptoms and symptoms of sexual dysfunction after childbirth

Review articles report an association between assisted vaginal delivery and degree of perineal trauma with sexual dysfunction [3, 43, 128]. However studies included in the reviews differ in type of questionnaires used to study sexual problems, study design (retrospective, prospective or cross-sectional), number of study participants, parity and length of follow up, making it difficult to draw overall conclusions. This reflects the conflicting evidence of the role of childbirth on sexual function, were some studies find an association with mode of delivery/delivery variables [108, 111, 112, 129-131] and others do not [109, 110, 113, 132-135]. Dyspareunia has by far received most attention in the above cited studies. Literature focusing on other vaginal symptoms and symptoms of sexual dysfunction are scarce.

Two years after the first delivery no association between dyspareunia and mode of delivery were found [132]. Six years after the index delivery, among 4214 women, women who had caesarean section reported better vaginal tone and sexual satisfaction compared to those having vaginal births or instrumental deliveries (p=0.002) [136].

Hormonal factors

At three months [110] and at six months after delivery [108, 111] breastfeeding has found to be associated with dyspareunia. Other studies show contradictory results [113, 115, 131]. Breastfeeding has a profound effect on postpartum hormonal levels [2]. In lactating women, high levels of prolactin suppress ovarian androgen and oestrogen production. Lower androgen levels may be a factor in lower sexual desire and lower estrogen levels may influence negatively on vaginal lubrication [5, 127]. Plausible, it may be that breastfeeding also indirectly affect PFM function [5]. Breastfeeding has also been found as an influencing factor on interest in sex [130], sexual desire, frequency of intercourse and sexual satisfaction [127]. Use of hormonal contraceptives seem to increase the risk of dyspareunia [137], but results are inconsistent [108].

Weakening of the pelvic floor muscles

Vaginal delivery is a risk factor for weakening of the PFM [24, 138, 139]. There is now a body of literature showing that soon after childbirth, decreases in levator ani resting pressure [121, 140, 141] and PFM strength occur [121, 135, 140-144]. Although PFM function seems to return to pre-pregnancy levels after some months [121, 135], Elenskaia et al [140] found that after one year, vaginal resting pressure was lower one year after delivery in primiparous women compared to pregnancy levels.

Weakening of the PFM may have a negative impact on sexual function [4, 145]. One theory is that "sagging" of the levator ani pull on the pudendal nerve, resulting in pelvic or perineal pain [6]. Another theory is that laxity or weakness of the PFM following childbirth cause vaginal hypoesthesia, coital incontinence and coital anorgasmia [5, 145]. The exact mechanism behind these theories is unclear.

A PubMed search prior to project start (January 2010) found two studies on PFM function and symptoms of sexual dysfunction in relation to childbirth [133, 146]. The study by de Souza Caroci et al [146] included 226 primiparous women during pregnancy and followed the women 30 days after delivery. The study found no association with weak PFM strength (assessed by perineometry and vaginal palpation) and dyspareunia. However, about half of the study population was lost to follow up. The study by Baytur et al [133] included 68 women >two years after delivery and found no association between low PFM strength and symptoms of sexual dysfunction, including dyspareunia.

Nerve injury

Vaginal delivery has shown to cause nerve denervation and alter PFM morphology and function [138, 139, 147, 148]. Lien et al [149] showed in a 3D computer simulation that the inferior rectal nerve branch of the pudendal nerve exhibited the maximum strain of 35% during the second stage of labour. Branches to the labia (the posterior labial nerve) exhibited far less strain (14.7%), mainly due to the lateral course of the branch along the pelvic sidewall. Increased duration of the second stage of labour and high fetal birth weight seems to be associated with pudendal nerve damage [139, 147, 148]. There is scant knowledge into studies investigating effect of nerve damage on symptoms of sexual dysfunction. However, due to the course of the nerve, damage to the pudendal nerve may lead to sensory, arousal and orgasm difficulty [150], and pelvic or perineal pain (dyspareunia and vulvodynia) [6]. The levator ani muscles are not innervated by the pudendal nerve, but through direct branches coming from spinal level S3 to S4 [26] (S5) [27]. Most likely there is an interaction between compression and strain during the second stage of labour as nerves within the pelvis are not so frequently injured [122, 149].

Role of connective tissue, ligaments and fascia

The connective tissue plays an important part in pelvic organ support [30, 33]. It may be alterations in the composition of ligaments and fascia during pregnancy, stretching and tearing of the connective tissue during delivery, as well as levator ani muscle weakness following childbirth that may lead to connective tissue abnormalities and possible loss of support [30, 33, 122, 123]. There are

limited knowledge into the link between connective tissue weakness and symptoms of sexual dysfunction. However, loss of pelvic organ support may result in PFD [30], further influencing female sexual function.

Levator ani muscle defects

Vaginal delivery may stretch and load the PFM beyond their physiological properties. Lien et al [151] showed that the medial part of the PFM (pubovisceral muscle) may be stretched three times their resting length during crowning of the foetal head. Other biomechanical studies have confirmed their findings [152, 153]. All women sustain stretching of their pelvic floor during birth, but only some experience injuries [122]. Several mechanisms for injury to the levator ani muscles have been proposed; neuropathy, tearing and stretching of the muscle, and compression [24]. Such defects of the levator ani muscles may occur unilateral or bilateral, and has shown to appear on imaging as an abnormal insertion of the muscle towards the pubic bone [72, 154]. Major levator ani defects have been found in 20-36% of women after delivery [154, 155]. The use of forceps and having a long second stage of labour has been associated with major defects of the levator ani [24, 156, 157]. Levator avulsion has shown to impact on PFM strength [158-160]. Levator avulsion may also alter pelvic floor anatomy and function [161], but not sexual activity three months after delivery [162].

Pelvic floor muscle training

Strength training

PFMT was introduced as early as 1948 by Kegel [47] with the focus on treating urinary incontinence and pelvic organ prolapse [34]. Based on results from updated Cochrane reviews, PFMT is recommended to be included in first-line conservative management programs for women with stress, urge, or mixed, urinary incontinence [10, 163] and pelvic organ prolapse [164]. The theory behind the rationale for strength training of the PFM is that the PFM, like other skeletal muscles, respond to strength training by improved neuromuscular function, increased muscular cross-sectional area, increased number of activated motor neurons and excitation, and improved muscle tone [165]. Strength training may also build up the structural support of the pelvic floor by elevating the levator plate inside the pelvis to a higher location and by enhancing hypertrophy and stiffness of the PFM and adjacent connective tissue [36].

Progressive overload embedded into the program design is a key component for maximizing strength, power, hypertrophy, and local muscular endurance [165, 166]. The key component is further

specific targeted training [167, 168]. This is achieved by performing a close to maximal contraction of the PFM as possible, without straining or the use of extra-pelvic musculature, and involves a squeeze and a lift of the PFM [11, 34, 80, 167]. Proper teaching of a correct PFM contraction is essential to achieve the desired effect of PFMT [34, 80, 169].

In PFMT the load may be altered in several ways; perform maximal contractions, lengthen the holding periods, increase the number of repetitions and sets completed, and reduce rest intervals [167]. The recommendations for strength training for novice adult trainers is; 8-12 repetitions maximum (60-70%), 1-3 set, 1-2 min rest in between sets, 2-3 days per week [166]. Training to improve local muscular endurance is recommended using high-volume and short rest interval workouts [165, 166]. Specific recommendations for local muscular endurance is using light to moderate load (40-60%) performed at a high number of repetitions >15, with short rest periods in between sets (<1 min), 2-3 days per week [166]. However, to improve muscular endurance, fatigue is a necessary component, and improvement in maximum strength usually improves local muscular endurance but not the other way around [16].

There is a significant interplay between neural and muscular adaptations during strength and power training [165]. In the initial phases of strength training, the gains in strength seem to be due to neural adaptions [170]. Later on, muscle hypertrophy becomes dominant [16, 170]. Recommended duration of training has been a minimum of 15-20 weeks [168], and Bø et al [171] found a significant effect after PFMT on PFM strength throughout a six months period of intensive training.

The physiological effects of strength training work directly on pelvic floor anatomy and function [36, 74] and may directly or indirectly influence female sexual function [172]. It has been demonstrated that women with stronger PFM has better orgasm and arousal potentials [173-175], better lubrication [174, 175] and report higher frequency of intercourse [176, 177]. It is not known whether this relationship exists amongst pregnant women or in women after childbirth.

Effect of pelvic floor muscle training on vaginal symptoms and symptoms of sexual dysfunction

Physical therapy, including PFMT, has been described as promising in treating aspects of sexual dysfunction in women [4, 145]. Combination therapy, including PFMT for certain pelvic floor pain conditions, has received Grade B recommendations [120].

Prior to project start in 2010, we identified six RCTs on the effect of PFMT for sexual dysfunction and symptoms of sexual dysfunction in women after delivery [178-180], in women with stress urinary incontinence [181] and in women with orgasmic disorders [182, 183]. After project start seven new RCTs were published in women with pelvic organ prolapse [184-187], in women with stress urinary incontinence [188, 189], and in gynecological cancer patients [190]. There were no new RCTs conducted during pregnancy or after childbirth after 2010. Results from all trials are summarized in Table 1. The RCTs varied in study population, type of intervention, training dosage, length and type of follow up, outcome measures and assessment methods of the PFM. Citak et al [178] was the only study investigating effect of PFMT in a healthy population. The search strategy revealed three non-randomized trials in women with urinary incontinence [191-193], showing some effect after pelvic floor rehabilitation, including PFMT. The PEDro score assessing quality [194] of the 13 RCTs ranged from four to eight and are summarized in Table 2.

Effect of pelvic floor muscle training on vaginal symptoms and symptoms of sexual dysfunction in the general female population

Six studies reported an overall positive effect of physical therapy for different aspects of sexual dysfunction: improved arousal, lubrication and orgasm, less problems with sex-life spoilt by urinary symptoms, increased control and stronger PFM, "tighter vagina", increased libido, less pain, increased sensibility and awareness around the pelvic floor, improved confidence and partner's sexual satisfaction [181, 184-186, 189, 190]. Of these, three studies included PFMT as the only treatment option [181, 184, 185]. Four studies showed contradictory results [182, 183, 187, 188].

Effect of pelvic floor muscle training on vaginal symptoms and symptoms of sexual dysfunction during pregnancy and after delivery

Two RCTs assessed the effect of PFMT after delivery [178, 179] and one study assessed the effect of PFMT during pregnancy [180]. Citak et al [178] reported improved arousal, lubrication and orgasm in favour of the intervention group seven months after childbirth, whereas the study by Mørkved et

al [180] found improved satisfaction with sexual life six years after the intervention. The RCT by Wilson and Herbison [179] showed no effect after PFMT on pain, interest in and satisfaction with sex, arousal, ability to orgasm, adequacy of vaginal tone and general feeling. The latter study had almost 37% loss to follow up with over twice as many in the intervention group. Differences in dosage, follow-up and start of the intervention period may also explain the conflicting results.

PFM strength improved in the study by Citak et al [178] and Mørkved et al [180], but not in the study by Wilson and Herbison [179]. There were no report of any association with improved PFM strength and improvement in sexual function.

Table 1*. Randomised controlled trials evaluating the effect of pelvic floor muscle training on female sexual function. From Tennfjord MK, Ellström Engh M, Bø K. Role of physical therapy in the treatment of female sexual dysfunction. In: Costantini E, Villari D, Filocamo M, eds., editors. Female sexual function and dysfunction: Springer, Cham; 2017.*

Author/year	Design	Study population	Intervention period	Dosage	Follow-up	Loss to follow up	Outcome measures	Results
During pregnancy and after childbirth								
Citak et al, 2010	Single blinded RCT	118 primiparous women (mean age 22.6)	4^{th}-7^{th} month postpartum	*PFMT*: 10 reps increasing to 15 reps daily, 2 sec contraction increasing to 5 and 10 sec *Control*: no treatment	*PFMT*: Telephone and meeting with nurse twice in the first month and once in the following months	Total: 43 (36.4%) Training:21 (17.8%) Control:22 (18.6%)	FSFI. PFM strength assessed by digital palpation and manometer	Positive effect in favor of training group on arousal, lubrication and orgasm. Improvement in PFM strength
Wilson and Herbison, 1998	RCT	230 incontinent primi/multi-parous women (mean age 28.4)	3-12 months postpartum	*PFMT*: 80-100 reps x 8-10 daily *Cones*: 20-100 g 15 min daily *PFMT and cones*: see above *Control Group:* standard treatment as recommended at hospital, but no	*PFMT and cones*: PT meeting 3, 4, 6 and 9 months after delivery	Total: 85 (36.9%) Intervention: 59 (25.7%) Control:26 (11.3%)	Postal questionnaire: pain, interest in and satisfaction with sex, arousal, ability to orgasm, adequacy of vaginal tone and general feeling. PFM strength and endurance assessed by	No between group difference

				follow up			perinometer	
Mørkved et al 2007	Single blind RCT (Abstract)	280 primiparous women with and without UI followed up after 6 years (mean age at inclusion 27.5)	Btw 20th and 36th months of pregnancy for 12 weeks	*PFMT*: 6–8 sec hold near maximum contraction with 3-4 fast contractions in 4 series. Resting period was about 6 seconds. Home training 8-12 repsx2 daily *Control*: no treatment	*PFMT*: Weekly group training led by PT	Total: 106 (38%)	Postal questionnaire: satisfaction with sex after delivery	Improved satisfaction in favor of training group
General female population								
Bø et al 2000	RCT	59 women with SUI (mean age 50.7)	6 months	*PFMT*: 8-12 x 3 daily (near maximum PFM contractions) *Control*: no treatment	*PFMT*: Weekly group training with PT	Total: 4 (6.8%) Training: 4 (6.8%) Control: 0	QoLS-N and B-FLUTS. PFM strength assessed with manometer	Fewer problems with sex-life spoilt by urinary symptoms in favor of training group. Improved PFM strength
Brækken et al 2014	Partially blinded RCT	109 women with POP (mean age 48.9)	6 months	*PFMT*: 8-12 x 3 daily (near maximum PFM contractions) *Control*: no	*PFMT*: Individual training weekly/every other week with PT	Total: 2 (1.8%) Training: 1 (0.9%)	POP-specific questionnaire, semi-structured interview, PFM function assessed	Improvement in sexual function in favor of training group. Improved PFM strength and

				treatment		Control: 1 (0.9%)	by manometer.	endurance, not vaginal resting pressure
Liebergall-Wischnitzer et al, 2012	RCT	187 women with SUI (mean age 46.7)	3 months	*PFMT*: 25 min exercises daily, rapid/prolonged/gradual contractions *Paula method*: 45 min exercises daily	*PFMT*: 6 group sessions with PT *Paula method:* Weekly private session with instructor	Total: 61 (32.6%) PFMT: 38 (20.3%) Paula: 23 (12.3%)	I-QOL and PISQ-12	Sexual function improved in both groups, no between group differences
Yang et al 2012	RCT (pilot)	34 women with gynecological cancer (mean age 52.4)	4 weeks	*Biofeedback*: 20 min with 40 cycles with 10 sec of maximum activity followed by 20 sec of relaxation. 20 min with an intensive core exercise session. Home training 10 reps x 2 daily *Control*: no treatment	*Biofeedback*: 45-min exercise session and a 30-min counseling session per week for 4 weeks led by PT	Total: 10 (29.4%) Training: 5 (14.7%) Control: 5 (14.7%)	Australian Pelvic floor questionnaire on sexual function. PFM strength assessed with perineometer	Improved sexual function, numbers being sexually active and PFM strength increased in favor of the training group. Improved PFM strength
Hagen et al 2014	parallel-group, multicenter	477 women with symptomatic POP (mean age 56.8	16 weeks	*PFMT*: Individualized: 10 sec maximum hold x 10	*PFMT*: 5 individualized	6 months:	PISQ-12	Sexual scores (interference of prolapse symptoms

	RCT	years)		and 50 fast contractions x 3 daily *Control*: no treatment	sessions led by PT	Training: 36 (16%) Control: 36 (16%) 12 months: Training: 75 (33.3%) Control: 77 (34.7%)		with sex life) improved at 6 months after intervention in favor of training group. 12 months after intervention no difference
Eftekhar et al 2014	RCT	90 women with grade <3 POP (mean age 36.5 years)	8 weeks	*Treatment:* Vaginal and anal biofeedback, infra-red, reinforcement exercises and relaxation including PFMT. PFMT included 6-8 sec of contractions with 6 sec rest in between for 15 min x 3 daily	*Treatment*: Home training taught by PT	Total: 0%	FSFI	Physical therapy improved orgasm and severe dyspareunia compared to surgical group. Libido and arousal improved in both groups with no between group differences

				Surgery: rectocele repair				
Wiegersma et al 2014	RCT	287 women with symptomatic, mild POP (mean age 64.3 years)	3 months	*Treatment:* PFMT, myofeedback, electrical stimulation, the knack, lifestyle advice (diet, body weight, toilet habits), PFM relaxation and general relaxation. PFMT: 2-3 times daily, 3-5 x per week *Control:* no treatment	*Treatment*: Once a week with PT at first, then every 2nd and 3rd week with an average of 7 visits.	Total: 48 (16.7%) Training: 31 (10.8%) Control: 17 (5.9%)	PISQ 12 PFM function (ability to contract and relax) measured by digital palpation	No effect and no improvement of PFM function
Chambless et al 1984	RCT	36 women with orgasmic disorder (mean age 27.4 years)	6 weeks	*PFMT:* 10 min daily *Placebo*: 10 nonsexual images concerning vaginal sensations 10 min daily *Control:* no treatment	*PFMT and placebo*: Weekly mail and telephone contact	Total: 21(58.3%) PFMT: 8 (22.2%) Placebo: 10 (27.7%)	SAI-E (arousal, anxiety, satisfaction), WSQ (orgasmic responsiveness, frequency of orgasm, stimulation) and expectancy due to treatment or assessment only. PFM strength	Higher expectancy scores in PFMT and placebo, but no between group differences. All groups improved in orgasm, but no between group differences. No improvement in strength.

						Control: 3 (8.3%)	assessed with perineometer	
Trudel and Saint-Laurent 1983	RCT	12 women with orgasmic disorder (mean age not stated)	8 weeks	*PFMT:* 3 sec contract and 3 sec relax with increasing intensity for 20 min daily *Sexual awareness, relaxation, breathing (SARB):* different exercises for 20 min daily	*Both groups*: Home training with weekly phone contact with experimenter	0%	SAI, SII, clinical questionnaire (sexual reactions, stimuli needed to reach orgasm)	No effect in main outcome: orgasmic responsitivity between groups. Higher scores for SARB group on sexual satisfaction, self-acceptance and perceptual accuracy scale, but no between group differences
Handa et al 2011	RCT	445 women with SUI, mean age 49.8 years	8 weeks (analysis done 3 months after intervention)	*Group 1:* continence pessary *Group 2:* behavioral therapy (pelvic floor muscle training and continence strategies) *Group 3:* combination therapy	*Group 1*: pessary fitted and used as desire to decrease UI *Group 2 and 3*: four visits over 8 weeks + home training with increasing difficulty over time	Total: 100 (22.5%)	Personal Experiences Questionnaire (SPEQ) (libido, arousal and dyspareunia) Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire	Change in measured aspects of sexual function did not differ among treatment groups. In those with improved SUI the combined therapy group had improved sexual

							(PISQ-12) PFM function measured with palpation	function compared to pessary group. In those with improved SUI the behavioral therapy had improved sexual function compared to pessary group. In those with no improved SUI, groups were similar. Change in PFM strength associated with improved SUI but not improved sexual function

SUI=stress urinary incontinence, POP=pelvic organ prolapse, PT=physical therapist, SUI=stress urinary incontinence, UI=urinary incontinence, RCT= Randomised controlled trials, FSFI=Female Sexual Function Index, QoLS-N= Quality of life scale, B-FLUTS = Bristol Female Lower Urinary tract symptoms, I-QOL= Incontinence quality of life questionnaire, PISQ-12=pelvic organ prolapse/urinary incontinence sexual questionnaire, SAI-E= sexual arousal inventory-expanded form, WSQ= Women's sexuality questionnaire, SAI= sexual arousal inventory, SII= sexual interaction inventory, International Consultation on Incontinence Modular Questionnaire sexual matters module (ICIQ-FLUTSsex), International Consultation on Incontinence Modular Questionnaire—Vaginal symptoms questionnaire (ICIQ-VS)

Table 2. *Methodological quality score (PEDro Scale) of controlled trials evaluating effect of pelvic floor muscle training in the general female population and during pregnancy and after childbirth. From Tennfjord MK, Ellström Engh M, Bø K. Role of physical therapy in the treatment of female sexual dysfunction. In: Costantini E, Villari D, Filocamo M, eds., editors. Female sexual function and dysfunction: Springer, Cham; 2017.*

Study	E	1	2	3	4	5	6	7	8	9	10	Total score
Citak et al 2010	+	+	-	+	-	-	+	-	-	+	+	5
Wilson and Herbison, 1998	+	+	-	+	-	-	+	-	-	+	+	5
Mørkved et al 2007 Abstract	+	+	+	+	-	-	+	-	-	+	+	6
Bø et al 2000	+	+	+	+	-	-	+	+	-	+	+	7
Brækken et al 2014	+	+	+	+	-	-	-	+	+	+	+	7
Liebergall-Wischnitzer et al, 2012	+	+	+	+	-	-	+	-	-	+	+	6
Yang et al 2012	+	+	-	+	-	-	+	+	-	+	+	6

Pilot												
Hagen et al 2014	+	+	+	+	-	-	+	-	+	+	+	7
Eftekhar et al 2014	+	+	-	+	-	-	-	+	+	+	+	6
Wiegersma et al 2014	+	+	+	+	-	-	+	+	+	+	+	8
Chambless et al 1984	+	+	-	-	-	-	+	-	-	+	+	4
Trudel and Saint-Laurent 1983	+	+	-	+	-	-	-	+	-	+	+	5
Handa et al 2011	+	+	+	+	-	-	+	-	-	+	+	6

E-eligibility criteria specified,1-subjects randomly allocated to groups, 2-allocation concealed, 3-groups similar at baseline, 4-subjects blinded, 5-therapist administering treatment, 6-assesors blinded, 7-measures of key outcomes obtained from >85% of subjects, 8-data analyzed by intention to treat, 9-statistical comparison between groups conducted, 10-point measures and measures of group variability provided.

+, criterion clearly satisfied, - criterion is not satisfied, ? not clear if criterion is satisfied. Total score is determined by counting the number of criteria satisfied, except "eligibility criteria satisfied" score is not used to generate the total score. Total scores are out of 10.

**point 4 and 5 are unable to meet satisfactory criteria in all studies as subjects allocated to PFMT and therapists administering the treatment are aware of the intervention*

Gaps of knowledge

Before project start there was lack of studies on:

1) Incidence and prevalence of dyspareunia and the relationship with PFM variables during pregnancy until 12 months after delivery. Presence of dyspareunia following childbirth has been well described, but there is lack of longitudinal studies on dyspareunia from before pregnancy till after childbirth, including level of bother. The evidence regarding PFM variables and dyspareunia are scarce. Furthermore the relationship with delivery variables and hormonal factors are conflicting.

2) The relationship between PFM variables and vaginal symptoms and coital incontinence 12 months after childbirth.

3) Conservative management on prevention or treatment of vaginal symptoms, coital incontinence and dyspareunia in primiparous women with and without major defect of the levator ani.

4) Intra –and interrater reliability and agreement of vaginal resting pressure, PFM strength and muscular endurance using Camtech AS, Sandvika, Norway.

Aims

Overall aims

The overall aims of this dissertation were: 1) to study presence of vaginal symptoms and symptoms of sexual dysfunction from before and during pregnancy and after childbirth, and study possible associations to PFM function, delivery variables and hormonal factors, 2) to evaluate effect of PFMT six months after delivery on vaginal symptoms and symptoms of sexual dysfunction in primiparous women with and without major levator ani defects, 3) to evaluate intra-and interrater reliability and agreement of vaginal resting pressure, PFM strength and endurance using manometer (Camtech AS).

Specific aims

Paper I: To study incidence and prevalence of dyspareunia cross-sectional and longitudinal, and level of bother from before pregnancy until 12 months after delivery. 2) To compare PFM variables in women with and without dyspareunia. 3) To compare delivery variables, numbers breastfeeding and numbers using hormonal contraceptives in women with and without dyspareunia.

Paper II: To study prevalence and bother of coital incontinence, vaginal symptoms and sexual matters 12 months after delivery, and whether coital incontinence and vaginal symptoms were associated with PFM variables.

Paper III: To study effect of PFMT on vaginal symptoms and sexual matters, dyspareunia and coital incontinence in primiparous women stratified by major or no defects of the levator ani muscle. To investigate whether a possible effect of PFMT was associated with a change in PFM variables.

Paper IV: To evaluate the intra- and interrater reliability and agreement of vaginal resting pressure, PFM strength and muscular endurance using manometer (Camtech AS).

Materials and methods

Study design and sampling

The papers were based on a prospective cohort study (Paper I-II), and a RCT (Paper III) (Figure 3) and an intra –and interrater reliability and agreement study (Paper IV). Paper I and II were a planned part of a prospective cohort study on pelvic floor changes and symptoms related to pelvic floor dysfunction during and after pregnancy [125, 195]. Data collection for paper I-III was performed at Akershus University Hospital in collaboration with the Norwegian School of Sport Sciences. The intra- and interrater reliability and agreement study was performed at a physiotherapy center (Vest-Helse) in Sandvika, Norway from March 2015 to April 2015. Women scheduled for delivery at Akershus University Hospital, Norway, from January 2010 until April 2011 were invited to participate when they attended their routine ultrasound examination at mid-pregnancy (N=2621).

In the RCT 175 primiparous were included six weeks after delivery (baseline). Follow up was at six months after delivery (post-intervention) (Figure 3). Paper III was a planned part of the RCT with the primary aim to assess the effect of PFMT on urinary incontinence after childbirth [196]. 2621 women (of all primiparous women scheduled for delivery between January 2010 until April 2011) were eligible for participation. From the cohort study (Paper I and II), 277 women who delivered vaginally and did not have a tear ≥3b were asked to participate in the RCT. Two-hundred-twenty-one women were eligible for participation (45 women had a caesarean section, six women had tears ≥3b, three had a stillborn delivery and two preterm delivery), of which 139 women agreed to participate. Thirty-six women were additionally recruited from the maternity ward at the hospital or from the community primary health care clinics within the same geographical area as the hospital.

The four papers had the following study design and samples:

Paper I: A cross-sectional study of 300 nulliparous women seen at four different time-points from mid-pregnancy until 12 months after delivery, including retrospective data from before pregnancy, and a longitudinal study based on the sample of 177 women attending all time points of the data collection. Data on dyspareunia from six weeks postpartum were excluded due to few women resuming sexual intercourse.

Paper II: A cross-sectional study 12 months after delivery of 177 primiparous women attending all time-points of the data collection.

Paper III: A two-armed assessor blinded parallel group RCT starting from six weeks to six months after delivery. One-hundred-seventy-five primiparous women were stratified on major levator ani muscle defects or not verified by transperineal ultrasound before randomization into either PFMT or control group.

Paper IV: An intra -and interrater reliability and agreement study of 23 women. Participants were tested twice on the same day by two independent assessors (intrarater). One week later MKT re-tested the same group of women at the same time-point as test one (interrater).

Figure 3*. Flowchart of study participants in the cohort study and RCT*

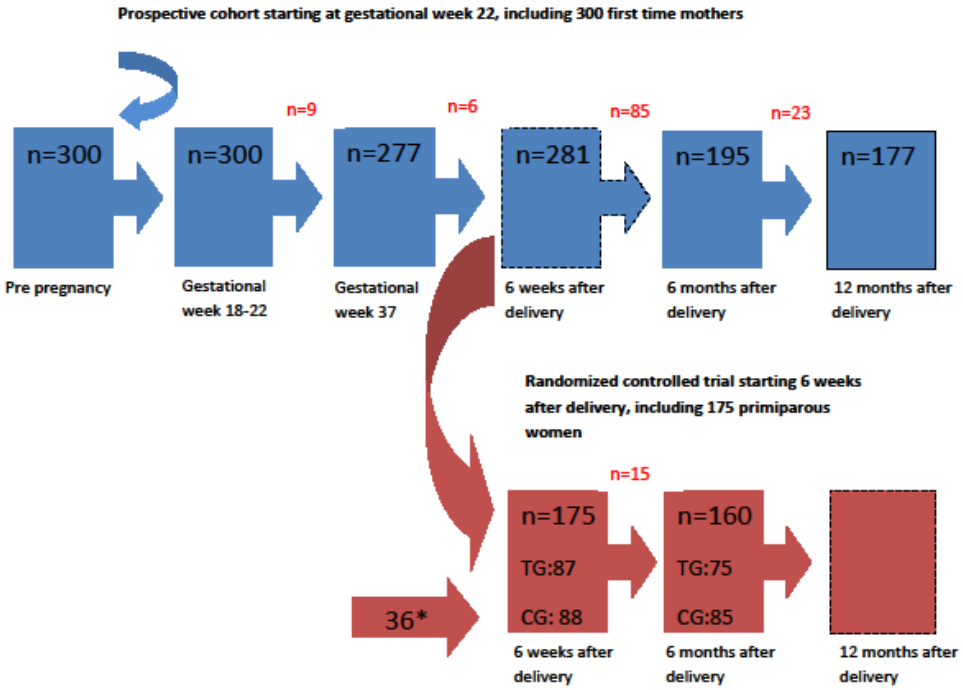

Figure illustrating the prospective cohort study (blue boxes) and the randomized controlled trial (red boxes), with numbers of participants at each stage of the data collection. Blue arrow indicating retrospective data for pre-pregnancy asked at gestational week 18-22. Red numbers is participants lost to follow up.

Paper I: Cross-sectional study including all time points of data collection (blue box with solid line), except six weeks after delivery (blue box with broken line). Longitudinal study following 177 women attending all time points of the data collection (blue box with solid line). Six weeks after delivery is not included (blue box with broken line).

Paper II: Cross-sectional study 12 months after delivery: n= 177 (blue box with solid line).

*Paper III: Randomized controlled trial, n=175, starting six weeks after delivery with a follow up at six months after delivery (red boxes with solid lines). 12 months after delivery is not included in this thesis (red box with broken line).TG=training group, CG=control group. *36 women were additionally recruited from the maternity ward at the hospital or from the community primary health care clinics.*

Inclusion criteria and clinical visits

Inclusion criteria

Paper I-II: Nulliparous, singleton pregnant woman able to speak and understand Scandinavian language were included. Exclusion criteria were multiple pregnancies and previous miscarriage after week 16 of pregnancy. Ongoing exclusion criteria were premature birth < week 32, stillbirth, serious illness to mother or child and subsequent pregnancies after six weeks of gestation. Women recruited to PFMT in the RCT (Paper III) were also excluded.

Paper III: Primiparous women able to understand Scandinavian languages who have had a vaginal delivery to a singleton infant after more than 32 weeks of gestation including normal or instrumental assisted deliveries were included. Women with and without vaginal symptoms were included. Exclusion criteria were caesarean section, ≥3b degree perineal tears and serious illness to mother or child. At the project hospital women with third or fourth degree perineal tears are routinely referred to physiotherapy for PFMT and could ethically not be allocated to a control group. Intrauterine foetal deaths/stillborn were also excluded.

Paper IV: Inclusion criterion was ability to contract the PFM correctly, defined as an inward movement and squeeze around the pelvic openings assessed by observation and vaginal palpation [34, 80]. Exclusion criterion was the inability to understand instructions given in any of the Scandinavian languages.

Clinical visits

The participating women came for appointed visits based on convenience with the routine controls at mid-pregnancy and six weeks after delivery. Further follow-up was scheduled six and 12 months after delivery (Figure 3)

Sample size

Inclusion of 300 nulliparous women into the cohort study (Figure 3) was based on sample size calculations for detecting changes in levator hiatus dimensions [125, 195].

Paper I-II: No specific sample size calculations were done to investigate presence of dyspareunia (Paper I) or for vaginal symptoms or sexual matters (Paper II). There were no sample size calculations to study associations between symptoms and vaginal resting pressure, PFM strength and muscular endurance during or after pregnancy. This present study was larger than the two studies on PFM function and dyspareunia available at project start [133, 146].

Paper III: Power calculation was done for the primary analyses on urinary incontinence [197] and was based on the results from a former study [198]. Since the study included stratified analysis on women with and without major levator ani defects, a sample size of 80 per group was estimated to be required. No specific power calculation was done for the planned secondary analysis on vaginal symptoms and symptoms of sexual dysfunction, but the trial aimed to include as many women as possible beyond what was estimated to be required. The small number of RCTs, variations in sample size and focus on different PFD in women after delivery [178-180], made it difficult to make sample size calculations for the present RCT during planning of the trial.

Paper IV: A convenient sample of 23 women was recruited to evaluate the intra –and interrater reliability and agreement of PFM function measured by manometer (Camtech AS). This was based on previous reliability studies in the field [76-79].

Data collection

Pelvic floor muscle function

For all studies (Paper I-IV) all participating women were given a short anatomy lecture and taught how to correctly contract the PFM using observation and palpation [34, 80] before measurement was taken. Vaginal resting pressure, PFM strength and muscular endurance were measured using a high precision pressure transducer connected to a vaginal balloon (Camtech AS, Sandvika, Norway) (Figure 4). The balloon catheter was compressed 10-20% to allow for air expansion at body temperature, before it was connected to the fibertip. A lubricating gel was applied to the balloon catheter. The device was positioned with the middle of the balloon 3.5 cm internal to the introitus in the vaginal high pressure zone [38, 199], a method found to be reliable an valid for assessment of PFM strength, with simultaneous observation of an inward movement of the catheter and no use of extra-pelvic muscle contraction [78, 80]. The atmospheric pressure on the balloon was calibrated to zero cmH_2O for each subject before it was placed in the vagina. Vaginal resting pressure was measured as the difference between the atmospheric pressure and the vaginal high pressure zone at rest, with no voluntary PFM activity, and was registered as cmH_2O. The measurement was taken before the first contraction and registered as a flat curve while the women was instructed to relax and given time to slowly breathe in and out. PFM strength was measured from the resting pressure line till the peak, not including the resting pressure, reported as the mean of three maximum voluntary contractions, and registered as cmH_2O. Local muscular endurance was defined as a sustained maximum contraction [45], and was quantified as the area

under the curve during ten seconds, measured during one attempt and registered as cmH_2Osec (Figure 5). The measurements were standardized and performed by two trained physiotherapists blinded to the questionnaire data and recorded with the woman in supine position, with legs bent and one leg resting against the wall on a flat bench with a small pillow underneath the head. The physiotherapists involved in the cohort study (Paper I-II) and RCT (Paper III) were different than the ones involved in the reliability and agreement study (Paper IV), but the same procedure were followed.

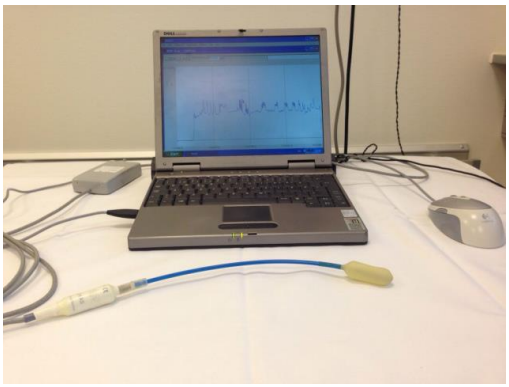

Figure 4*. Camtech AS, Sandvika, Norway. From: Tennfjord, M.K., Engh, M.E. & Bø, K. Int Urogynecol J (2017). doi:10.1007/s00192-017-3290-y. An intra –and interrater reliability and agreement study of vaginal resting pressure, pelvic floor muscle strength and muscular endurance using manometer.*

Manometry analysis

Data showing pressure values and pressure curves was stored at the apparatus' hard disk using the unique ID number for each woman. Each assessor analyzed their own measurement. The ID number of each woman was the only link to the clinical data. Questionnaire data and recordings from prior assessments were not available during analysis.

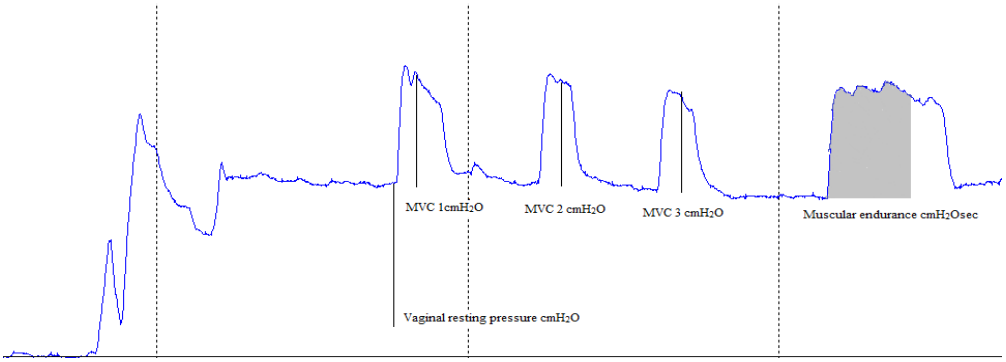

***Figure 5**. Manometer assessment showing vaginal resting pressure, PFM strength and muscular endurance. From Tennfjord, M.K., Engh, M.E. & Bø, K. Int Urogynecol J (2017). doi:10.1007/s00192-017-3290-y. An intra –and interrater reliability and agreement study of vaginal resting pressure, pelvic floor muscle strength and muscular endurance using manometer.*

Questionnaire data

Electronic questionnaire, including background data and symptoms, were sent out prior to the clinical visits (Figure 3). The participating women were asked to fill in the questionnaire and recall the last four weeks for all time points. For pre-pregnancy symptoms the women were asked to recall the last three months before the pregnancy when they received the questionnaire at the first clinical visit at mid-pregnancy. Data from the electronic questionnaire were used for paper I-III. For paper IV the women were asked background questions when they met for their scheduled appointment.

ICIQ-VS [94] were used to assess vaginal symptoms and sexual matters. Level of bother was assessed on a scale from 0-10, were 0 were no bother and 10 were major bother. For paper II all questions were included, but no sum score was used. For paper III all questions were used except for question 5a:" Are you aware of a lump or bulge coming down in your vagina?" and question 6a: "Do you feel a lump or bulge coming out of your vagina, so that you can feel it on the outside or see it on the outside?". These questions were not the focus of this dissertation and published by Bø et al [200]. ICIQ-VS has shown good validity, reliability and is sensitivity to change [94], but has not undergone linguistic validation into Norwegian. This was done by our study group during planning of the study.

A Norwegian validated version of ICIQ-FLUTSsex was used to address symptoms of dyspareunia with question 4a: "Do you have pain when you have sexual intercourse?" (Paper I)

and coital incontinence with question 5a: "Do you leak urine when you have sexual intercourse?" (Paper II). Level of bother was asked for both questions [96, 100]. ICIQ-FLUTSsex has been established as a reliable, valid and responsive assessment tool to address sexual issues. [96]

Obstetric data

Data on delivery mode and other delivery variables were gathered from the women's electronic medical record (PARTUS) (Paper I-III). Data was anonymised and stored safely with the unique ID number of each woman as the only link to the data.

Ultrasound assessment of major levator ani muscle defects

Tomographic ultrasound imaging was performed by two trained gynaecologists using three and four-dimensional transperineal ultrasound (GE Kretz Voluson E8 - RAB4-8) in a standardized lithotomy position after voiding [67, 69]. The method was used to identify major defects of the levator ani muscle which allowed for stratification of major defects or not in the RCT (Paper III). The participating women were asked to perform three maximum PFM contractions, taught by the physiotherapists involved in the study. All three PFM contractions were recorded. The volume with the best contraction, defined as the volume with the largest reduction in the anterior-posterior diameter of the levator hiatus during contraction, was used for assessment of major levator ani defects [73]. Major defects of the levator ani muscle were diagnosed using the axial plane at maximal PFM contraction. For reference, the plane of minimal hiatal dimensions was used [73, 201, 202], described by Dietz et al 2005 [203]. Tomographic slices were taken at 2.5 mm slice intervals starting from 5 mm caudal to 12.5 mm cranial to the reference plane, giving eight slices [73, 201, 202]. Major defects were diagnosed when there was an abnormal insertion of the medial part of the levator ani muscle into the pubic bone, present in all three central slices [201]. The method has shown very good intra- and inter-rater reliability six weeks after childbirth [73].

Randomisation and blinding

The participants were randomised in blocks of ten to either PFMT or control with usual care after being stratified according to major or no defects of the levator ani muscle at the very end of the baseline assessment (paper III). The randomization sequence was computer-generated and opaque, sealed envelopes were used. All investigators were blinded to the participants' answers on the questionnaire when performing the clinical measurements. The project coordinator

(midwife) administrated the allocation process outside the clinical assessment room. Blinding of investigators to group allocation during the clinical measurements was therefore possible throughout the study.

Intervention

The training group attended a weekly PFMT class led by one of three trained physiotherapists at three different locations for four months, starting six weeks after delivery. The exercise protocol has been described previously by Bø et al [204, 205] and Mørkved and Bø [206] and follows recommendations for strength training [166, 207]. In between sets of PFM exercises, body awareness, breathing, relaxation, and strength exercises for the abdominals, back, arms and thigh muscles were done. In addition, the intervention group was instructed to perform three sets of 8–12 close to maximum PFM contractions daily at home. The intervention group also received an additional booklet and a DVD for further instructions on PFMT. Participants recorded adherence to the home program in a training diary, and the physiotherapists registered class participation. The control group received no intervention beyond the written information received at discharge from the hospital containing information about postpartum PFMT and the individual assessment of how to perform a correct PFM contraction.

Statistics

Demographic data and descriptive variables were given as mean values with standard deviations (SD), or in case of categorical data as frequencies with percentages. For all paper the level of significance was set to ≤ 0.05. Normality tests were performed. Data for all papers were analysed using SPSS, version 15 (SPSS, Inc., Armonk, NY, USA).

Paper I: Data from PFM variables were reasonable normally distributed. Both parametric and nonparametric analysis were performed and showed equal results (no difference), thus Independent samples t-test was used to analyze differences in PFM variables (vaginal resting pressure, PFM strength and muscular endurance) between groups of women with and without dyspareunia. This was done to ease comparisons with previous research on this topic [133, 146]. The relationship with dyspareunia and breastfeeding, use of hormonal contraceptives, and data on delivery variables, were analysed using Chi-squared test for independence and independent samples t-test potential were appropriate. To assess whether breastfeeding influenced PFM variables, independent samples t-test was used. An additional effect size calculation was done using the Cohen‘s criteria [208].

Paper II: Spearman's rank order correlation was used to analyze the relationship between PFM variables and coital incontinence and vaginal symptoms and was used because there was categorical data in the analysis. We were interested in the relationship between PFM function and vaginal symptoms at 12 months after childbirth. PFM variables were reasonable normally distributed, and both parametric and non-parametric tests showed equal results, thus Independent sample t-test was used. Differences between symptomatic and asymptomatic women on delivery mode were analysed separately using chi-square test. The effect of use of hormonal contraceptives and breastfeeding on vaginal symptoms was analyzed using Chi-square test. An additional effect size calculation was done using the Cohen's criteria [208].

Paper III: Between-group comparisons on categorical data for vaginal symptoms, sexual matters, coital incontinence and dyspareunia were analysed by chi-square and the Mantel-Haenszel risk ratio (relative risk, RR). For continuous data, an Independent sample t-test was used, and was chosen as these data were reasonable normally distributed. No within-group analysis was done due to different number of women having intercourse at baseline and post-intervention.

Data was analysed as intention-to-treat. In principle, when there were missing values post intervention, the method of last observation carried forward was used for categorical data. For continuous data the baseline value plus the added average change observed in the corresponding control group was used. Assumptions using intention-to-treat were explored through sensitivity analysis. An additional per protocol analysis was performed based on women completing the trial and adhering to more than 80% of the prescribed training sessions (at home and during group training) who did not have a new pregnancy post intervention at six months after delivery.

A sub-analysis was performed using multiple regression on the effect of PFMT (a difference in symptoms between training and control group seen at post intervention), to the possible change in PFM variables (assessed as the change in vaginal resting pressure, PFM strength or muscular endurance from six weeks to six months postpartum). Before change score was calculated, baseline comparability of PFM variables was ensured [209]. An interaction effect was tested across stratum groups (major or no defect of the levator ani muscle), symptom variables, and between training and control groups. The treatment effect was estimated using independent sample t-test.

Paper IV: intra-class correlation coefficient (ICC, average measures) using a two-way mixed model for absolute agreement with 95% confidence interval (CI). Common ICC values suggested were used; ICC <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. One sample t-test was used to calculate the mean difference (bias) between measurements and the corresponding SD and 95% CI. The Bland-Altman approach was

used to assess for systematic bias and random error using the mean difference and 95% limits of agreement (1.96 SD) [210]. Data from PFM variables were right-skewed as shown in The Bland-Altman plot. We did not proceed with further adjustments of the data [211] as this would make comparisons to other studies more difficult. Minimal detectable change was calculated to identify the smallest amount of change above the threshold of error using the SD of the mean difference (bias) multiplied with 1.96 SD [211].

Ethics

- The study procedures were in accordance with the World Medical Association, Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects (updated 2013) [212].
- The cohort study (Paper I-II) was approved by The Regional Medical Ethics Committee (REK South East 2009/170) and Data Protect Officer at Akershus University hospital (2799026) was informed. (Appendix I)
- The RCT (Paper III) was approved by The Regional Medical Ethics Committee (REK South East 2009/289a) and the Data Protect Officer at Akershus University hospital (2799004) was informed about the study. The study was registered at ClinicalTrials.gov (NCT01069484). (Appendix II)
- Information about the study was given and written consent was taken for all participants before entering the study (Appendix III including Paper I-III).
- For the intra –and interrater reliability and agreement study (Paper IV) The Regional Medical Ethics Committee (2014/1768) approved the study and the Data Protection Officer at Akershus University hospital (15-018) was informed about the study. Change in location was approved by the The Regional Medical Ethics Committee (2014/1768). Information about the study was given and written consent was taken for all participants before entering the study (Appendix IV)

Results

The following section summarizes the main findings from paper I-IV. For details, the reader is referred to the original papers included at the end of the thesis.

Paper I

Three hundred nulliparous women (mean age 28.7 mean 4.3, mean BMI 23.9 (SD 3.9)) were seen at four different time-points from gestational week 18-22 until 12 months postpartum, including retrospective data from before pregnancy (Figure 3). Presence of all severity dyspareunia was 27.8% at pre-pregnancy, 30.5% at gestational 22, 41.4% at gestational week 37, 44.6% at six months postpartum and 33.1 % at 12 months postpartum. Most women reported dyspareunia as "a little". Mean level of bother was lowest at pre-pregnancy: 3.4 out of 10, SD 2.5 and highest at 12 months after delivery: mean 5.1 out of 10, SD 2.9. No statistically significant difference in PFM variables was found between women with and without dyspareunia. A borderline significant difference in numbers with dyspareunia was found for women breastfeeding (>once daily) at six months after delivery 65/132 (49.2 %) versus those not breastfeeding (<once daily) 13/43 (30.2 %) (p=0.05). The effect size was considered low (Phi 0.165). No difference was found for women breastfeeding or not at 12 months after delivery, use of contraceptives at six or 12 months after delivery or in delivery variables between women with and without dyspareunia. Results from the longitudinal analysis showed new cases of dyspareunia both during pregnancy and after delivery, but total prevalence declined throughout the study.

Paper II

One-hundred-seventy-seven primiparous women were included for analysis 12 months after delivery. No significant differences was found in background characteristics for the total study sample at 12 months postpartum (n=177) or between women with no vaginal symptoms (n=47), with vaginal symptoms (n=130) and vaginal symptoms interfering with sexual life (n=61) (p>0.05).

Two (1.2%) out of the 166 women having sexual intercourse complained of coital incontinence. Overall, 73.4% (130) of all participants reported at least one vaginal symptom, whereas 34.5% (61) reported at least one vaginal symptom interfering with sexual life. At 12 months after delivery, 166 (93.8%) women had sexual intercourse. Of those eleven not having sexual intercourse at the time, two was due to vaginal symptoms and nine were due to "other reasons".

Symptoms of "vagina feels dry" were most prevalent (41.2%) followed by "vagina feels sore" (26%) and "vagina feels loose or lax" (26%). Thirty-two percent reported worries that the vaginal symptoms affected their sexual life and 23% reported that the relationship with their partner was affected as a result of the vaginal symptoms. The overall bother given by the question "how much do you feel that your sex life has been spoilt by vaginal symptoms?" was low (1.4 out of 10 SD 2.5).

Breastfeeding (>once daily) was associated with "vagina feels sore" compared to those not breastfeeding (<once daily); 24/64 (37.5%) versus 22/113 (19.5%) (p=0.01). A borderline significant difference was found for "vagina feels dry" in women breastfeeding versus those not breastfeeding; 33/64 (51.6%) versus 40/113 (35.4%) (p=0.05), respectively. No difference was found for use of hormonal contraceptives (p>0.05).

Vaginal resting pressure, PFM strength and muscular endurance showed a weak negative correlation with the symptom "vagina feels loose or lax": vaginal resting pressure: r_s=-0.16, p=-0.03, PFM strength, r_s=-0.20, p=0.007 and endurance, r_s=-0.21, p=0.005. The mean difference for women with and without the symptom was 3.6 cmH_2O (95%CI 0.7, 6.6) for vaginal resting pressure, 9.0 cmH_2O (95%CI 2.6, 15.4) for PFM strength and 80.0 cmH_2Osec (95%CI 32.6, 127.5) for muscular endurance.

There was no difference between women with no vaginal symptoms, with vaginal symptoms, and with vaginal symptoms interfering with sexual life when grouped by delivery mode. Looking at each vaginal symptom separately, "vagina feels loose or lax" was the only symptom associated with delivery mode (Table 3). When comparing women with and without the symptom, more women with the symptom had a normal vaginal delivery and an instrumental delivery versus caesarean section (p-value=0.02).

Table 3*. Distribution of symptom ("vagina feels loose or lax") with delivery mode.*

	No loose or lax	Loose or lax	Total
NVD	80 (68.4%)	37 (31.6%)	117
IVD	19 (73.1%)	7 (26.9%)	26
CS	32 (94.1%)	2 (5.9%)	34
Total	131	46	177

Presented with numbers with percentages (%). NVD=normal vaginal delivery; IVD= instrumental vaginal delivery (vacuum/forceps); CS=caesarean section. Pre-labor CS (n=16) and CS during labor (n=18) were pooled. (Table for the results published in Paper II. The percentage is calculated according to delivery mode).

Paper III

One-hundred-seventy-five primiparous women were included at six weeks after delivery (mean 6.1 weeks, SD 0.9, range 3.9-8.7). Of these, 55 women were diagnosed with major levator ani muscle defect and 120 women with no defect of the levator ani muscle. Women in the control group had significantly higher education level than women in the training group (p=0.01). There was no association between education and any of the outcome variables of interest, so no further adjustments were done. No other differences in demographic variables were seen between groups at inclusion.

Among the 15 women lost to follow up, a higher percentage with lower education (46.7%) was found when compared with the 160 women completing the trial (15.6%) p=0.01) [196]. Ninety-six percent (72/75) of women in the training group adhered to 80% of the required attendance both for class sessions and for daily home training [196]. Two women from the control group were pregnant with their second child at six months after delivery.

No baseline differences were found for the outcome variables for vaginal symptoms, sexual matters, dyspareunia and coital incontinence except for "vagina feels sore" (p = 0.04). At follow-up six months after delivery no significant difference in outcome variables between groups for the total study sample (n=175) or in the stratum with no defects (n=120) were found. In the stratum with major defects (n=55) at post intervention significantly fewer women in the training group had symptoms of "vagina feels loose or lax" than the control group; RR: 0.55 (95% CI: 0.31, 0.95, p=0.03). Results from the multiple regression analysis showed that the effect of PFMT on the symptom "vagina feels loose or lax" in the stratum with major defects was not related to changes in PFM variables between training and control group. No difference was found between groups in relation to the question "how much do you feel that your sex life has been spoilt by vaginal symptoms?" (95% CI: -1.0, 0.6, p=0.59). The bother was considered low: mean 1.3 (SD 2.4) versus 1.1 (SD 2.1) for training and control, respectively. Similar results were found for all outcomes when performing a per-protocol analysis. There was no difference between groups in number of women not having intercourse at six months postpartum: 9/72 (12.5%) versus 10/83 (12%) (p=0.81) for the training group and control group, respectively.

Paper IV

Twenty-three women were recruited to the study. One woman was excluded due to inability to insert the probe (owing to restricted vaginal opening) and one woman did not meet for her scheduled appointment. Furthermore, one had to be excluded owing to poor quality of the pressure curves, leaving 20 women for analysis (mean age 56.2 years (range 27-71), mean parity 1.7 (range 0-3) and mean body mass index 23.6 (range 18.4-27.2, SD 2.4). The majority, 18 (85.7%), had a college/university degree and 10 (47.6%) reported having strenuous physical work. All participants were familiar with PFMT and they were all able to perform a correct PFM contraction after instructions. Fourteen (66.7%) reported that they sometimes experienced minor symptoms from the pelvic floor. Two were pregnant with their second child, second and third trimester.

Results from the intra -and interrater analysis showed considerable intervariation and the distribution of scores was right-skewed. ICC values were very good for all measurements for both intra -and interrater assessments (ICC >0.90).

Results from the one-sample t-test showed some systematic bias, only statistically significant for vaginal resting pressure (mean difference -2.44 (95% CI -0.36, -4.51) in the intrarater assessment and PFM strength (mean difference 2.24 (95% CI 0.03, 4.45) in the interrater assessment. The Bland-Altman plot showed random error to be present for all assessments as indicated by relatively wide limits of agreement. The results were more or less the same for both the intra – and interrater analysis. Outliers were observed in all measurements, representing the strongest women. Bias and minimal detectable change for intrarater agreement were; vaginal resting pressure: -2.44 ±8.7 cmH_2O, PFM strength -0.22 ±7.6 cmH_2O and muscular endurance 0.75 ±59.49 cmH_2Osec. Interrater agreement for vaginal resting pressure was: 1.36 ±9.0 cmH_2O, for PFM strength 2.24 ±9.0 cmH_2O and for muscular endurance 15.89 ±69.7 cmH_2Osec.

Discussion

Summary of main findings

Number of women reporting dyspareunia at each time point from pre-pregnancy until 12 months after delivery was close to or above 30%. The majority reported severity of dyspareunia as "a little". There was no difference between women with and without dyspareunia in relation to PFM variables or delivery variables. Longitudinal data showed new cases of dyspareunia during pregnancy and after delivery, but total prevalence of dyspareunia declined throughout the study. Other vaginal symptoms were prevalent (73.4%) 12 months after delivery, but few of the symptoms were severe, and 34.5% reported the symptoms to interfere with their sexual life. Overall bother of the vaginal symptoms were low (mean 1.4 out of 10). Significantly lower vaginal resting pressure, PFM strength and muscular endurance were found for women reporting "vagina feels loose or lax" 12 months after delivery compared to women with no symptoms. In the RCT, no effect of PFMT was seen in the total group (n=175) or in the group with no defects (n=120) on vaginal symptoms or the questions related to sexual function. However, the results indicate that PFMT may have a preventative effect of "vagina feels loose or lax" in women with major levator ani defects. Bias and minimal detectable change for manometer (Camtech AS) were; vaginal resting pressure: -2.44 ±8.7 cmH_2O, PFM strength -0.22 ±7.6 cmH_2O and muscular endurance 0.75 ±59.49 cmH_2Osec (Intrarater). Interrater agreement for vaginal resting pressure was: 1.36 ±9.0 cmH_2O, for PFM strength 2.24 ±9.0 cmH_2O and for muscular endurance 15.89 ±69.7 cmH_2Osec. Camtech AS seems less accurate for the strongest women in this sample, and a statistically significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement.

Methodological considerations

Paper IV

Strengths and limitations

The use of Camtech AS, Sandvika, Norway (Figure 4b) has found to be reliable and valid for assessment of PFM strength, with simultaneous observation of an inward movement of the catheter and no use of extra-pelvic muscle contraction [78, 80]. This measurement was used in the data collection of PFM function and is included in all papers in this dissertation. Performing this

study last was probably not optimal as all the measurements had already been done, but the results and discussions concerning PFM function in Paper I-III in this dissertation, inspired us to carry out this study. In order to have a meaningful interpretation of the results from Paper I-III, Paper IV will be discussed first.

Strengths of paper IV was the study design, standardisation of test procedures (including vaginal resting pressure, PFM strength and muscular endurance) and the use of recommended statistical methods for assessing reliability and agreement [80, 199, 211, 213, 214]. Appropriate checklists were used [214]. The testers were trained by the main supervisor of the project and both testers had extensive experience in use of the method. The testers were also blinded to each other's results and results from the first test were unavailable during the second test.

A limitation was that we did not perform an apriori sample size calculation, but based the number of participants on previous studies assessing reliability of manometer measurements in this field [76-79]. Although this dissertation is on first time mothers, we choose a heterogeneous study population with the aim to be able to generalize the findings into everyday clinical life. This was also done for comparison with the previous reliability study by Bø et al [78]. We could still question the generalizability of the results. Our results indicate that the apparatus seem less accurate for the strongest women in this sample. We could perhaps have included more women into the study to give better estimates to the limits of agreement [213], but this would probably not changed the overall outcome, because of the large differences between those being weak and strong. Increasing sample size would not change the SD (measure of variability) in this sample which was used for calculating the limits of agreement [215].

Another limitation is that there were no predefined cut-off values for what is clinically significant. Ideally it should be defined a head of the study to help with the interpretation of the data and calculate sample size [210]. However, defining clinical cut-off values would be difficult to estimate, as there are no known "normal" values [11].

Interpretation

Our results show ICC values >0.90 for all measurements. This indicates high reliability [211]. However ICC values are not a robust measure of reliability, as it is largely sample dependent [210]. The large variation in scores amongst the participants would probably explain the high ICC values [210]. Whether the cut-off for determining good ICC values used in this present study and others [76, 77] are appropriate can be discussed as they are equal to that of other correlational studies like Pearson's r [211].

Including Bland and Altman plots with limits of agreement showed relatively large random errors. This was more or less the same for all measurements. Other studies report of some variation around their test differences [76, 78, 79]. Bø et al [78] test-retest study on PFM strength using Camtech AS concluded reproducible results, but with wide confidence intervals. This is in accordance with our results. To our knowledge, no studies on reliability or agreement of vaginal resting pressure and muscular endurance have been performed using Camtech AS. Using Peritron, Frawley et al [77] found ICC values for resting pressure to be 0.74 and for endurance 0.05. This indicates moderate and poor reliability, respectively [211]. However, our results are not directly comparable due to the use of different devices and probes [81, 216]. Further, Frawley et al [77] tested muscular endurance as multiple repeated muscle contractions (20 fast contractions). Our approach for testing muscular endurance was using the area under the curve (Figure 5) as this will include the force applied during a specific time (10 sec). To ensure maximal tension in the muscle it is commonly recommended that the contraction is held >six sec [170]. Local muscular endurance may also be defined as the ability to repeatedly develop near maximal or maximal force determined by number of repetitions [45], but using time in seconds will not give details on the exact force.

We were surprised that vaginal resting pressure had the same amount of error as did PFM strength and muscular endurance. Guaderrama et al [38] described the vaginal pressure profile during rest and squeeze and found the highest pressure in the mid zone of the vagina. Anatomic correlates of this pressure zone are not known, but Bø et al [199] found the highest squeeze pressure when the vaginal balloon was 3.5 cm inside from the vaginal introitus. There were however individual differences [199] and it has also been found marked asymmetry in both rest and squeeze pressure recordings from left to right and from anterior to posterior [38]. It comes to stand that measurement of vaginal resting pressure and squeeze pressure may be inheritably problematic due to the above considerations.

Indication of bias was seen for vaginal resting pressure and PFM strength for the intra –and interrater measurements, respectively, but the relatively large amount of random error may have precluded bias [217]. Bias could be a result of a learning effect, although we tried to rule out this by changing order of testers and giving the women opportunity to practice a few contractions before measurement was taken. Previous studies in this field have not found bias in their measurements [76, 78, 79].

Measurements recorded for the strongest women were more problematic than measurements recorded for the weakest women. The vaginal balloon may be pulled more inside the vagina during contraction, and may not have been in the high pressure zone [38], a possible explanation

for the outliers seen in our sample. For the balloon to stay in the high pressure zone [199], the assessors had to control the movement of the balloon which could yield a potential source of error. This may have led to the limits of agreement being wider apart than they should for the lowest scores and narrower than they should for the highest scores [210].

Clinical implications

As seen from our results on intra –and interrater agreement there were some random error present. Using Camtech AS, we emphasize that recordings should preferably be done by one tester, minimum two, and careful attention should be paid to a standardised procedure with placement of the probe. Probably, the use of Camtech AS would be more reliable in research settings as there is an average of results rather than individual results as we see in the clinic. However, to transfer data into clinical practice, examiners must be aware that a statistically significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement [210]. Our results highlight a need to continue developing new instruments which is reliable and valid for the measurement of PFM function. The use of dynamometry might be more reliable and less sensitive to the movement of the apparatus during contraction as the device is more fixed inside the vagina [62]. However, this device is not commercially available [58]. Regarding vaginal resting pressure, vaginal surface EMG might be a more reliable tool to assess the resting condition of the PFM as no voluntary muscle activation is present and the measurement would be less biased by cross-talks from nearby muscles at rest than during contraction [11, 55].

Paper I-III

Strengths and limitations

All women scheduled for delivery at Akershus University Hospital (N=2621) were invited to participate in this study. The women in the cohort (Paper I and II) and RCT (Paper III), were similar to that of the total population (N=2621) with respect to age, marital status and body mass index (BMI), except that they had a higher level of education (75.3% versus 47%, respectively $p<0.001$) (non-published data). However, the inclusion criteria were the ability to understand Scandinavian languages, which make generalization to all primiparous women difficult.

Another strength is the low variation in time for attendance for each of the four visits minimizing possible bias due to the altered pelvic floor function during pregnancy and the natural remission after childbirth [218].

Few women were lost to follow up throughout the cohort study (11.6%). However, 71 women were excluded from the cohort to participate in the planned parallel ongoing RCT, leaving 177 women for analysis at 12 months after delivery. This was done because these women would have had a different intervention than the women remaining in the cohort. At 12 months after delivery, there were no significant differences regarding age, education or marital status amongst those women lost to follow up and those excluded, or for the women recruited to PFMT in the RCT compared to the women participating in the study at 12 months postpartum. In the RCT, (Paper III) more women in the training group versus the control group were lost to follow up. Differential lost to follow up may have biased the results [219], but sensitivity analysis (intention-to-treat and per-protocol) showed similar results, making bias less likely. Intention-to-treat analysis maintain the groups similar apart from the random variation, but the approach with imputation of missing data may be a limitation as it may give a biased estimate of the treatment effect [220]. However, few women were lost to follow up and reasons for loss to follow up were not related to the intervention itself.

The randomization procedure adds strength, and is vital for the internal validity of the trial [221-223]. Triple blinding is considered the strongest design in the RCT [224], but this was not possible in our exercise trial. There was imbalance at baseline where the control group had statistically higher educational level than the treatment group, which may have underestimated our results.

Appropriate checklists for the observational studies Paper I and II (STROBE) [225] and for the RCT Paper III (CONSORT) [221] were used and helps secure transparency.

Lack of a-priori sample size calculations is a limitation (Paper I-III). This may give insufficient statistical power and lead to a type 2 error [226]. This may have been the case regarding less common variables not reaching statistical significance in Paper II and III. However, the finding "vaginal feels loose or lax" was seen as common and clinically relevant (26% 12 months after delivery). Paper I was larger than the studies finding no difference between women with and without dyspareunia in relation to PFM function after childbirth [133, 146, 227]. All these studies had performed an apriori sample size, but differences in study design and follow-up make comparisons with our study difficult.

Neither the ICIQ-VS [94] nor the ICIQ-FLUTSsex [96] covered all aspects of sexual function, e.g.; satisfaction, orgasm, desire, partner, social life. However, the questionnaires allowed us to study a

range of vaginal symptoms that was thought to be relevant in this group of women, how the symptoms affected sexual life, including bother of the problem, which adds strength. Another limitation was that the questionnaires were not validated amongst pregnant women or in women after childbirth. The validation of ICIQ-VS into Norwegian done by our study group may also add a limitation, although these questions were thought to be relatively easy to interpret.

The cross-sectional analysis in Paper I and II does not allow us to determine the time order of events between PFM function and symptoms, or evidence of causation [228]. We therefore included the longitudinal analysis in paper I looking into incidence and prevalence of dyspareunia among the same women in the cohort. Pre-pregnancy dyspareunia was asked retrospectively, which could bias the results [228]. Although ideal, following women from before their first pregnancy is a well known difficulty.

P-values were reported for all tests without adjusting for multiple testing (Paper II-III). This involves a risk of making a type 1 error [229]. If the outcome variables were independent of each other an adjustment for multiple testing would perhaps had been more appropriate [229, 230]. A possibility could be to exclude some questions that correlated with each other, but the use of sexual matters (the questions covering all vaginal questions) made us use all vaginal symptoms in the questionnaire. The results of statistically significance were therefore judged upon clinical relevance and left unadjusted.

Paper I

Interpretation

No difference in PFM variables were found for women with and without dyspareunia in our study. Our findings confirm the results from existing literature on associations with dyspareunia and PFM strength after childbirth [133, 146, 227]. Studies from the general female population assessing women with sexual pain disorders (superficial) compared to asymptomatic controls, suggestions of lower PFM strength [231, 232] and muscular endurance [233] have been found. Reasons for these conflicting results may be that we did not differentiate dyspareunia as superficial or deep, which was a diagnostic criteria in those studies from the general female population. Distal vaginal palpation may elicit vaginisimus, which are reflex contractions of the superficial PFM and levator ani muscle. With deeper vaginal palpation other pelvic floor disorders may be triggered [234].

Vaginal resting pressure has been though to be a factor in relation to dyspareunia [11]. We did not find any difference in vaginal resting pressure among women with and without dyspareunia, and

vaginal resting pressure was not included in the other studies investigating dyspareunia in women after childbirth [133, 146, 227]. Using vaginal palpation [232], EMG [233, 235] and transperineal ultrasound [231] in women with sexual pain disorders compared to asymptomatic controls from the general population PFM hyper tonicity have been found. However, it has not been clearly established whether it is the pain that causes the PFM hyper tonicity or if it is the hyper tonicity that causes the pain [236]. There are no gold standard for measurement of PFM function [11] and no consensus for cut-off points for determining PFM hyper tonicity [236]. Recent ultrasound studies have shown alterations in vaginal anatomy and function during pregnancy [125] and after childbirth [195, 237, 238]. This may make measurement of PFM function, especially vaginal resting pressure, problematic. A larger sample including more women with more severe dyspareunia could have been appropriate in our study, as there may be different findings in PFM function according to severity of pain and diagnosis.

Dyspareunia gradually declined throughout pregnancy. Still, at 12 months after delivery 34 (19%) reported dyspareunia. Although most cases were mild, bother was 5.1 out of 10 (cross-sectional data from 12 months). The relatively large SD at the different time-points indicates however a wide range in bother of dyspareunia. From the longitudinal analyses 18% were new cases from six months after delivery. This is in contrast to previous literature [2, 3, 114], were dyspareunia seems to be a problem within the first six months before women resume intercourse. After this project started in 2010 a few longer-term studies have been found reporting dyspareunia as bothersome and that it may impact on quality of life 18 months [239, 240] and five years after delivery [238]. De Souza et al [241] reported of improved pain levels (FSFI score) one year after delivery [241].

In our study, women breastfeeding reported more dyspareunia at six months after delivery, but the finding was only borderline significant; 65 (49 %) amongst those breastfeeding versus 13 (30%) of those not breastfeeding (p=0.05). It is difficult to draw overall conclusions on the impact of breastfeeding on dyspareunia due to the conflicting results from previous research finding an association [108, 110, 111] and not finding this association [113, 115, 131].

There was no difference between women with and without dyspareunia in relation to delivery variables in our study. There may be several reasons for this. From the longitudinal analysis numbers with dyspareunia prior to pregnancy was 27.1%. This means that dyspareunia was not simply a "product" of the delivery, as confirmed by other studies [240, 242]. Second, the question of dyspareunia was not differentiated as pain on first vaginal intercourse after childbirth or subsequent intercourse. MacDonald et al [239] reported that 85.7% of primiparous women experienced pain on first vaginal intercourse and that 23.3% of those described the pain as

severe. In our cohort most women resumed intercourse between six weeks and six months after delivery. Asking about dyspareunia the last four weeks at six months after delivery may not have captured those with pain on first sex and/or those with more intense dyspareunia. Furthermore, the literature on delivery mode and dyspareunia is conflicting [243]. Operative vaginal deliveries has been found to be associated with dyspareunia in large studies on postnatal women [111, 112, 129, 130, 240]. However, conflicting results exists [109, 110, 113, 132, 133, 135]. These latter findings may partly be explained by lower sample size, which could also be a reason for the lack of association in our study. Literature on associations with episiotomy and dyspareunia is also conflicting, were some studies find an association [131, 240], and others don't [113]. Since dyspareunia is a symptom it may be an end-product of a complex circle and reveal little about the cause or pathophysiology [43, 107, 120].

Paper II

Interpretation

The focus on vaginal symptoms in relation to sexual function during pregnancy and after childbirth has emerged since this project started in 2010 [143, 238, 242, 244-247]. Before this project started only a few studies had looked into symptoms other than dyspareunia, but there was lack of data beyond six months after childbirth [108, 111]. A few other studies have been published since then, assessing vaginal symptoms 12 months after delivery [131, 242]. Prevalence of vaginal symptoms (e.g. vaginal tightness and vaginal laxity) has been found more or less in the same range as our study.

One literature review from 2012 [2] as well as previous reviews [3, 114] have concluded with lack of studies addressing bother in relation to symptoms of sexual dysfunction. Roos et al [248] found that only half of the women reporting a sexual complaint reported it to be bothersome. This underlies the importance of addressing sexual problems in the clinic, as well as the bother of the complaint. We addressed nine questions related to vaginal symptoms and found that the overall bother of symptoms on sexual life was low. This was supported by van Delft et al [143, 244]. Twelve months after delivery, 93.8% of the women had sexual intercourse in our study. Our questionnaire does not address frequency of intercourse, which we acknowledge as an important factor. However, low mean overall bother of vaginal symptoms support our findings that vaginal symptoms 12 months after childbirth does not seem to affect the sexual life of primiparous women to a great extent. However, the 2.5 SD indicates some range in bother.

Breastfeeding was found to be associated with vaginal dryness and soreness 12 months after childbirth. Although vaginal dryness was barely significant (P-value=0.05), vaginal soreness and

breastfeeding was a stronger finding (P-value=0.01). Vaginal soreness and dryness was found to correlate in our study ($p<0.01$). Dyspareunia correlated with vaginal soreness and dryness ($p<0.01$). Since breastfeeding has shown to have a profound effect of postpartum hormonal levels [2], affecting negatively on vaginal lubrication [5, 127], this finding may be clinically relevant.

The only symptom that correlated significantly with PFM function was "vagina feels loose or lax". Differences in PFM strength and muscular endurance between women with and without the symptom were also above the error of measurement and thought to be clinically significant (9.0 cmH_2O and 80.0 cmH_2Osec, respectively). Differences in vaginal resting pressure was however low (3.6 cmH_2O). From clinical experience and previous research [245] women may have a feeling of increased vaginal laxity. It may that this feeling is more subjective than objective. Most likely the finding of reduced PFM strength and muscular endurance in women with loose or lax vagina was mediated through mode of delivery as more women with this symptom had had a vaginal delivery and instrumental delivery compared to caesarean delivery in our study. This finding was supported by Thibault-Gagnon et al [245]. We did not control for delivery mode as we were interested in the situation between PFM function and vaginal symptoms 12 months after childbirth.

There are several studies reporting on the relationship with delivery mode and levator avulsion on various vaginal symptoms [143, 238, 242, 244-246]. An association between levator avulsion and vaginal laxity has been found [143, 244, 245]. However, Laterza et al [249] found no difference among women with and without levator avulsion on the sum score of different sexual function domains, including vaginal laxity. The main focus in this present paper was the relationship between PFM variables and vaginal symptoms 12 months postpartum and no analysis regarding the effect of defects was performed. Further discussion related to defects is below related to Paper III.

Paper III

Interpretation

From Table 1, 13 RCTs on PFMT for prevention and treatment of symptoms related to sexual dysfunction were found. These were in either postpartum women [178-180], in women with pelvic organ prolapse (POP) [184-187], in women with stress urinary incontinence (SUI) [181, 188, 189], in women with orgasmic disorders [182, 183] and in gynecological cancer patients [190]. No new RCTs were found for women during or after pregnancy after project start. The three RCTs in women after delivery published prior to project start [178-180] will therefore be discussed in light of the findings from our study.

The only symptom that had effect after PFMT was on "vagina feels loose or lax". This effect was seen in the stratum with major defects only. This finding may be relevant as several studies find an association with levator avulsion and PFM strength [143, 158-160, 247, 250] and vaginal laxity [143, 244, 245]. Although diagnosing major levator ani defects has shown good reliability [72, 73], we cannot rule out false positives due to haematoma early after birth [251]. None of the other RCTs in women after delivery [178-180] studied the effect of PFMT on vaginal laxity.

We did not find an association with effect after PFMT and change in PFM strength. There was a low overall difference in change between the training and control group in PFM strength from baseline to follow-up (3.6 cmH_2O) in favour of the training group [200]. From the results of Paper IV this is well below the minimal detectable change of 9.0 cmH_2O for PFM strength. The same training program has been utilized previously demonstrating a change above the minimal detectable change for PFM strength [204, 205, 252]. It may be that timing of our trial was not optimal to study vaginal symptoms and symptoms of sexual dysfunction as there seems to be a natural resolution after delivery until six months [195]. This may also explain the lack of findings from the same trial on urinary incontinence [196] and pelvic organ prolapse [200]. Furthermore, women may have less often sex during this period, a possible explanation for the lack of findings for the questions on sexual matters in our study. Since there are no normative data to assess PFM function in general, a non-statistically significant improvement in PFM variables after PFMT does not mean lack of a clinical significant improvement in symptoms [253]. A positive effect of PFMT may also influence on psychosocial aspects such as improved self-esteem and self-acceptance, body awareness and satisfaction [184]. Both Citak et al [178] and Mørkved et al [180] showed an increase in PFM strength and symptoms studied after PFMT. However, none of the studies reported on any correlation with improvement in sexual function and improvement in PFM strength.

Paper I-III

Clinical implications

Despite the high prevalence of dyspareunia (Paper I) and other vaginal symptoms (Paper II) during pregnancy and after childbirth the overall bother of symptoms affecting sexual life was low. This should be reassuring to the majority of women. Openness and understanding regarding women expressing bothersome symptoms is important.

From clinical experience some postpartum women and health professionals fear that PFMT may create and exacerbate PFM pain and dyspareunia. Some literature also suggest that PFMT should

be avoided in women with hypertonic PFM, described as "short" or "tight" PFM [4, 7]. This present RCT did not show any effect of PFMT on dyspareunia, or adverse effects. Other RCTs in women after delivery did not find effect of PFMT on dyspareunia [178, 179]. One observational study in women after delivery [254] found no adverse effect of PFM contractions on pain early after delivery. Amongst nulliparous women with provoked vestibulodynia [255] a PFM contraction indicated lower vaginal resting pressure. In general, therapists should be careful giving recommendations based on theories with poor supporting evidence.

We have shown that women reporting "vagina feels loose or lax" had lower PFM strength and muscular endurance than those not reporting this symptom (Paper II). We have also shown that PFMT may have a preventative effect of "vagina feels loose or lax" in women with major levator ani defects, although no effect of PFMT was seen for other vaginal symptoms or the questions related to sexual function (Paper III). From a clinically point of view the findings of effect after PFMT is important. There has been an increasing amount of women wanting surgical help for this problem (loose or lax vagina) [68]. This corresponds to what we have seen in the clinic. In addition there are limited data on prevention of PFD [256], and evidence of changes in pelvic floor physiology already during pregnancy [125]. Whether or not vaginal laxity is a sexual problem remains unknown. Some studies include vaginal symptoms as a sexual dysfunction [242, 249], whereas others describe the vaginal symptoms as separate from a sexual dysfunction [143, 238, 244, 245]. The fact that few women were bothered by their vaginal symptoms makes this unlikely, although individually, symptoms may be more bothersome.

To date, there are no clinical guidelines for prevention or treatment of symptoms of sexual dysfunction, and due to the large heterogeneity of studies related to women's sexual function, recommendations through pooled effects in systematic reviews are challenging [223, 257]. One systematic literature review from 2015 on PFMT in women with sexual dysfunction [258] concluded that PFMT gave an overall improvement of at least one sexual variable which was studied. The authors emphasized that the results needs to be interpreted with caution due to methodological limitations of the studies included. It may be that women would benefit from a variety of interventions, including PFMT, and a multidisciplinary approach for their problems [259]. The results from the present thesis should be followed up in future studies [229].

Studies investigating long-term effects after pregnancy and childbirth would be of importance. Recent studies have shown that delivery mode impact on dyspareunia and various sexual complaints 18 months [240] and five years [238] after the first birth. The reported complaints are probably not solely due to mode of delivery due to the multifactorial picture of women's sexual function [4, 256].

Conclusions

I. Numbers with dyspareunia was high before, during and after pregnancy. New cases of dyspareunia were seen throughout pregnancy and postpartum, but numbers with dyspareunia decreased throughout the study. The severity of dyspareunia was described as a "little". No relationship with dyspareunia and PFM variables or delivery variables was found.

II. 12 months after delivery prevalence of vaginal symptoms was high, but the overall bother of symptoms affecting sexual life was low. Women reporting "vagina feels loose or lax" had lower vaginal resting pressure, PFM strength and muscular endurance.

III. Six months after delivery, no effect of PFMT was seen in the total group or in the stratum with any defects on vaginal symptoms or symptoms of sexual dysfunction. However, the results indicate that PFMT may have a preventative effect of "vagina feels loose or lax" in women with major levator ani defects.

IV. Clinical reference values for PFM variables were found for: intrarater agreement for vaginal resting pressure: -2.44 ±8.7 cmH_2O, for PFM strength -0.22 ±7.6 cmH_2O and for muscular endurance 0.75 ±59.49 cmH_2Osec. Interrater agreement for vaginal resting pressure was found to be: 1.36 ±9.0 cmH_2O, for PFM strength 2.24 ±9.0 cmH_2O and for muscular endurance 15.89 ±69.7 cmH_2Osec. Manometry (Camtech AS) seems less accurate for the strongest women in this sample, and a statistically significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement.

Further research

I. Further research into studies assessing PFM variables in relation to various severity types of dyspareunia, differencing dyspareunia as superficial or deep and dyspareunia at first or subsequent intercourse after delivery. Follow-up studies years after first delivery is needed and knowledge into factors influencing dyspareunia before, during and after childbirth would be important.

II. Further research into factors influencing vaginal symptoms and symptoms of sexual dysfunction are needed. To study less common symptoms e.g. coital incontinence, large epidemiologic studies are needed. Follow-up studies years after the first delivery would be important.

III. There is need for well powered high quality RCTs with the primary focus into vaginal symptoms and symptoms of sexual dysfunction. The start of the intervention should preferably be after six months after delivery as most women resume intercourse at this point. The use of validated questionnaires is important, and a more qualitative approach to capture in-depth knowledge into women's sexual function.

IV. To continue further improvement of reliable and valid methods for measurements of the PFM to be used in clinic and research.

References

1. Health NIoP. Medical Birth Registry of Norway 2017 [Available from: https://statistikk.fhi.no/mfr/.

2. Leeman LM, Rogers RG. Sex after childbirth: postpartum sexual function. Obstet Gynecol. 2012;119(3):647-655.

3. Abdool Z, Thakar R, Sultan AH. Postpartum female sexual function. Eur J Obstet Gynecol Reprod Biol. 2009;145(2):133-137.

4. Graziottin A. Female sexual dysfunction. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence based physical therapy for the pelvic floor Bridging science and clinical practice. 1 ed. Philadelphia: Churchill Livingstone Elsevier; 2015. p. 243-270.

5. Berman J, Berman L, Kanaly K. Female sexual dysfunction: new perspectives on anatomy, physiology, evaluation and treatment. EAU Update Series. 2003;1(3):166-177.

6. Shafik A. The role of the levator ani muscle in evacuation, sexual performance and pelvic floor disorders. International urogynecology journal and pelvic floor dysfunction. 2000;11(6):361-376.

7. FitzGerald MP, Kotarinos R. Rehabilitation of the short pelvic floor. II: Treatment of the patient with the short pelvic floor. Int Urogyn J. 2003;14:269-275.

8. Bø K. Overview of physical therapy for pelvic floor dysfunction. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 1 ed. Philadelphia: Churchill Livingstone elsevier; 2015. p. 1-8.

9. Gynecologists TACoOa. Committee opinion: Physical activity and exercise during pregnancy and the postpartum period. 2015;650.

10. Boyle R, Hay-Smith EJ, Cody JD, Morkved S. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. Cochrane database of systematic reviews. 2012;10:CD007471.

11. Messelink B, Benson T, Berghmans B, Bo K, Corcos J, Fowler C, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn. 2005;24(4):374-380.

12. Healey CH, Borley NR, Mundy A. True pelvis, pelvic floor and perineum. In: Standring S EH, Healy J.C, Johnson D, Williams A, editors., editor. Gray's anatomy: The anatomical basis of clinical practice. Edinburgh: Elsevier Churchill Livingstone; 2005. p. 1357-1371.

13. Ashton-Miller JA, DeLancey JO. Functional anatomy of the female pelvic floor. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier 2015. p. 19-34.

14. Dietz HP, Hoyte L, Steensma AB. Atlas of Pelvic Floor Ultrasound. Dordrecht: Springer; 2008.

15. Herschorn S. Female Pelvic Floor Anatomy: The Pelvic Floor, Supporting Structures, and Pelvic Organs. Reviews in urology. 2004;6(5).

16. Bø K, Aschehoug A. Strength training. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone elsevier; 2015. p. 117-130.

17. Critchley HOD, Dixon JS, Gosling JA. Comparative Study of the Periurethral and Perianal Parts of the Human Levator ani Muscle. Urol Int. 1980;35:226–232

18. koelbl H, Strassegger H, Riss PA, Gruber H. Morphologic and functional aspects of pelvic floor muscles in patients with pelvic relaxation and genuine stress incontinence. Obstet Gynecol. 1989;47(5):789-195.

19. Hoffman BL, Schorge JO, Schaffer JI, Halvorson LM, Bradshaw KD, Cunningham FG. Williams Gynecology. 2 ed. Texas: McGraw-Hill Medical; 2012.

20. Delancey JOL. The anatomy of the pelvic floor. Curr Opin Obstet Gynecol. 1994;6:313-316.

21. Kearney R, Sawhney R, DeLancey J. Levator ani muscle anatomy evaluated by origin-insertion pairs. Obstet Gynecol. 2004;104(1):168-173.

22. Margulies RU, Hsu Y, Kearney R, Stein T, Umek WH, DeLancey JOL. Appearance of the Levator Ani Muscle Subdivisions in Magnetic Resonance Images. Obstet Gynecol. 2006;107:1064–1069.

23. Ashton-Miller JA, Howard D, DeLancey JO. The functional anatomy of the female pelvic floor and stress continence control system. Scand J Urol Nephrol Suppl. 2001(207):1-7; discussion 106-125.

24. DeLancey JO, Ashton-Miller JA. MRI of intact and injured female pelvic floor muscles. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 1. 2 ed. Philadelphia: Churchill Livingstone Elsevier 2015. p. 97-109.

25. Tunn R, DeLancey JO, Howard D, Thorp JM, Ashton-Miller JA, Quint LE. MR imaging of levator ani muscle recovery following vaginal delivery. International urogynecology journal and pelvic floor dysfunction. 1999;10(5):300-307.

26. Percy JP, Swash M, Neill ME, Parks AG. Electrophysiological Study Of Motor Nerve Supply Of Pelvic Floor. The Lancet. 1981;1(8210):16-17.

27. Barber MD, Bremer RE, Thor KB, Dolber PC, Kuehl TJ, Coates KW. Innervation of the female levator ani muscles. American journal of obstetrics and gynecology. 2002;187(1):64-71.

28. Vodusek DB. Neuroanatomy and neurophysiology of pelvic floor muscles. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 1. 2 ed. Philadelphia: Churchill Livingstone Elsevier; 2007. p. 35-43.

29. Achtari C, Dwyer PL. Sexual function and pelvic floor disorders. Best practice & research Clinical obstetrics & gynaecology. 2005;19(6):993-1008; quiz A1001-1008.

30. Ashton-Miller JA, DeLancey JO. Functional anatomy of the female pelvic floor. Ann N Y Acad Sci. 2007;1101:266-296.

31. Delancey JOL. Anatomy and biomechanics of genital prolapse. Clin Obstet Gynecol. 1993;36(4):897-909.

32. Taverner D, Smiddy FG. An electromyographic study of the normal function of the external anal sphincter and pelvic diaphragm. Dis Colon Rectum. 1959;2(2):153-160.

33. Norton PA. Pelvic floor disorders: the role of fascia and ligaments. Clin Obstet Gynecol. 1993;36(4):926-938.

34. Kegel AH. Stress incontinence and genital relaxation; a nonsurgical method of increasing the tone of sphincters and their supporting structures. Ciba clinical symposia. 1952;4(2):35-51.

35. Bo K, Lilleas F, Talseth T, Hedland H. Dynamic MRI of the pelvic floor muscles in an upright sitting position. Neurourol Urodyn. 2001;20(2):167-174.

36. Bø K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? International urogynecology journal. 2004;15:76-84.

37. Betschart C, Kim J, Miller JM, Ashton-Miller JA, Delancey JOL. Comparison of muscle fiber directions between different levator ani muscle subdivisions: in vivo MRI measurements in women. International urogynecology journal. 2014;25:1263–1268.

38. Guaderrama NM, Nager CW, Liu J, Pretorius DH, Mittal RK. The vaginal pressure profile. Neurourol Urodyn. 2005;24(3):243–247.

39. Brækken IH, Majida M, Engh ME, Bø K. Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. Neurourol Urodyn. 2008;28(1):68-73.

40. Colstrup H. Voluntary contractions in the female urethra. J Urol. 1985;134:902-906.

41. Bø K, Talseth T. Change in urethral pressure during voluntary pelvic floor muscle contraction and vaginal electrical stimulation. International urogynecology journal. 1997;8:3-7.

42. Ruo H. The relationships of urethral and pelvic floor muscles and the urethral pressure measurements in women with stress urinary incontinence. Eur Urol. 2000;37:149-155.

43. Jha S, Thakar R. Female sexual dysfunction. Eur J Obstet Gynecol Reprod Biol. 2010;153:117-123.

44. Knuttgen HG, Kraemer WJ. Terminology and measurment in exercise performance. Journal of strength and conditioning research / National Strength & Conditioning Association. 1987;1(1):1-10.

45. Wilmore JH, Costill DL. Physiology of sport and exercise. 2 ed. Leeds: Human Kinetics; 1999.

46. Bø K, Sherburn M. Evaluation of female pelvic-floor muscle function and strength. Phys Ther. 2005;85(3):269-282.

47. Kegel AH. Progressive Resistance Exercise to the Functional Restoration of the Perineal Muscles. Am J Obst Gynec. 1948;56:238-248.

48. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn. 2009;28(4):295-300.

49. Laycock J. Clinical evaluation of the pelvic floor. In: Schussler B, Laycock J, Norton PA, Stanton SL, (eds), editors. Pelvic floor re-education, Principles and Practice. London: Springer-Verlag; 1994. p. 42–48.

50. Bø K, Finckenhagen HB. Vaginal palpation of pelvic floor muscle strength: inter-test reproducibility and comparison between palpation and vaginal squeeze pressure. Acta Obstet Gynecol Scand. 2001;80:883–887.

51. Morin M, Bourbonnais D, Gravel D, Dumoulin C, Lemieux MC. Pelvic floor maximal strength using vaginal digital assessment compared to dynamometric measurements. Neurourol Urodyn. 2004a;23(4):336-341.

52. Devreese A, Staes F, De Weerdt W, Feys H, Van Assche A, Penninckx F, et al. Clinical Evaluation of Pelvic Floor Muscle Function in Continent and IncontinentWomen. Neurourol Urodyn. 2004;23:190-197.

53. van delft K, Thakar R, Sultan AH. Pelvic floor muscle contractility: digital assessment vs transperineal ultrasound. Ultrasound Obstet Gynecol. 2015;45:217–222.

54. Flury N, Koenig I, Radlinger L. Crosstalk considerations in studies evaluating pelvic floor muscles using surface electromyography in women: a scoping review. Arch Gynecol Obstet. 2017;295(4):799-809.

55. Vodusek DB. Electromyography. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier; 2015. p. 53-60.

56. Auchincloss CC, McLean L. The reliability of surface EMG recorded from the pelvic floor muscles. J Neurosci Methods. 2009;182(1):85-96.

57. Glazer HI, Romanzi L, Polaneczky M. Pelvic floor muscle surface electromyography: reliability and clinical predicitive validity. J Reprod Med. 1999;44:779-782.

58. Dumoulin C, Morin M. Pelvic floor dynamometry. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier 2015. p. 66-76.

59. Sampselle CM, Miller JM, Mims BL, Delancey JOL, Ashton-miller JA, Antonakos CL. Effect of Pelvic Muscle Exercise on Transient Incontinence During Pregnancy and After Birth. Obstet Gynecol. 1998;91(3):406-412.

60. Miller JM, Ashton-Miller JA, Perruchini D, al. E. Test-retest reliability of an instrumented speculum for measuring vaginal closing force. Neurourol Urodyn. 2007;26(6):858-863.

61. Dumoulin C, Bourbonnais D, Lemieux MC. Development of a Dynamometer for Measuring the Isometric Force of the Pelvic Floor Musculature. Neurourol Urodyn. 2003;22:648-653.

62. Dumoulin C, Gravel D, Bourbonnais D, Lemieux MC, Morin M. Reliability of Dynamometric Measurements of the Pelvic Floor Musculature. Neurourol Urodyn. 2004;23:134-142.

63. Ashton-Miller JA, Zielinski R, Miller JM, DeLancey JOL. Validity and Reliability of an Instrumented Speculum Designed to Minimize the Effect of Intra-abdominal Pressure on the Measurement of Pelvic Floor Muscle Strength. Clin Biomech. 2014;29(10):1146–1150.

64. Morin M, Gravel D, Bourbonnais D, Dumoulin C, Ouellet S. Reliability of Dynamometric Passive Properties of the Pelvic Floor Muscles in Postmenopausal Women With Stress Urinary Incontinence. Neurourol Urodyn. 2008;27:819–825.

65. Morin M, Bourbonnais D, Gravel D, Dumoulin C, Lemieux MC. Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements. Neurourol Urodyn. 2004b;23(7):668-674.

66. Dietz HP, Shek C, Clarke B. Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound. Ultrasound Obstet Gynecol. 2005;25(6):580-585.

67. Majida M, Braekken IH, Bo K, Benth JS, Engh ME. Validation of three-dimensional perineal ultrasound and magnetic resonance imaging measurements of the pubovisceral muscle at rest. Ultrasound Obstet Gynecol. 2010;35(6):715-722.

68. Dietz HP. Ultrasound in the assessment of pelvic floor muscle and pelvic organ descent. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier 2015. p. 84-97.

69. Majida M, Braekken IH, Umek W, Bo K, Saltyte Benth J, Ellstrom Engh M. Interobserver repeatability of three- and four-dimensional transperineal ultrasound assessment of pelvic floor muscle anatomy and function. Ultrasound Obstet Gynecol. 2009;33(5):567-573.

70. Brækken IH, Majida M, Ellstrøm-Engh M, Dietz HP, Umek W, Bø K. Test–retest and intra-observer repeatability of two-, three- and four-dimensional perineal ultrasound of pelvic floor muscle anatomy and function. International urogynecology journal and pelvic floor dysfunction. 2007;19:227-235.

71. Siafarikas F, Staer-Jensen J, Braekken IH, Bo K, Engh ME. Learning process for performing and analyzing 3D/4D transperineal ultrasound imaging and interobserver reliability study. Ultrasound Obstet Gynecol. 2013;41(3):312-317.

72. Dietz HP. Quantification of major morhological abnormalities of the levator ani. Ultrasound Obstet Gynecol. 2007;29:329-334.

73. Staer-Jensen J, Siafarikas F, Hilde G, Braekken IH, Bo K, Engh ME. Pelvic floor muscle injuries 6 weeks post partum-an intra- and inter-rater study. Neurourol Urodyn. 2013;32(7):993-997.

74. Braekken IH, Majida M, Engh ME, Bø K. Morphological changes after pelvic floor muscle training measured by 3-dimensional ultrasonography: a randomized controlled trial. Obstet Gynecol. 2010;115(2 Pt 1):317-324.

75. Bø K. Vaginal squeeze pressure measurement. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier; 2015. p. 61-66.

76. Sigurdardottir T, Steingrimsdottir T, Arnason A, Bø K. Test-retest intra-rater reliability of vaginal measurement of pelvic floor muscle strength using myomed 932. Acta Obstet Gynecol Scand. 2009;88:939-943.

77. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bø K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn. 2006;25(3):236-242.

78. Bø K, Hagen R, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic muscle strength. Neurourol Urodyn. 1990;9(5):471-477.

79. Ferreira CH, Barbosa PB, de Oliveira Souza F, Antonio FI, Franco MM, Bø K. Inter-rater reliability study of the modified Oxford Grading Scale and the Peritron manometer. Physiotherapy. 2011;97(2):132-138.

80. Bø K, Hagen RR, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II. Validity of vaginal pressure measurements of pelvic muscle strength and the necessity of supplementary methods for control of correct contraction. Neurourol Urodyn. 1990;9(5):479-487.

81. Bø K, Raastad R, Finckenhagen HB. Does the size of the vaginal probe affect measurement of pelvic floor muscle strength? Acta Obstet Gynecol Scand. 2005;84:129-133.

82. Bo K, Frawley HC, Haylen BT, Abramov Y, Almeida FG, Berghmans B, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint

report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. International urogynecology journal. 2016.

83. Weber AM, Abrams P, Brubaker L, Cundiff G, Davis G, Dmochowski RR, et al. The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders. International urogynecology journal. 2001;12:178-186.

84. Nygaard I, Barber MD. Prevalence of Symptomatic Pelvic Floor Disorders in US Women. JAMA. 2008;17:1311-1316.

85. Bump RC, Norton PA. Epidemiology and natural history of pelvic floor dysfunction. Obstet Gynecol Clin North Am. 1998;25(4):723-746.

86. Delancey JO, Kane Low L, Miller JM, Patel DA, Tumbarello JA. Graphic integration of causal factors of pelvic floor disorders: an integrated life span model. American journal of obstetrics and gynecology. 2008;199(6):610 e611-615.

87. Kammerer-Doak D. Assessment of sexual function in women with pelvic floor dysfunction. International urogynecology journal. 2009;20 (suppl 1):45-50.

88. Rosen RC, Brown C, Heiman J, Leiblum S, Meston CM, Sabsigh R, et al. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther. 2000;26:191–208.

89. Creti L, Fichten CS, Libman E, Amsel R, Brender W. Female sexual functioning: a global score for Nowinski and Lopiccolo's sexual history form. Canadian Psychological Association; Montreal, Quebec1988.

90. Rust J, Golombok S. The GRISS: a psychometric instrument for the assessment of sexual dysfunction. Arch Sex Behav. 1986;15(2):157-165.

91. Verit FF, Verit A. Validation of the female sexual function index in women with chronic pelvic pain. The journal of sexual medicine. 2007;4(6):1635-1641.

92. Meston CM. Validation of the Female Sexual Function Index (FSFI) in women with female orgasmic disorder and in women with hypoactive sexual desire disorder. J Sex Marital Ther. 2003;29:36-46.

93. Baessler K, O'Neill SM, Maher CF, Battistutta D. Australian pelvic floor questionnaire: a validated interviewer-administered pelvic floor questionnaire for routine clinic and research. International urogynecology journal and pelvic floor dysfunction. 2009;20:149–158.

94. Price N JS, Avery K, Brookes ST, Abrams P Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: the ICIQ-VS. BJOG : an international journal of obstetrics and gynaecology. 2006;113:700-712.

95. Rogers RG, Kammerer-Doak DN, Villarreal A, Coates K, Qualls C. A new instrument to measure sexual function in women with urinary incontinence or pelvic organ prolapse. American journal of obstetrics and gynecology. 2001;184:552–558.

96. Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P. The Bristol Female Lower Urinary Tract Symptoms questionnaire: development and psychometric testing. Br J Urol. 1996;77(6):805-812.

97. Mouritsen L, Larsen JP. Symptoms, bother and POPQ in women referred with pelvic organ prolapse. Int Urogyn J pelvic floor dysfunction. 2003;14:122-127.

98. Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. American journal of obstetrics and gynecology. 2001;185(6):1388-1395.

99. Rogers RG, Coates KW, Kammerer-Doak DN, Khalsa S, Qualls C. A short form of the pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12). Int Urogyn J pelvic floor dysfunction. 2003;14:164–168.

100. Abrams P, Avery K, Gardener N, Donovan J, Board IA. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol. 2006;175(3 Pt 1):1063-1066; discussion 1066.

101. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. International urogynecology journal. 2010;21(1):5-26.

102. Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States: prevalence and predictors. JAMA. 1999;281(6):537-544.

103. MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. BJOG : an international journal of obstetrics and gynaecology. 2000;107:1460-1470.

104. Moran PA, Dwyer PL, Ziccone SP. Urinary leakage during coitus in women. J Obstet Gynaecol. 1999;19(3):286-288.

105. Serati M, Salvatore S, Uccella S, Nappi RE, Bolis P. Female urinary incontinence during intercourse: a review on an understudied problem for women's sexuality. The journal of sexual medicine. 2009;6(1):40-48.

106. Shaw C. A systematic review of the literature on the prevalence of sexual impairment in women with urinary incontinence and the prevalence of urinary leakage during sexual activity. Eur Urol. 2002;42(5):432-440.

107. Mouritsen L. Pathophysiology of sexual dysfunction as related to pelvic floor disorders. International urogynecology journal. 2009;20:19-25.

108. Barrett G, Pendry E, Peacock J, Victor C, Thakar R, Manyonda I. Women's sexual health after childbirth. BJOG : an international journal of obstetrics and gynaecology. 2000;107(2):186-195.

109. Serati M, Salvatore S, Khullar V, Uccella S, Bertelli E, Ghezzi F, et al. Prospective study to assess risk factors for pelvic floor dysfunction after delivery. Acta Obstet Gynecol Scand. 2008;87(3):313-318.

110. Connolly A, Thorp J, Pahel L. Effects of pregnancy and childbirth on postpartum sexual function: a longitudinal prospective study. International urogynecology journal and pelvic floor dysfunction. 2005;16(4):263-267.

111. Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. American journal of obstetrics and gynecology. 2001;184(5):881-890.

112. Brown S, Lumley J. Maternal health after childbirth: results of an Australian population based survey. Br J Obstet Gynaecol. 1998;105(2):156-161.

113. Andrews V, Thakar R, Sultan AH, Jones PW. Evaluation of postpartum perineal pain and dyspareunia-A prospective study. Eur J Obstet Gynecol Reprod Biol. 2008;137:152-156.

114. Serati M, Salvatore S, Siesto G, Cattoni E, Zanirato M, Khullar V, et al. Female sexual function during pregnancy and after childbirth. The journal of sexual medicine. 2010;7(8):2782-2790.

115. Pauls RN, Occhino JA, Dryfhout VL. Effects of pregnancy on female sexual function and body image: a prospective study. The journal of sexual medicine. 2008;5:1915-1922.

116. Dolan LM, Walsh D, Hamilton S, Marshall K, Thompson K, Ashe RG. A study of quality of life in primigravidae with urinary incontinence. International urogynecology journal. 2004;15(3):160-164.

117. Ege E; Akin B; Altuntug K; Benli S AA. Prevalence of urinary incontinence in the 12-months postpartum period and related risk factors in Turkey. Urol Int. 2008;80:355-361.

118. Delancey JOL. The hidden epidemic of pelvic floor dysfunction: Achievable goals for improved prevention and treatment. AJOG. 2005;192:1488-1495.

119. Handa VL, Cundiff G, Chang HH, Helzlsouer KJ. Female sexual function and pelvic floor disorders. Obstet Gynecol. 2008;111(5):1045-1052.

120. Basson R, Wierman ME, Van Lankveld J, Brotto L. Summary of the recommendations on sexual dysfunctions in women. The journal of sexual medicine. 2010;7(1 Pt 2):314-326.

121. Shafik A, El-Sibai O. Levator ani muscle activity in pregnancy and the postpartum period: a myoelectric study. Clin Exp Obstet Gynecol. 2000;27(2):129-132.

122. Ashton-Miller JA, Delancey JOL. On the Biomechanics of Vaginal Birth and Common Sequelae. Annu Rev Biomed Eng. 2009;11:163–176.

123. Lavin JM, Smith ARB, Anderson J, Grant M, Buckley H, Critchley H, et al. The effects of the first pregnancy on the connective tissue of the rectus sheath. Neurourol and Urodyn. 1997;16:381-382.

124. Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY. Williams Obstetrics. 23 ed: McGraw-Hill Medical; 2010.

125. Stær-Jensen J, Siafarikas F, Hilde G, Bø K, Engh ME. Ultrasonographic evaluation of pelvic organ support during pregnancy. Obstet Gynecol. 2013;122(2):329-336.

126. Erol B, Sanli O, Korkmaz D, Seyhan A, Akman Ta, Kadioglu A. A cross-sectional study of female sexual function and dysfunction during pregnancy. The journal of sexual medicine. 2007;4(5):1381–1387

127. DeJudicibus MA, McCabe MP. Psychological factors and the sexuality of pregnant and postpartum women. J Sex Res. 2002;39(2):94-103.

128. Hicks TL, Goodall SF, Quattrone EM, Lydon-Rochelle MT. Postpartum Sexual Functioning and Method of Delivery: Summary of the Evidence. Journal of midwifery & women's health. 2004;49(5):430–436.

129. Thompson JF, Roberts CL, Currie M, Ellwood DA. Prevalence and persistence of health problems after childbirth: associations with parity and method of birth. Birth. 2002;29(2):83-94.

130. Glazener CMA. Sexual function after childbirth: women's experiences, persistent morbidity and lack of professional recognition. BJOG : an international journal of obstetrics and gynaecology. 1997;104:330-335.

131. Fodstad K, Staff AC, Laine K. Sexual activity and dyspareunia the first year postpartum in relation to degree of perineal trauma. Int Urogyn J. 2016;10:1513-1523.

132. Klein K, Worda C, Leipold H, Gruber C, Husslein P, Wenzl R. Does the mode of delivery influence sexual function after childbirth? Journal of women's health. 2009;18(8):1227-1231.

133. Baytur YB, Deveci A, Uyar Y, Ozcakir HT, Kizilkaya S, Caglar H. Mode of delivery and pelvic floor muscle strength and sexual function after childbirth. Int J Gynaecol Obstet. 2005;88(3):276-280.

134. Brubaker L, Handa VL, Bradley CS, Connolly AM, Moalli P, Brown MB, et al. Sexual Function 6 Months After First Delivery. Obstet Gynecol. 2008;111(5):1040-1044.

135. Meyer S, Hohlfeld P, Achtari C, Russolo A, De Grandi P. Birth trauma: short and long term effects of forceps delivery compared with spontaneous delivery on various pelvic floor parameters. BJOG : an international journal of obstetrics and gynaecology. 2000;107:1360-1365.

136. Dean N, Wilson D, Herbison P, Glazener C, Aung T, Macarthur C. Sexual function, delivery mode history, pelvic floor muscle exercises and incontinence: A cross-sectional study six years post-partum. Aust N Z J Obstet Gynaecol. 2008;48:302–311.

137. Champaneria R, D'Andrea RM, Latthe PM. Hormonal contraception and pelvic floor function: a systematic review. Int Urogyn J. 2016;27:709-722.

138. Snooks SJ, Setchell M, Swash M, Henry MM. Injury to innervation of pelvic floor sphincter musculature in childbirth. Lancet. 1984;2(8402):546-550.

139. Allen RE, Hosker GL, Smith AR, Warrell DW. Pelvic floor damage and childbirth: a neurophysiological study. Br J Obstet Gynaecol. 1990;97(9):770-779.

140. Elenskaia K, Thakar R, Sultan AH, Scheer I, Beggs A. The effect of pregnancy and childbirth on pelvic floor muscle function. International urogynecology journal. 2011;22(11):1421-1427.

141. Hilde G, Staer-Jensen J, Siafarikas F, Engh ME, Braekken IH, Bo K. Impact of childbirth and mode of delivery on vaginal resting pressure and on pelvic floor muscle strength and endurance. American journal of obstetrics and gynecology. 2013;208(1):51-57.

142. Peschers UM, Schaer GN, DeLancey JOL, Schuessler B. Levator ani function before and after childbirth. BJOG : an international journal of obstetrics and gynaecology. 1997;104:1004-1008.

143. van Delft KWM, Thakar R, Sultan AH. The natural history of levator avulsion one year following childbirth: a prospective study. BJOG : an international journal of obstetrics and gynaecology. 2014;122:1266-1273.

144. Sigurdardottir T, Steingrimsdottir T, Arnason A, Bø K. Pelvic floor muscle function before and after first childbirth. International urogynecology journal. 2011;22:1497-1503.

145. Rosenbaum TY. Pelvic floor involvement in male and female sexual dysfunction and the role of pelvic floor rehabilitation in treatment: a literature review. The journal of sexual medicine. 2007;4:4-13.

146. de Souza Caroci A, Riesco MLG, da Silva Sousa W, Cotrim AC, Sena EM, Rocha NL, et al. Analysis of pelvic floor musculature function during pregnancy and postpartum: a cohort study: (a prospective cohort study to assess the PFMS by perineometry and digital vaginal palpation during pregnancy and following vaginal or caesarean childbirth). J Clin Nurs. 2010;19:2424-2433.

147. Snooks SJ, Swash M, Henry MM, Setchell M. Risk factors in childbirth causing damage to the pelvic floor innervation. Int J Colorectal Dis. 1986;1(1):20-24.

148. Sultan AH, Kamm MA, Hudson CN. Pudendal nerve damage during labour : prospective study before and after childbirth. BJOG : an international journal of obstetrics and gynaecology. 1994;101:22-28.

149. Lien KC, Morgan DM, DeLancey JOL, Ashton-Miller JA. Pudendal nerve stretch during vaginal birth: A 3D computer simulation. AJOG. 2005;192:1669-1676.

150. Wohlrab KJ, Rardin CR. Impact of Route of Delivery on Continence and Sexual Function. Clin Perinatol. 2008;35:583–590.

151. Lien KC, Mooney B, DeLancey JO, Ashton-Miller JA. Levator ani muscle stretch induced by simulated vaginal birth. Obstet Gynecol. 2004;103(1):31-40.

152. Hoyte L, Damaser MS, Warfield SK, Chukkapalli G, Majumdar A, Choi DJ, et al. Quantity and distribution of levator ani stretch during simulated vaginal childbirth. American journal of obstetrics and gynecology. 2008;199(2):198-205.

153. Parente MP, Jorge RM, Mascarenhas T, Fernandes AA, Martins JA. Deformation of the pelvic floor muscles during a vaginal delivery. Int Urogyn J pelvic floor dysfunction. 2008;19(1):65-71.

154. DeLancey JO, Kearney R, Chou Q, Speights S, Binno S. The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery. Obstet Gynecol. 2003;101(1):46-53.

155. Dietz HP, Lanzarone V. Levator Trauma After Vaginal Delivery. Obstet Gynecol. 2005;106(4):707-712.

156. Kearney R, Miller JM, Ashton-Miller JA, Delancey JOL. Obstetrical factors associated with levator ani muscle injury after vaginal birth. Obstet Gynecol. 2006;107(1):144-149.

157. Kearney R, Fitzpatrick M, Brennan S, Behan M, Miller JM, Keane D, et al. Levator ani injury in primiparous women with forceps delivery for fetal distress, forceps for second stage arrest, and spontaneous delivery. 111. 2010;1:19-22.

158. Dietz HP, Shek C. Levator avulsion and grading of pelvic floor muscle strength. International urogynecology journal. 2008;19:633–636.

159. DeLancey JOL, Morgan DM, Fenner DE, Kearney R, Guire K, Miller JM, et al. Comparison of Levator Ani Muscle Defects and Function in Women With and Without Pelvic Organ Prolapse. Obstet Gynecol. 2007;109(2).

160. Rogers RG, Leeman LM, Migliaccio L, Albers LL. Does the severity of spontaneous genital tract trauma affect postpartum pelvic floor function? International urogynecology journal. 2008;19:429–435.

161. Clark NA, Brincat CA, Yousuf AA, al. e. Levator defects affect perineal position independently of prolapse status. American journal of obstetrics and gynecology. 2010;203(595):17-22.

162. Rogers RG, Leeman LM, Migliaccio L, Albers LL. Does the severity of spontaneous genital tract trauma affect postpartum pelvic floor function? Int Urogynecol J Pelvic Floor Dysfunct. 2008;19(3):429-435

163. Hay-Smith EJ, Herderschee R, Dumoulin C, Herbison GP. Comparisons of approaches to pelvic floor muscle training for urinary incontinence in women. Cochrane database of systematic reviews. 2011(12):CD009508.

164. Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. Cochrane database of systematic reviews. 2011(12):CD003882.

165. Kraemer WJ, Ratamess NA. Fundamentals of resistance training: progression and exercise prescription. Med Sci Sports Exerc. 2004;36(4):674-688.

166. American College of Sports M. American College of Sports Medicine position stand. Progression models in resistance training for healthy adults. Med Sci Sports Exerc. 2009;41(3):687-708.

167. Bø K. Pelvic Floor Muscle Exercise for the Treatment of Stress Urinary Incontinence An Exercise Physiology Perspective. International urogynecology journal. 1995;6:282-291.

168. Garber CE, Blissmer B, Deschenes MR, Franklin BA, Lamonte MJ, Lee I-M, et al. ACSM Position Stand: Quantity and Quality of Exercise for Developing and Maintaining Cardiorespiratory, Musculoskeletal, and Neuromotor Fitness in Apparently Healthy Adults: Guidance for Prescribing Exercise. Med Sci Sports Exerc. 2011:1334-1359.

169. Bø K, Mørkved S. Motor learning. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 1 ed. Philadelphia: Churchill Livingstone Elsevier; 2007. p. 113-119.

170. Åstrand PO, Rodahl K, Dahl HA. Textbook of work physiology; physiological basis of exercise: Human Kinetics, Champaign, IL; 2003.

171. Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. III. Effects of two different degrees of pelvic floor muscle exercises. Neurourol Urodyn. 1990;9:489-502.

172. Bø K. Pelvic floor muscle training in treatment of female stress urinary incontinence, pelvic organ prolapse and sexual dysfunction. World J Urol. 2012;30(4):437-443.

173. Lowenstein L, Gruenwald I, Gartman I, Vardi Y. Can stronger pelvic muscle floor improve sexual function? International urogynecology journal. 2010;21(5):553-556.

174. Martinez CS, Ferreira FV, Castro AAM, Gomide LB. Women with greater pelvic floor muscle strength have better sexual function. Acta Obstetrica et Gynaecologica Scandinavia. 2014;93:457-502.

175. de Menezes Franco M, Driusso P, Bø K, de Abreu DCC, da Silva Lara LA, de Sá Rosa ACJ, et al. Relationship between pelvic floor muscle strength and sexual dysfunction in postmenopausal women: a cross-sectional study. International urogynecology journal. 2016:1-6.

176. Chambless DL, Stern T, Sultan FE, Williams AJ, Goldstein AJ, Lineberger MH, et al. The pubococcygens and female orgasm: a correlational study with normal subjects. Arch Sex Behav. 1982;11(6):479-490.

177. Kanter G, Rogers RG, Pauls RN, Kammerer-Doak D, Thakar R. A strong pelvic floor is associated with higher rates of sexual activity in women with pelvic floor disorders. International urogynecology journal. 2015;26(7):991-996.

178. Citak N, Cam C, Arslan H, Karateke A, Tug N, Ayaz R, et al. Postpartum sexual function of women and the effects of early pelvic floor muscle exercises. Acta Obstet Gynecol Scand. 2010;89(6):817-822.

179. Wilson PD, Herbison GP. A randomized controlled trial of pelvic floor muscle exercises to treat postnatal urinary incontinence. International urogynecology journal and pelvic floor dysfunction. 1998;9(5):257-264.

180. Mørkved S, Rømmen K, Schei B, Salvesen KA, Bø K. No difference in urinary incontinence between training and control group six years after cessation of a randomized controlled trial, but improved sexual satisfaction in the training group. Neurourol Urodyn. 2007;26(5):667.

181. Bo K, Talseth T, Vinsnes A. Randomized controlled trial on the effect of pelvic floor muscle training on quality of life and sexual problems in genuine stress incontinent women. Acta Obstet Gynecol Scand. 2000;79(7):598-603.

182. Chambless DL, Sultan FE, Stern TE, O'Neill C, Garrison S, Jackson A. Effect of pubococcygeal exercise on coital orgasm in women. J Consult Clin Psychol. 1984;52(1):114-118.

183. Trudel G, Saint-Laurent S. A comparison between the effects of Kegel's exercises and a combination of sexual awareness relaxation and breathing on situational orgasmic dysfunction in women. J Sex Marital Ther. 1983;9(3):204-209.

184. Braekken IH, Majida M, Ellstrom Engh M, Bo K. Can Pelvic Floor Muscle Training Improve Sexual Function in Women with Pelvic Organ Prolapse? A Randomized Controlled Trial. The journal of sexual medicine. 2014.

185. Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, et al. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. Lancet. 2014;383(9919):796-806.

186. Eftekhar T, Sohrabi M, Haghollahi F, Shariat M, Miri E. Comparison effect of physiotherapy with surgery on sexual function in patients with pelvic floor disorder: A randomized clinical trial. Iranian journal of reproductive medicine. 2014;12(1):7-14.

187. Wiegersma M, Panman CM, Kollen BJ, Berger MY, Lisman-Van Leeuwen Y, Dekker JH. Effect of pelvic floor muscle training compared with watchful waiting in older women with symptomatic mild pelvic organ prolapse: randomised controlled trial in primary care. BMJ. 2014;349:g7378.

188. Liebergall-Wischnitzer M, Paltiel O, Hochner Celnikier D, Lavy Y, Manor O, Woloski Wruble AC. Sexual function and quality of life of women with stress urinary incontinence: a randomized controlled trial comparing the Paula method (circular muscle exercises) to pelvic floor muscle training (PFMT) exercises. The journal of sexual medicine. 2012;9(6):1613-1623.

189. Handa VL, Whitcomb E, Weidner AC, Nygaard I, Brubaker L, Bradley CS, et al. Sexual function before and after non-surgical treatment for stress urinary incontinence. Female pelvic medicine & reconstructive surgery. 2011;17(1):30–35.

190. Yang EJ, Lim JY, Rah UW, Kim YB. Effect of a pelvic floor muscle training program on gynecologic cancer survivors with pelvic floor dysfunction: a randomized controlled trial. Gynecol Oncol. 2012;125(3):705-711.

191. Beji NK, Yalcin O, Erkan HA. The effect of pelvic floor training on sexual function of treated patients. International urogynecology journal and pelvic floor dysfunction. 2003;14(4):234-238; discussion 238.

192. Zahariou AG, Karamouti MV, Papaioannou PD. Pelvic floor muscle training improves sexual function of women with stress urinary incontinence. International urogynecology journal and pelvic floor dysfunction. 2008;19(3):401-406.

193. Rivalta M, Sighinolfi MC, Micali S, De Stefani S, Bianchi G. Sexual function and quality of life in women with urinary incontinence treated by a complete rehabilitation program (biofeedback, functional electrical stimulation, pelvic floor muscle exercises, and vaginal cones). The journal of sexual medicine. 2010;7:1200-1208.

194. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther. 2003;83(8):713-721.

195. Staer-Jensen J, Siafarikas F, Hilde G, Benth JS, Bo K, Engh ME. Postpartum recovery of levator hiatus and bladder neck mobility in relation to pregnancy. Obstet Gynecol. 2015;125(3):531-539.

196. Hilde G, Staer-Jensen J, Siafarikas F, Ellstrom Engh M, Bo K. Postpartum pelvic floor muscle training and urinary incontinence: a randomized controlled trial. Obstet Gynecol. 2013;122(6):1231-1238.

197. Hilde G, Staer-Jensen J, Ellstrom Engh M, Braekken IH, Bo K. Continence and pelvic floor status in nulliparous women at midterm pregnancy. International urogynecology journal. 2012;23(9):1257-1263.

198. Mørkved S, Bø K. The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence. International urogynecology journal and pelvic floor dysfunction. 1997;8(4):217-222.

199. Bø K. Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. Neurourol Urodyn. 1992;11(2):107-113.

200. Bo K, Hilde G, Staer-Jensen J, Siafarikas F, Tennfjord MK, Engh ME. Postpartum pelvic floor muscle training and pelvic organ prolapse-a randomized trial of primiparous women. American journal of obstetrics and gynecology. 2015;212(1):38 e31-37.

201. Dietz HP, Bernardo MJ, Kirby A, Shek KL. Minimal criteria for the diagnosis of avulsion of the puborectalis muscle by tomographic ultrasound. International urogynecology journal. 2011;22(6):699-704.

202. Dietz HP, Shek KL. Tomographic ultrasound imaging of the pelvic floor: which levels matter most? Ultrasound Obstet Gynecol. 2009;33(6):698-703.

203. Dietz HP, Shek K, Clarke B. Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound Ultrasound Obstet Gynecol. 2005;25:580-585.

204. Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ. 1999;318:487–493.

205. Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic Floor Muscle Exercise for the Treatment of Female Stress Urinary Incontinence: III. Effects of Two Different Degrees of Pelvic Floor Muscle Exercises. Neurourol Urodyn. 1990;9:489-502.

206. Morkved S, Bo K. The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence. International urogynecology journal and pelvic floor dysfunction. 1997;8(4):217-222.

207. DiNubile NA. Strength training. Clin Sports Med. 1991;10(1):33-62.

208. Cohen J. Statistical power analysis for the behavioural sciences. 2 ed. Hillsdale, NJ: Lawrence Earlbaum Associates; 1988.

209. Vickers AJ, Altman DG. Statistical notes. Analysing controlled trials with baseline and follow up measurements. BMJ. 2001;323:1123-1124.

210. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. The Lancet 1986;8:307-310.

211. Atkinson G, Nevill AM. Statistical Methods For Assessing Measurement Error (Reliability) in Variables Relevant to Sports Medicine. Sports Med. 1998:217-238.

212. WMA. Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects Fortaleza Brazil 2013 [Available from: www.wma.net/en/30/publictions/10policies/b3/.

213. De Vet HCV, Terwee CB, Mokkink LB, Knol DL, editors. Measurement in medicine a practical guide. United States of America, New York: Cambridge University Press; 2011.

214. Kottner JA, Audige L, Brorson S, Donner A, Gajewski BJ, Hròbjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. Int J Nurs Stud. 2011;48:661–671.

215. Altman DG, Bland JM. Statistics Notes Standard deviations and standard errors. BMJ. 2005;331:903.

216. Barbosa PB, Franco MM, Souza FO, Antônio FI, Montezuma T, Ferreira CHJ. Comparison between measurements obtained with three different perineometers. Clinics. 2009;64(6):527-533.

217. Bland JM, Altman DG. Comparing two methods of clinical measurement: a personal history. Int J Epidemiol. 1995;24:7-14.

218. Koelbl H, Nitti V, Baessler K, Salvatore S, Sultan A, Yamaguchi O. Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors., editors. Incontinence: 4th International Consultation on Incontinence. Paris: Health Publication Ltd; 2009. p. 255-330.

219. Morshed S, Tornetta P, Bhandari M. Analysis of Observational Studies: A Guide to Understanding Statistical Methods. Bone Joint Surg Am. 2009;91(3):50-60.

220. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. BMJ. 1999;319:670-674.

221. Moher D HS, Schulz K.F, Montori V, Gøtzsche P.C, Devereaux P.J, Elbourne D, Egger M, Altman D.G. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. International Journal of Surgery. 2012;10:28-55.

222. Bø K, Herbert RD. When and how should new therapies become routine clinical practice? Physiotherapy. 2009;95:51–57.

223. Herbert R. Critical appraisal of randomized trials and systematic reviews of the effects of physical therapy interventions for the pelvic floor. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence-based physical therapy for the pelvic floor Bridging science and clinical practice. 2 ed. Philadelphia: Churchill Livingstone Elsevier 2015. p. 9-17.

224. Brubaker L, Nygaard I, Bø K, Tincello DG, Homma K, Cook J, et al. Research methodology. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence 5th International Consultation on Incontinence. 5th ed. Paris: European Association of Urology; 2013. p. 1865-1893.

225. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies J Clin Epidemiol. 2008;61(4):344-349.

226. Jennie A. Freiman JA, Chalmers TC, Smith Jr H, Kuebler RR. The Importance of Beta, the Type II Error and Sample Size in the Design and Interpretation of the Randomized Control Trial — Survey of 71 Negative Trials. N Engl J Med. 1978;299:690-694.

227. Mendes EPB, Oliveira SMJV, Caroci AS, Francisco AA, Oliveira SG, Silva RL. Pelvic floor muscle strength in primiparous women according to the delivery type: cross-sectional study. Rev Latino-Am Enfermagem. 2016;24.

228. Rothman KJ, Greenland S, Lash TL. Modern epidemiology. 3 ed. Philadelphia: Lippincott Williams & Wilkins; 2008.

229. Bendera R, Lange S. Adjusting for multiple testing—when and how? J Clin Epidemiol. 2001;54 343–349.

230. Bland JM, Altman DG. Multiple significance tests: the Bonferroni method. BMJ. 1995;310:170.

231. Morin M, Bergeron S, Khalife S, Mayrand MH, Binik YM. Morphometry of the pelvic floor muscles in women with and without provoked vestibulodynia using 4D ultrasound. The journal of sexual medicine. 2014;11(3):776-785.

232. Reissing ED, Binik YM, Khalife S, Cohen D, Amsel R. Vaginal spasm, pain, and behavior: an empirical investigation of the diagnosis of vaginismus. Arch Sex Behav. 2004;33(1):5-17.

233. Næss I, Bø K. Pelvic floor muscle function in women with provoked vestibulodynia and asymptomatic controls. International urogynecology journal. 2015;26(10):1467–1473.

234. Hoffman BL, Schorge JO, Schaffer JI, Halvorson LM, Bradshaw KD, Cunningham FG. Williams Gynecology. 2 ed. Texas: McGraw-Hill Medical; 2012.

235. Both S, Laan E. Simultaneous measurement of pelvic floor muscle activity and vaginal blood flow: a pilot study. The journal of sexual medicine. 2007;4(3):690-701.

236. Frawley H. Pelvic floor pain and the overactive pelvic floor. In: Bø K BB, Mørkved S, van Kampen M, editor. Evidence based physical therapy for the pelvic floor Bridging science and clinical practice. 2. Philadelphia: Churchill Livingstone Elsevier; 2015. p. 333-253.

237. Falkert A, Willmann A, Endress E, Meint P, Seelbach-Gobel B. Three-dimensional ultrasound of pelvic floor: is there a correlation with delivery mode and persisting pelvic floor disorders 18-24 months after first delivery? Ultrasound Obstet Gynecol. 2013;41(2):204-209.

238. Elenskaia K, Thakar R, Sultan AH, Scheer I, Onwude J. Effect of childbirth on pelvic organ support and quality of life: a longitudinal cohort study. International urogynecology journal. 2013;24:927-937.

239. McDonald EA, Gartland D, Small R, Brown JS. Frequency, severity and persistance of postnatal dyspareunia to 18 months post partum: A cohort study. Midwifery. 2016;34:15-20.

240. McDonald EA, Gartland D, Small R, Brown JS. Dyspareunia and childbirth: a prospective study. BJOG : an international journal of obstetrics and gynaecology. 2015;122:672-679.

241. De Souza A, Dwyer PL, Charity M, Thomas E, Ferreira CHJ, Schierlitz L. The effects of mode delivery on postpartum sexual function: a prospective study. BJOG : an international journal of obstetrics and gynaecology. 2015.

242. Durnea CM, Khashan AS, Kenny LC, Tabirca SS, O'Reilly BA. The role of prepregnancy pelvic floor dysfunction in postnatal pelvic morbidity in primiparous women. International urogynecology journal. 2014;25:1363–1374.

.

243. Yeniel AO, Petri E. Pregnancy, childbirth, and sexual function: perceptions and facts. International urogynecology journal. 2014;25(1):5-14.

244. van Delft K, Sultan A, Thakar R, Schwertner-Tiepelmann N, Kluivers K. The relationship between postpartum levator ani muscle avulsion and signs and symptoms of pelvic

floor dysfunction. BJOG : an international journal of obstetrics and gynaecology. 2014;121:1164-1171.

245. Thibault-Gagnon S, Yusuf S, Langer S, Wong V, Shek KL, Martin A, et al. Do women notice the impact of childbirth-related levator trauma on pelvic floor and sexual function? Results of an observational ultrasound study. International urogynecology journal. 2014;25:1389–1398.

246. Laterza RM, Schrutka L, Umek W, Albrich S, Koelbl H. Pelvic floor dysfunction after levator trauma 1-year postpartum: a prospective case-control study. International urogynecology journal. 2014.

247. Cyr M-P, Kruger J, Wong V, al. e. Pelvic floor morphometry and function in women with and without puborectalis avulsion in the early postpartum period. AJOG. 2017;216(274):e1-8.

248. Roos AM, Sultan AH, Thakar R. Sexual problems in the gynecology clinic: are we making a mountain out of a molehill? International urogynecology journal. 2012;23(2):145-152.

249. Laterza RM, Schrutka L, Umek W, Albrich S, Koelbl H. Pelvic floor dysfunction after levator trauma 1-year postpartum: a prospective case-control study. Int Urogyn J 2015;26:41-47.

250. Guzman Rojas R, Wong V, Shek KL, Dietz HP. Impact of levator trauma on pelvic floor muscle function. International urogynecology journal. 2014;25:375-380.

251. Van Delft K, Shobeiri A, Sultan AH, Thakar R. Haematomas may masquerade as levator ani muscle defects. Int Urogyn J. 2012;23:S237.

252. Brækken IH, Majida M, Engh ME, Bø K. Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial. American journal of obstetrics and gynecology. 2010;203(2):170 e171-177.

253. Bland JM, Altman DG. Absence of evidence is not evidence of absence. BMJ. 1995;311:485.

254. Neels H, De Wachter S, Wyndaele JJ, Wyndaele M, Vermandel A. Does pelvic floor muscle contraction early after delivery cause perineal pain in postpartum women? European Journal of Obstetrics & Gynecology and Reproductive Biology. 2017;208:1-5.

255. Næss I, Bø K. Can a pelvic floor muscle contraction reduce vaginal resting pressure and resting EMG activity? . Abstract International Continence Society, Barcelona. 2013.

256. Bazi T, Takahashi S, Ismail S, Bø K, Ruiz-Zapata AM, Duckett J, et al. Prevention of pelvic floor disorders: international urogynecological association research and development committee opinion. International urogynecology journal. 2016.

257. Herbert RD, Bø K. Analysis of quality of interventions in systematic reviews. BMJ. 2005;331:507–509.

258. Ferreira CHJ, Dwyer PL, Davidson M, De Souza A, J.A. U, Frawley HC. Does pelvic floor muscle training improve female sexual function? A systematic review. International urogynecology journal. 2015.

259. Tennfjord MK, Ellström Engh M, Bø K. Role of physical therapy in the treatment of female sexual dysfunction. In: Costantini E, Villari D, Filocamo M, eds., editors. Female sexual function and dysfunction: Springer, Cham; 2017.

Paper I-IV

Paper I

Int Urogynecol J (2014) 25:1227–1235
DOI 10.1007/s00192-014-2373-2

ORIGINAL ARTICLE

Dyspareunia and pelvic floor muscle function before and during pregnancy and after childbirth

M. K. Tennfjord · G. Hilde · J. Stær-Jensen · M. Ellström Engh · K. Bø

Received: 19 January 2014 / Accepted: 10 March 2014 / Published online: 1 April 2014

Abstract
Introduction and hypothesis There is limited knowledge on dyspareunia during pregnancy and postpartum and the role of the pelvic floor muscles (PFM) in women with dyspareunia. Aims of the study were to investigate the presence of dyspareunia before and during pregnancy and postpartum, and to compare vaginal resting pressure (VRP), PFM strength, and endurance between women with and those without dyspareunia. It was hypothesized that there is no difference in PFM variables between women with and those without dyspareunia.
Methods Three hundred nulliparous women participated in this prospective cohort and answered questions about dyspareunia and the level of bother at gestational weeks 22 and 37, 6 and 12 months postpartum, and retrospectively prior to their pregnancies using ICIQ-FLUTSsex. PFM variables were assessed by manometer at gestational week 22, and 6 and 12 months postpartum. Comparisons between groups were analyzed using independent samples *t* test.
Results Twenty-eight and 30 % of the women reported dyspareunia at pre-pregnancy and at gestational week 22 respectively. At gestational week 37, and 6 and 12 months postpartum, the percentages were 40, 45, and 33 respectively. No difference in PFM variables was found between women with and those without dyspareunia. Level of bother was higher postpartum than before and during pregnancy.
Conclusions Symptoms of dyspareunia were common at all time points. No link could be made between PFM function and dyspareunia. Women suffering from dyspareunia postpartum reported it as being bothersome. Our findings suggest that women should be asked about symptoms of dyspareunia related to pregnancy, and that future research should aim for preventative and therapeutic strategies.

Keywords Dyspareunia · Level of bother · Manometer · Pelvic floor · Postpartum · Pregnancy

M. K. Tennfjord (✉) · G. Hilde · K. Bø
Department of Sports Medicine, Norwegian School of Sport Sciences, PO Box 4014, Ullevål stadion, 0806 Oslo, Norway
e-mail: merete.kolberg@gmail.com

M. K. Tennfjord · G. Hilde · J. Stær-Jensen · M. Ellström Engh · K. Bø
Department of Obstetrics and Gynecology, Akershus University Hospital, Lørenskog, Norway

M. Ellström Engh
Faculty Division, Akershus University Hospital, University of Oslo, Oslo, Norway

Introduction

Dyspareunia is the "complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration" [1]. It has been found in about 15 % of women between 30 and 50 years of age [2] and varies between 30 and 60 % amongst women postpartum [3, 4]. The overall impression from published research is that dyspareunia is prevalent in the first 6 months after childbirth and after this period it gradually declines [5]. Associations between pre-pregnancy and postpartum dyspareunia have been found [3, 6], but these results are based on retrospective studies.

The etiology of dyspareunia is considered multifactorial, with a combination of biological, psychosexual, and contextual factors [7]. Dyspareunia occurring during pregnancy and childbirth may be a result of morphological and hormonal changes of the pelvic floor [3, 6, 8], and has been shown to correlate with delivery mode [6, 9]. In women breastfeeding, a reduction in estrogen may lead to reduced vaginal lubrication as a response to sexual stimulation [10]. The relationship between the pelvic floor muscles (PFM) and dyspareunia is poorly understood, and the existing literature in pregnant and

postpartum women is sparse. Amongst women in the general population, dyspareunia has been linked to overactivity of the PFM [11, 12]. Whether this is a cause or effect is debated [7]. Overactivity of the PFM is defined as a "situation in which the PFM do not relax or may even contract when relaxation is functionally needed" [13]. However, no standardized measurement tool exists to evaluate the resting condition of the PFM [13, 14], and poor inter-observer reliability has been reported regarding commonly used methods such as visual observation and vaginal palpation [15]. In addition, there is no cut-off point for classifying the PFM as overactive or underactive [13].

To date, there have been few studies investigating dyspareunia beyond 6 months post-delivery and studies that compare pre-pregnancy and pregnancy dyspareunia with postpartum symptoms of dyspareunia. Although dyspareunia has received some attention in the existing literature, level of bother in relation to dyspareunia is seldom reported. Furthermore, the extent to which dyspareunia is related to overactive or weak PFM has not been established [11, 12].

The aims of the present study were to investigate the presence of dyspareunia cross-sectionally and longitudinally, and to study level of bother from before pregnancy until 12 months postpartum. Further, we aimed to compare vaginal resting pressure (VRP), PFM strength and endurance in women with and without dyspareunia, and to assess the impact of confounding variables on dyspareunia and PFM function. Null-hypothesis: there is no difference in VRP, PFM strength and endurance between women with and those without dyspareunia.

Materials and methods

This was a prospective cohort study assessing aspects of PFM function and symptoms of PFM dysfunction. The Regional Medical Ethics Committee (2009/170) and the Norwegian Social Science Data Services (2799026) approved the study. The study procedures were in accordance with the Helsinki Declaration (2000). All subjects gave written informed consent before entering the study.

Participants

Women scheduled for delivery at Akershus University Hospital, Norway, from January 2010 until April 2011, were invited to participate when they attended their routine ultrasound examination at mid-pregnancy (gestational weeks 18–22). Background information on the presence and level of bother of dyspareunia were collected through an electronic questionnaire at five different time points: pre-pregnancy, at gestational weeks 22 and 37, and at 6 and 12 months postpartum. The retrospective data for pre-pregnancy were collected at gestational week 22.

Inclusion criteria were being a healthy, nulliparous, and singleton pregnant woman able to speak and understand a Scandinavian language. Exclusion criteria were multiple pregnancies and previous miscarriage after week 16 of pregnancy. Ongoing exclusion criteria were premature birth < week 32, stillbirth, serious illness to mother or child, and subsequent pregnancies within 6 weeks of gestation. Women who were recruited to PFM training in a randomized controlled trial (RCT) starting 6 weeks postpartum were also excluded.

Power calculation

This study is part of a project investigating several questions related to the pelvic floor during pregnancy and postpartum. There was no specific a priori power calculation for questions on dyspareunia.

Outcomes

Dyspareunia was defined as one or more episodes of pain during intercourse within the last 3 months before pregnancy, and within the last 4 weeks at gestational weeks 22 and 37, and at 6 and 12 months postpartum. Level of bother was assessed on a scale ranging from 0 to 10, 0 being no bother and 10 a major bother. A Norwegian translated version of The International Consultation on Incontinence Modular Questionnaire, sexual matters module (ICIQ-FLUTSsex) was used to assess the presence and level of bother of dyspareunia [16]. Questions 4a "do you have pain when you have sexual intercourse?" and 4b "how much does this bother you?" were used. ICIQ-FLUTSsex has shown good construct validity and reliability, excellent stability, and acceptable criterion validity [17].

Assessments of VRP, PFM strength, and endurance were performed at gestational week 22, and at 6 and 12 months postpartum. During the first clinical visit, women were taught how to perform a correct PFM contraction defined as an inward movement and squeeze around the pelvic openings [18, 19]. PFM contraction without any movement of the pelvis or visible contraction of the glutei, hip or abdominal muscles was emphasized [19]. Instructions continued during observation and one-digit vaginal palpation with the participant in a supine position with knees bent. Vaginal palpation was undertaken to evaluate if the women were able to contract their PFM. VRP, PFM strength, and endurance were assessed with a high-precision pressure transducer connected to a vaginal balloon (Camtech AS, Sandvika, Norway). The device was positioned with the middle of the balloon 3.5 cm internal to the introitus [20], a method found to be reliable and valid if used with simultaneous observation of inward movement of the perineum/catheter during a contraction [19, 21].

Vaginal resting pressure was measured as vaginal pressure, with no voluntary PFM activity, and was registered as cmH_2O. PFM strength was reported as the mean of three maximum voluntary contractions, and registered as cmH_2O. PFM endurance was defined as a sustained maximum contraction and was quantified as the area under the curve during 10 s, measured during one attempt and registered as cmH_2Osec [22]. The atmospheric pressure on the balloon was calibrated to 0 cmH_2O for each subject before it was placed in the vagina. The two trained female physical therapists measuring the PFM were unaware of the answers provided in the electronic questionnaire, and therefore blinded to the participant's dyspareunia status. The physical therapists were, however, not blinded to any reactions on discomfort or pain during examination. Data on delivery outcomes including delivery mode (caesarean section, vacuum extraction/forceps), use of episiotomy, length of second stage of labor (>120 min), perineal tears (3rd and 4th degree) and infant birth weight were collected from the women's electronic medical birth records at the hospital. During the examination a towel was put on each woman's stomach in order to blind the investigators for any information related to mode of delivery.

Statistical analysis

Statistical analysis was performed using SPSS version 15. Background and descriptive variables were presented as frequencies with percentages and means with standard deviations (SD). Data showed normal distribution for exposure variables: VRP, PFM strength, and endurance. Outcome measures of dyspareunia were dichotomized into dyspareunia or no dyspareunia and women were registered as not having dyspareunia if they answered "not at all" to the question "do you have pain when you have sexual intercourse?" and registered as having dyspareunia if they answered "a little," "somewhat," or "a lot" to the same question. Women who reported that they were not having sexual intercourse were excluded from the analysis. Independent samples *t* test was used to analyze differences in PFM function between groups of women with and without dyspareunia. Background factors such as breastfeeding and use of hormonal contraceptives, and data on delivery outcomes, were considered potential confounders. Chi-squared test for independence and independent samples *t* test were used to assess the influence of these confounders on dyspareunia. Women who had vaginal births assisted by either vacuum extraction or forceps were pooled together for the analysis. To assess whether breastfeeding influenced PFM variables, independent samples *t* test was used. *P* values were two-sided and < 0.05 was considered significant. Missing data were listed in the tables and excluded from the analysis where appropriate.

Results

Participants

Three hundred nulliparous pregnant women were included at gestational week 22. One hundred and ninety-five women were seen at 6 months postpartum and 177 at 12 months postpartum. At 6 weeks postpartum, 71 women were recruited to an ongoing parallel RCT and excluded from the study. Twelve women were excluded owing to subsequent pregnancies, 3 because of stillbirth and 1 because of premature delivery < week 32. Thirty-six women were lost to follow-up throughout the study period (12 %). One hundred and seventy-seven women attending at all time points of the data collection were included in the longitudinal analysis. Background characteristics for the 300 women included at gestational week 22 are presented in Table 1.

Presence of dyspareunia and level of bother

Between 28 and 45 % of the women reported symptoms of dyspareunia at the different time points. Most women reported dyspareunia as "a little" (Table 2). Mean level of bother was higher postpartum than prior to and during pregnancy (Table 3).

Dyspareunia and PFM variables

Table 4 shows mean VRP, PFM strength, and endurance in women with and those without dyspareunia at the different time points. No statistically significant differences were found between the groups with regard to any of the PFM measurements. No significant difference in VRP (95%CI: −0.7, 5.1 and 95%CI: −4.5, 0.9), PFM strength (95%CI: −0.7, 11.9 and 95%CI: −11.3, 0.6) or endurance (95%CI: −22.4, 109.2 and 95%CI: −95.5, 7.1) was found between women breastfeeding and those not breastfeeding at 6 or 12 months postpartum respectively.

Factors related to dyspareunia

Amongst women who were breastfeeding 65 (49 %) reported dyspareunia at 6 months postpartum versus 13 (30 %) of those not breastfeeding ($p=0.05$). At 12 months postpartum there was no difference: 22 (38 %) vs 32 (30 %) respectively ($p=0.38$). At 6 months postpartum there was no difference between those using contraceptives and those not using contraceptives in relation to symptoms of dyspareunia: 25 (36 %) vs 50 (49 %) respectively ($p=0.12$). Nor was there a difference at 12 months postpartum on the use of contraceptives in relation to dyspareunia: 21 (28 %) using contraceptives vs 34 (37 %) not using contraceptives ($p=0.317$). No statistically significant difference was found for women with and those

Table 1 Background variables of the study population

	Pre-pregnancy *N*=300	Gestational week 22 *N*=300	Gestational week 37 *N*=277	6 months postpartum *N*=195[a]	12 months postpartum *N*=177
Age (years) *n* (SD)	28.7 (SD 4.3)				
BMI (kg/m^2) *n* (SD)	23.9 (SD 3.9)				
Civil status, *n* (%)					
Married/cohabitant	287 (95.7)				
Living alone	13 (4.3)				
Educational level, *n* (%)					
College/university	226 (75.3)				
Primary/high school/other	74 (24.7)				
Breastfeeding, *n* (%)	n.a	n.a	n.a		
≥ Once daily				147 (75)	61 (34.5)
< Once daily				5 (2.5)	3 (1.7)
Smoking, *n* (%)	77 (25.6)	16 (5.3)	12 (4.3)	18 (9)	20 (11.3)
Contraceptives, *n* (%)	n.a	n.a	n.a	75 (38.5)	77 (43.5)

Results presented as frequency with percentages (%) or standard deviation (SD)

BMI body mass index, *n.a* not applicable

[a] Three missing

without dyspareunia with regard to delivery mode, use of episiotomy, prolonged second stage of labor (>120 min), 3rd and 4th degree perineal tears or infant birth weight at 6 or 12 months postpartum (Table 5).

Longitudinal data

Figure 1 shows longitudinal data on the incidence and prevalence of dyspareunia. There was a higher incidence of dyspareunia during pregnancy and at 6 months postpartum compared with 12 months postpartum. For women with dyspareunia prior to pregnancy and for women with new symptoms of dyspareunia during pregnancy and postpartum, there was a decline in prevalence throughout the study.

Discussion

Almost one third of the women reported pre-pregnancy dyspareunia and the prevalence of dyspareunia was high at all time points. No difference in VRP, PFM strength or endurance was found between women with and those without dyspareunia. The results support the null hypothesis that there is no difference in VRP, PFM strength and endurance between women with and those without dyspareunia. Dyspareunia was more frequently present amongst women breastfeeding at 6 months postpartum, whilst use of contraceptives, delivery mode, episiotomy, prolonged second stage of labor (>120 min), 3rd and 4th degree perineal tears or infant birth weight showed no differences between the groups. For women with dyspareunia prior to pregnancy and for women with

Table 2 Presence and severity of dyspareunia

	Pre-pregnancy *N*=299	Gestational week 22 *N*=285	Gestational week 37 *N*=227	6 months postpartum *N*=175[a]	12 months postpartum *N*=166
Not having intercourse, *n* (%)	1 (0.3)	15 (5)	50 (18.1)	20 (10.3)	11 (6.2)
No dyspareunia, *n* (%)	216 (72.2)	198 (69.5)	133 (58.6)	97 (55.4)	111 (66.9)
Dyspareunia, *n* (%)	83 (27.8)	87 (30.5)	94 (41.4)	78 (44.6)	55 (33.1)
A little, *n* (%)	69 (83.1)	73 (83.9)	73 (77.7)	59 (75.6)	35 (63.6)
Somewhat, *n* (%)	11 (13.3)	11 (12.6)	15 (15.9)	9 (11.5)	14 (25.5)
A lot, *n* (%)	3 (3.6)	3 (3.4)	6 (6.4)	10 (12.8)	6 (10.9)

Severity of dyspareunia (little, somewhat, a lot) represents percentages of those with dyspareunia

Results presented as frequency with percentages (%)

[a] Three missing

Table 3 Level of bother of women with dyspareunia

	Mean (SD)
Pre-pregnancy, *n*=83	3.4 (2.5)
Gestational week 22, *n*=87	3.5 (2.3)
Gestational week 37, *n*=94	4.0 (2.5)
6 months postpartum, *n*=78[a]	4.5 (2.9)
12 months postpartum, *n*=55	5.1 (2.9)

Results presented as mean with standard deviation (SD)

[a] Three missing

new symptoms of dyspareunia during pregnancy and postpartum, there was a decline in prevalence throughout the study. Women still suffering from dyspareunia postpartum reported it as being bothersome.

Other studies report dyspareunia as being common 6 months after childbirth [3, 4]. We found that the number of women with dyspareunia was still high at 12 months postpartum. This is higher than previously found by other researchers [4, 23]. Connolly et al. [4] had fewer women included in their analysis compared with our study, and Serati et al. [23] investigated new cases of dyspareunia and excluded those with sexual problems prior to and during pregnancy. Interestingly, we found that the number of women reporting dyspareunia before pregnancy was high, but only 14.6 % of these had dyspareunia at 12 months postpartum. The results also indicate that the majority of women with new symptoms of dyspareunia during pregnancy were symptom-free by 12 months postpartum. Our findings could be interpreted in such a way that most symptoms of dyspareunia occurring during this period resolve naturally. However, an underestimation of the prevalence of dyspareunia could exist. Data from women not having sexual intercourse were excluded from the analysis and it is possible that dyspareunia was a reason for not having intercourse. Our results are lower than a previous study where 60 % of the women with pre-pregnancy dyspareunia were still symptomatic at 6 months postpartum [3]. In the present study 89.7 % of the women resumed intercourse by 6 months postpartum, despite the fact that 44.6 % were complaining of dyspareunia. One explanation could be that most symptoms were described as constituting "a little" dyspareunia. Still, level of bother was highest postpartum. Since dyspareunia and sexual dysfunction are strongly associated with personal experiences and relationship factors [2], the question of bother in this study covers just part of this complexity. Few studies address the level of bother and the ones that do show conflicting results regarding the impact on sexual life in the postpartum months [4, 10].

No statistically significant difference in PFM strength and endurance was found between women with and without dyspareunia. Other studies investigating dyspareunia in pregnant and postpartum women found no relationship between

Table 4 Mean vaginal resting pressure (*VRP*), pelvic floor muscle (*PFM*) strength, and endurance in women with and without dyspareunia

Total	Gestational week 22			6 months postpartum[a]			12 months postpartum		
	N=285			*N*=175			*N*=166		
	Dyspareunia *n*=87 (SD)	No dyspareunia *n*=198 (SD)	Mean difference with 95 % CI	Dyspareunia *n*=78 (SD)	No dyspareunia *n*=97 (SD)	Mean difference with 95 % CI	Dyspareunia *n*=55 (SD)	No dyspareunia *n*=111 (SD)	Mean difference with 95 % CI
VRP (cmH_2O)	43.1 (11.3)	42.9 (9.3)	−0.17 (−2.7, 2.3)	35.4 (9.0)	34.2 (8.7)	−1.5 (−3.8, 1.5)	36.2 (9.5)	34.8 (8.8)	−1.4 (−4.3, 1.5)
PFM strength (cmH_2O)	33.0 (18.4)	36.0 (17.7)	3.0 (−1.5, 7.5)	34.2 (19.3)	29.8 (18.3)	−4.4 (−10, 1.2)	34.2 (19.0)	35.3 (20.2)	1.1 (−5.3, 7.6)
Endurance (cmH_2Osec)	223.5 (133.3)	249.0 (131.5)	25.5 (−7.9, 58.9)	267.8 (158.7)	233.9 (159.3)	−33.9 (−81.6, 13.9)	273.2 (165.4)	282.7 (173.1)	9.5 (−46.1, 65.1)

[a] Three missing

Table 5 Number of women with elective and acute cesarean section, operative vaginal delivery, episiotomy, prolonged second stage (>120 min), 3rd and 4th degree perineal tears, and weight of infant amongst women with and without dyspareunia at 6 and 12 months postpartum

	Dyspareunia (%)	No dyspareunia (%)	*p* value
6 months postpartum			
Numbers with elective cesarean section	3/78 (3.8)	4/97 (4.1)	1.0
Numbers with acute cesarean section	16/78 (20.5)	12/97 (12.4)	0.2
Numbers with operative vaginal delivery (vacuum and forceps)	11/78 (14.1)	13/97 (13.4)	1.0
Numbers with episiotomy	17/78 (21.8)	29/97 (29.9)	0.4
Numbers with prolonged second stage (> 120 min)	7/63 (11.1)[a]	16/80 (20.0)[a]	0.23
Numbers with 3rd and 4th degree perineal tears	4/78 (5.1)	1/97 (1.0)	0.25
Weight of infant	3,526.5 kg	3,476.3 kg	0.54 (95%CI: −209.6, 109.1)
12 months postpartum			
Numbers with elective cesarean section	2/55 (3.6)	6/111 (5.4)	0.9
Numbers with acute cesarean section	11/55 (20.0)	13/111 (11.7)	0.23
Numbers with operative vaginal delivery (vacuum and forceps)	9/55 (16.4)	15/111 (13.5)	0.8
Numbers with episiotomy	12/55 (21.8)	32/111 (28.8)	0.35
Numbers with prolonged second stage (> 120 min)	6/44 (13.6)[a]	14/91 (15.4)[a]	1.0
Numbers with 3rd and 4th degree perineal tears	2/55 (3.6)	5/111 (4.5)	1.0
Weight of infant	3,563.5 kg	3,474.4 kg	0.3 (95%CI: −258.1, 80.0)

[a] Incomplete information for 32 women at 6 months postpartum, incomplete information for 31 women at 12 months postpartum

weak PFM and dyspareunia [24, 25]. Both studies had fewer women in their analysis compared to our study, 68 and 110 respectively. We did see a decline in VRP, PFM strength and endurance following delivery in both groups, which may be seen as a response to the effect of pregnancy and delivery found in our study group [26] and in the study by Elenskaia et al. [27]. This did not seem to influence differences between those with and those without dyspareunia and nor did delivery outcomes. This is in contrast to previous studies [6, 9]. However, to what extent dyspareunia is related to mode of delivery

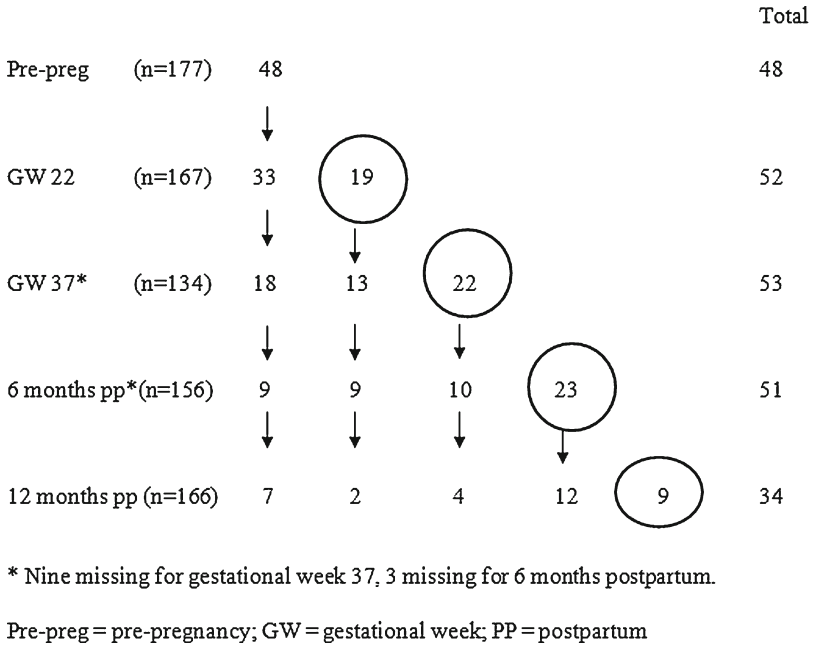

Fig. 1 Incidence and prevalence of dyspareunia from pre-pregnancy until 12 months postpartum. Prevalence of women with dyspareunia is given in the column on the right side. *Numbers in brackets* are the total number of women having sexual intercourse. The *encircled numbers* represent incidence, prevalence is given for pre-pregnancy dyspareunia. *Arrows* show changes in frequency amongst the same women with dyspareunia through different time points. *GW* gestational week, *PP* postpartum

is not well established [5]. Since we did not separate women into low- or high-risk pregnancy categories, we cannot rule out that any gestational diseases might affect dyspareunia status and PFM function in our study. Since 63 to 83 % reported having "a little" dyspareunia, a difference in PFM function could perhaps be seen if more women reported having "moderate" or "a lot" of dyspareunia. One conclusion could therefore be that a little dyspareunia was not associated with the PFM in this study. Despite the decline seen in PFM variables at 6 months postpartum, our results indicate that PFM strength and endurance are back to pregnancy levels at 12 months postpartum in both groups. VRP was, however, lower at 12 months postpartum than at pregnancy levels in both groups. The study by Elenskaia et al. [27] reported similar findings, although the authors did not look into symptoms of dyspareunia.

This study did not find a statistically significant difference in VRP between women with and those without dyspareunia. We consider VRP to be the most important factor as it is a measurement of the resting condition without any voluntary PFM contraction. A post power calculation, based on the SD in the dyspareunia group with 90 % power and a 5 % significance level, showed that a difference in VRP of 4–5 cmH_2O would be needed to demonstrate a statistically significant difference based on the number of women included. The difference in VRP between the groups in our study was about 1 cmH_2O. This difference is neither statistically nor clinically relevant. No studies to our knowledge have investigated the resting condition of the PFM in relation to dyspareunia amongst pregnant and postpartum women. Amongst women with symptoms of dyspareunia in the general female population, conflicting results exist regarding higher PFM activity at rest and the presence of dyspareunia [11, 12]. The study by Both and Laan [12] found higher PFM activity on vaginal surface electromyography (EMG) in women with dyspareunia than in women with no dyspareunia. The investigators did not confirm a correct PFM contraction before testing, and the increase in muscle activity may be influenced by extra-pelvic muscle contractions. Vaginal surface EMG may also be biased by cross-talks from nearby muscles [13, 14]. The study by Reissing et al. [11] used vaginal palpation to assess overactivity of the PFM in women with dyspareunia, but these findings were not confirmed by vaginal surface EMG. Palpation of PFM overactivity has been shown to be unreliable [15]. It remains unclear whether dyspareunia causes muscle changes or whether VRP, PFM strength, and endurance cause dyspareunia. To date, only one RCT has investigated the effect of PFM training on symptoms of dyspareunia [28]. This study found no statistically significant difference between the group exercising their PFM and the control group. There is a need for high-quality RCTs on pelvic floor muscle training in this area.

Significantly more women who were breastfeeding reported dyspareunia at 6 months postpartum, but not at 12 months postpartum. Breastfeeding has previously been identified as a factor associated with dyspareunia [3, 6]. The fact that this relationship was not present at 12 months postpartum could be due to fewer women breastfeeding at this point, whilst most who continued had reduced the frequency of feeds between 6 and 12 months postpartum. Use of contraceptives did not seem to influence the presence of dyspareunia. This is in line with the report by Barrett et al. [3].

To our knowledge, this is the first prospective study investigating dyspareunia and PFM function longitudinally, including data on several time points, before and during pregnancy, and postpartum. Moreover, we studied a large sample of the cohort longitudinally regarding change in symptoms of dyspareunia. These results contribute to a greater knowledge of symptoms of dyspareunia as we investigated the women from mid-pregnancy until 12 months postpartum, including pre-pregnancy symptoms. This study also assessed level of bother in relation to dyspareunia and relatively few cases were lost to follow-up. Further, a PFM contraction without any use of the pelvis or visible contraction of the glutei, hip or abdominal muscles was emphasized, minimizing the influence of intra-abdominal pressure and the use of extra-pelvic muscle contractions. The use of manometry has shown good to very good reliability for the measurement of PFM variables [29]. However, VRP may be influenced by anatomy and altered tissue tension, especially after childbirth [8].

One limitation is that there was no a priori power calculation for studying PFM variables in women with and without dyspareunia. As far as we have ascertained, our results represent the largest prospective study in this group of women. However, a type II error cannot be ruled out. Another limitation is that the ICIQ-FLUTSsex has not yet been validated amongst pregnant and postpartum women, nor has it been validated in the Norwegian language. Although dyspareunia may be a sensitive topic, we believe that the questions on dyspareunia were relatively easy to answer and would not influence the validity of our results to a great extent. In addition, no questions addressed reasons for not having intercourse, if the reported dyspareunia was superficial/introital or deep and if it was present during every occurrence of intercourse. Moreover, no questions addressed other factors that have been strongly linked with sexual complaints, such as sexual arousal, sexual desire, and orgasm [30]. We acknowledge that this information could give a more complete understanding of dyspareunia, as it may be dependent on several organic and psychological mechanisms [7]. Since this cohort was not a select sample of women with dyspareunia, but a cohort investigating other pelvic floor dysfunctions in pregnancy and postpartum as well, no specific palpation was undertaken to elicit pain or diagnose dyspareunia in these women. This makes it difficult to report on underlying causes of dyspareunia and does not allow direct comparisons of studies reported in the general population [11, 12]. The amount of women being examined at several time points made it necessary to use two examiners to undergo the pelvic floor

measurements. However, both physical therapists were experienced and trained prior to the study. Although, the physical therapists were blinded to the dyspareunia status of each participant, the examiners were not blinded to any reactions of pain or discomfort during the examination. However, all women tolerated vaginal palpation at all time points during data collection. The results on incidence and prevalence should be interpreted with caution since we had several inclusion and exclusion criteria. Women in this study are comparable to other primiparous women delivering at the same hospital with respect to age and body mass index, except that they had a higher level of education. To date, there is limited knowledge to support any suggestion that women with a higher level of education have fewer sexual complaints than others [2]. Lastly, retrospective questions about the condition prior to pregnancy can be considered a weakness. The inclusion of women in studies before they get pregnant is a well-recognized challenge, and this was not possible in our study.

Conclusions

The number of women complaining of dyspareunia was high before pregnancy and throughout the follow-up period. No statistically significant difference was found between women with and those without dyspareunia in any of the PFM variables, nor was there a significant relationship with dyspareunia with regard to the use of contraceptives, delivery mode, episiotomy, prolonged second stage of labor (>120 min), 3rd or 4th degree perineal tears or infant birth weight. Only breastfeeding was significant as a factor related to dyspareunia at 6 months postpartum. Incidence and prevalence of dyspareunia were lower at 12 months postpartum compared with symptoms before and during pregnancy, but women still suffering from dyspareunia postpartum reported it to be bothersome. Our findings suggest that women should be asked about symptoms of dyspareunia prior to and during pregnancy, and that future research should aim for preventative and treatment strategies, especially for those still suffering from dyspareunia in the postpartum period. There is also a need to investigate anatomical and morphological changes in women with dyspareunia using ultrasound and magnetic resonance imaging.

Acknowledgements We thank midwife Tone Breines Simonsen, gynecologist Franziska Siafarikas, and physical therapist Kristin Gjestland for excellent work with recruiting participants, clinical testing, and data entry. We thank Gill Brook for help with English grammar editing on this manuscript. We acknowledge the South-Eastern Norway Regional Health Authority and the Norwegian Research Council for financing the original study. We also gratefully acknowledge financial funding for the present project on sexual dysfunction and the pelvic floor through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

Conflicts of interest None.

References

1. Haylen BT, Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN (2010) An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J 21:5–26
2. Laumann EO, Paik A, Rosen RC (1999) Sexual dysfunction in the United States: prevalence and predictors. JAMA 281:537–544
3. Barrett G, Pendry E, Peacock J, Victor C, Thakar R, Manyonda I (2000) Women's sexual health after childbirth. BJOG 107:186–195
4. Connolly A, Thorp J, Pahel L (2005) Effects of pregnancy and childbirth on postpartum sexual function: a longitudinal prospective study. Int Urogynecol J Pelvic Floor Dysfunct 16:263–267. doi:10.1007/s00192-005-1293-6
5. Yeniel AO, Petri E (2014) Pregnancy, childbirth, and sexual function: perceptions and facts. Int Urogynecol J 25:5–14
6. Signorello LB, Harlow BL, Chekos AK, Repke JT (2001) Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. Am J Obstet Gynecol 184:881–890. doi:10.1067/mob.2001.113855
7. Graziottin A (2007) Pelvic floor dysfunction and evidence-based physical therapy. In: Bø K, Berghmans B, Mørkved S, Van Kampen M (eds) Evidence based physical therapy for the pelvic floor. Bridging science and clinical practice, 1st edn. Churchill Livingstone Elsevier, Philadelphia, pp 266–287
8. Falkert A, Willmann A, Endress E, Meint P, Seelbach-Gobel B (2013) Three-dimensional ultrasound of pelvic floor: is there a correlation with delivery mode and persisting pelvic floor disorders 18–24 months after first delivery? Ultrasound Obstet Gynecol 41:204–209. doi:10.1002/uog.11214
9. Thompson JF, Roberts CL, Currie M, Ellwood DA (2002) Prevalence and persistence of health problems after childbirth: associations with parity and method of birth. Birth 29:83–94
10. DeJudicibus MA, McCabe MP (2002) Psychological factors and the sexuality of pregnant and postpartum women. J Sex Res 39:94–103. doi:10.1080/00224490209552128
11. Reissing ED, Binik YM, Khalife S, Cohen D, Amsel R (2004) Vaginal spasm, pain, and behavior: an empirical investigation of the diagnosis of vaginismus. Arch Sex Behav 33:5–17. doi:10.1023/B:ASEB.0000007458.32852.c8
12. Both S, Laan E (2007) Simultaneous measurement of pelvic floor muscle activity and vaginal blood flow: a pilot study. J Sex Med 4:690–701. doi:10.1111/j.1743-6109.2007.00457.x
13. Messelink B, Benson T, Berghmans B, Bo K, Corcos J, Fowler C, Laycock J, Lim PH, van Lunsen R, a Nijeholt GL, Pemberton J, Wang A, Watier A, Van Kerrebroeck P (2005) Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 24:374–380. doi:10.1002/nau.20144
14. Auchincloss CC, McLean L (2009) The reliability of surface EMG recorded from the pelvic floor muscles. J Neurosci Methods 182:85–96. doi:10.1016/j.jneumeth.2009.05.027
15. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME (2009) Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn 28:295–300. doi:10.1002/nau.20659
16. Abrams P, Avery K, Gardener N, Donovan J (2006) The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol 175:1063–1066
17. Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P (1996) The Bristol Female Lower Urinary Tract

Symptoms questionnaire: development and psychometric testing. Br J Urol 77:805–812
18. Kegel AH (1952) Stress incontinence and genital relaxation; a non-surgical method of increasing the tone of sphincters and their supporting structures. CIBA Clin Symp 4:35–51
19. Bo K, Hagen R, Kvarstein B, Larsen S (1990) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. I. Reliability of vaginal pressure measurements of pelvic muscle strength. Neurourol Urodyn 9:471–477
20. Bo K (1992) Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. Neurourol Urodyn 11:107–113. doi:10.1002/nau.1930110205
21. Bo K, Hagen RR, Kvarstein B, Larsen S (1990) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II. Validity of vaginal pressure measurements of pelvic muscle strength and the necessity of supplementary methods for control of correct contraction. Neurourol Urodyn 9:479–487. doi:10.1002/nau.1930090504
22. Braekken IH, Majida M, Ellstrom Engh M, Holme IM, Bo K (2009) Pelvic floor function is independently associated with pelvic organ prolapse. BJOG 116:1706–1714. doi:10.1111/j.1471-0528.2009.02379.x
23. Serati M, Salvatore S, Khullar V, Uccella S, Bertelli E, Ghezzi F, Bolis P (2008) Prospective study to assess risk factors for pelvic floor dysfunction after delivery. Acta Obstet Gynecol Scand 87:313–318. doi:10.1080/00016340801899008
24. Baytur YB, Deveci A, Uyar Y, Ozcakir HT, Kizilkaya S, Caglar H (2005) Mode of delivery and pelvic floor muscle strength and sexual function after childbirth. Int J Gynaecol Obstet 88:276–280. doi:10.1016/j.ijgo.2004.12.019
25. Caroci Ade S, Riesco ML, Sousa Wda S, Cotrim AC, Sena EM, Rocha NL, Fontes CN (2010) Analysis of pelvic floor musculature function during pregnancy and postpartum: a cohort study: (a prospective cohort study to assess the PFMS by perineometry and digital vaginal palpation during pregnancy and following vaginal or caesarean childbirth). J Clin Nurs 19:2424–2433. doi:10.1111/j.1365-2702.2010.03289.x
26. Hilde G, Staer-Jensen J, Siafarikas F, Engh ME, Braekken IH, Bo K (2013) Impact of childbirth and mode of delivery on vaginal resting pressure and on pelvic floor muscle strength and endurance. Am J Obstet Gynecol 208:51–57. doi:10.1016/j.ajog.2012.10.878
27. Elenskaia K, Thakar R, Sultan AH, Scheer I, Beggs A (2011) The effect of pregnancy and childbirth on pelvic floor muscle function. Int Urogynecol J 22:1421–1427. doi:10.1007/s00192-011-1501-5
28. Citak N, Cam C, Arslan H, Karateke A, Tug N, Ayaz R, Celik C (2010) Postpartum sexual function of women and the effects of early pelvic floor muscle exercises. Acta Obstet Gynecol Scand 89:817–822. doi:10.3109/00016341003801623
29. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K (2006) Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn 25:236–242. doi:10.1002/nau.20201
30. Basson R, Wierman ME, Van Lankveld J, Brotto L (2010) Summary of the recommendations on sexual dysfunctions in women. J Sex Med 7:314–326. doi:10.1111/j.1743-6109.2009.01617.x

Paper II

Coital Incontinence and Vaginal Symptoms and the Relationship to Pelvic Floor Muscle Function in Primiparous Women at 12 Months Postpartum: A Cross-Sectional Study

Merete Kolberg Tennfjord, Msc,*† Gunvor Hilde, PhD,† Jette Stær-Jensen, MD,† Franziska Siafarikas, MD,†‡ Marie Ellström Engh, PhD,†‡ and Kari Bø, PhD*

*Department of Sports Medicine, Norwegian School of Sport Sciences, Oslo, Norway; †Department of Obstetrics and Gynecology, Akershus University Hospital, Lørenskog, Norway; ‡University Faculty Division, Akershus University Hospital, University of Oslo, Oslo, Norway

DOI: 10.1111/jsm.12836

ABSTRACT

Introduction. Symptoms related to sexual dysfunction postpartum are scarcely addressed in the literature, and the relationship to pelvic floor muscle (PFM) function is largely unknown.

Aims. The aim of this study was to investigate primiparous women 12 months postpartum and study: (i) prevalence and bother of coital incontinence, vaginal symptoms, and sexual matters; and (ii) whether coital incontinence and vaginal symptoms were associated with vaginal resting pressure (VRP), PFM strength, and endurance.

Methods. International Consultation on Incontinence Modular Questionnaire (ICIQ) sexual matters module and ICIQ-Vaginal Symptoms Questionnaire were used for questions on coital incontinence, vaginal symptoms, and sexual matters, respectively. PFM function was assessed by manometer (Camtech AS, Sandvika, Norway).

Main Outcome Measures. Coital incontinence, vaginal symptoms, and PFM function were the main outcome measures.

Results. One hundred seventy-seven primiparous women, mean age 28.7 (standard deviation [SD] 4.3) participated. Of the 94% of women having sexual intercourse, coital incontinence was found for 1.2% whereas 34.5% reported at least one vaginal symptom interfering with the sexual life of primiparous women. Of the symptoms investigated, "vagina feels dry," "vagina feels sore," and "vagina feels loose or lax" were most prevalent, but the overall impact on the woman's sexual life was minimally bothersome, mean 1.4 out of 10 (SD 2.5). Women reporting "vagina feels loose or lax" had lower VRP, PFM strength, and endurance when compared with women without the symptom.

Conclusions. Twelve-month postpartum coital incontinence was rare, whereas the prevalence of vaginal symptoms interfering with sexual life was more common. The large majority of primiparous women in our study had sexual intercourse at 12 months postpartum and the reported overall bother on sexual life was low. Women reporting "vagina feels loose or lax" had lower VRP, PFM strength, and endurance when compared with women without the symptom. **Tennfjord MK, Hilde G, Stær-Jensen J, Siafarikas F, Engh ME, and Bø K. Coital incontinence and vaginal symptoms and the relationship to pelvic floor muscle function in primiparous women at 12 months postpartum: A cross-sectional study. J Sex Med 2015;12:994–1003.**

Key Words. Coital Incontinence; Pelvic Floor Muscle Function; Postpartum; Sexual Function; Vaginal Symptoms

Introduction

Symptoms of pelvic floor dysfunctions are listed as urinary incontinence, bladder storage and sensory symptoms of the bladder, voiding and postmicturition symptoms, pelvic organ prolapse, sexual dysfunction, anorectal dysfunction, lower urinary tract pain and pelvic pain, and lower urinary

tract infection [1]. Whereas childbirth is considered a risk factor for symptoms related to urinary incontinence, fecal incontinence, and pelvic organ prolapse [2], symptoms related to sexual dysfunction have received less attention and the impact of childbirth on sexual function is conflicting [3–5]. A recent published study reported that 58% of primiparous women 12 months postpartum mentioned at least one symptom related to sexual dysfunction. Mode of delivery gave minimal risk of having sexual dysfunction in this study, except for the women reporting vaginal laxity where vaginal delivery and forceps showed a fourfold increased risk when compared with caesarean section [6]. Dyspareunia has been found to be associated with lacerations following vaginal delivery [7], but the published literature is controversial [6,8,9].

Vaginal childbirth has been previously shown to be associated with lower vaginal resting pressure (VRP), pelvic floor muscle (PFM) strength, and endurance [10,11]. Low PFM strength has also been found to be related to poorer orgasm and arousal function [12], whereas no link has been found between sexual dysfunction in terms of dyspareunia and VRP, PFM strength, and endurance [9,12]. However, we are not aware of any studies investigating how other vaginal symptoms may be associated with PFM function after childbirth and if there is an association between coital incontinence and PFM function postpartum. The 0-hypothesis: There is no difference in VRP, PFM strength, and endurance between primiparous women with and without coital incontinence and vaginal symptoms at 12 months postpartum.

Aims

Aims of the present study were to investigate primiparous women at 12 months postpartum and study:

1. The prevalence and bother of coital incontinence.
2. The prevalence and bother of vaginal symptoms and sexual matters.
3. Whether coital incontinence and vaginal symptoms were associated with VRP, PFM strength, and endurance.

Materials and Methods

Study Design

The current study is a planned part of a prospective cohort study on pelvic floor changes and symptoms related to pelvic floor dysfunction during and after pregnancy using electronic questionnaire data, ultrasonography, manometer, and information from hospital records. In the period January 2010 until April 2011, all nulliparous women scheduled for delivery at Akershus University Hospital, Norway were invited to participate in the cohort study. They were invited via a letter sent out together with the written invitation for the regular ultrasound examination at gestational week 18. Three hundred nulliparous, singleton pregnant women were included at mean gestational week 20.9, standard deviation (SD) 1.4. The cohort study has data from six different time points: pre-pregnancy, gestational week 22 and 37, 6 weeks, and 6 and 12 months postpartum. Different data from the cohort study have been presented by members in our study group on urinary incontinence and the relationship to PFM function in nulliparous pregnant women [13]. This article describes coital incontinence, vaginal symptoms, and sexual matters as defined by the International Consultation on Incontinence Modular Questionnaire sexual matters module (ICIQ-FLUTSsex) and the ICIQ-Vaginal Symptoms Questionnaire (ICIQ-VS), respectively, with data from an electronic questionnaire at 12 months postpartum, manometer assessment of VRP, PFM strength, and endurance at the same time point, and information from hospital records on delivery mode. The Regional Medical Ethics Committee (2009/170) and the Norwegian Social Science Data Services (2799026) approved the study. The study procedures were in accordance with the World Medical Association, Helsinki Declaration (2008). All participants gave written informed consent before entering the study. The study followed the STROBE reporting guidelines and used terminology as recommended by Haylen et al. [1].

Inclusion and Exclusion Criteria

Inclusion criteria for the present study were being a nulliparous singleton, pregnant woman able to speak and understand Scandinavian language. Exclusion criteria were multiple pregnancies and previous miscarriage after gestational week 16. Ongoing exclusion criteria were premature birth <week 32, stillbirth, serious illness to mother or child, subsequent pregnancies of 6 weeks or more of gestation, and recruitment to pelvic floor muscle training (PFMT) in an ongoing randomized controlled trial (RCT) starting 6 weeks postpartum (ClinicalTrials.gov NCT01069484).

Outcomes

A Norwegian version of the validated ICIQ-FLUTSsex was used to address symptoms of coital incontinence and level of bother over the last 4 weeks [14,15]. Answers given for coital incontinence were dichotomized. Women answering "not at all" to the question "Do you leak urine when you have sexual intercourse?" were registered with no coital incontinence and women answering "a little," "somewhat," and "a lot" to the same question were registered as having coital incontinence. Women who answered "not having sexual intercourse" were excluded in this analysis. In those being symptomatic, severity of coital incontinence was reported with a cutoff at "a lot." Level of bother was assessed on a scale ranging from 0 to 10, 0 being no bother and 10 major bother. The women having no sexual intercourse were registered by using the ICIQ-VS by the question "Do you have a sex life at present?" with the answers being "no, because of my vaginal symptoms" and "no, because of other reasons" [16].

ICIQ-VS was used for questions on vaginal symptoms and sexual matters on average over the last 4 weeks. Sexual matters included the following questions: "Do worries about your vagina interfere with your sex life?"; "Do you feel that your relationship with your partner is affected by vaginal symptoms?"; and "How much do you feel that your sex life has been spoilt by vaginal symptoms?" [16]. Sexual matters will be used throughout the article to cover these questions. The questions on vaginal symptoms and sexual matters were dichotomized into having the symptom or not having the symptom. In those being symptomatic, severity of symptoms was reported with a cutoff at "a lot" or "most of the time" and "all of the time" and bother for each vaginal symptom and sexual matters was analyzed as described for coital incontinence. The degree of overall bother of the vaginal symptoms on sexual life was assessed through a scale answering the question "How much do you feel that your sex life has been spoilt by vaginal symptoms?" The scale was denoted with 0 being no bother and 10 being major bother.

The participating women were taught how to perform a correct PFM contraction by the two trained female physical therapists when entering the cohort study at mid-pregnancy. A correct PFM contraction was defined as inward movement and squeeze around the pelvic openings [17,18]. PFM contraction without any movement of the pelvis or visible contraction of the glutei, hip, or abdominal muscles was emphasized [17,19]. Instructions continued during observation and vaginal palpation with the participant in a crook-lying position (supine lying with hips and knees flexed) after voiding. Vaginal palpation was undertaken to evaluate if the women were able to contract their PFM. VRP, PFM strength, and endurance were assessed with a high precision pressure transducer connected to a vaginal balloon (Camtech AS, Sandvika, Norway). The device was positioned with the middle of the balloon 3.5 cm internal to the introitus [20], a method found to be reliable [19] and valid for assessment of PFM strength, if used with simultaneous observation of inward movement of the perineum/catheter during the contraction [17].

VRP was measured as vaginal pressure, with no voluntary PFM activity, and was registered as cmH_2O. PFM strength was reported as the mean of three maximum voluntary contractions, and registered as cmH_2O. PFM endurance was defined as a sustained maximum contraction and was quantified as the area under the curve during 10 seconds, measured during one attempt and registered as cmH_2Osec [21]. The atmospheric pressure on the balloon was calibrated to 0 cmH_2O for each subject before it was placed in the vagina. The two physical therapists measuring the PFM were unaware of the answers provided in the electronic questionnaire, and therefore blinded to the participant's symptoms. During the examination, a towel was put on each woman's stomach in order to blind the investigators for any information related to delivery mode. Data on delivery outcomes included delivery mode (normal vaginal delivery, caesarean section [prelabor caesarean section >3 cm cervical dilation and caesarean section during labour <3 cm cervical dilation], and instrumental delivery [forceps and vacuum extraction]).

Statistical Analysis

Statistical analysis was performed using SPSS version 15 (SPSS, Inc., Chicago, IL, USA). Background and descriptive data were presented as frequencies with percentages or means with SDs. Spearman's rank order correlation was used to analyze the relationship between coital incontinence and vaginal symptoms with PFM variables and was used because the number in each categorical variable of symptoms was not equal. Independent sample *t*-test and chi-square test were used for differences in PFM variables and delivery outcomes between symptomatic and asymptomatic

women, respectively. Use of hormonal contraceptives and breastfeeding were thought to have an effect of symptoms like "vagina feels dry" or "vagina feels sore" because of reduction in estrogen levels and therefore analyzed separately using chi-square. Missing data were listed throughout the article in text, figure, and tables. $P \leq 0.05$ was considered statistically significant.

Power Calculation

This study was part of a project investigating several questions related to the pelvic floor during pregnancy and after childbirth. There was no specific a priori power calculation for questions on coital incontinence, vaginal symptoms, or sexual matters.

Main Outcome Measures

Coital incontinence and vaginal symptoms assessed by ICIQ-FLUTSsex and ICIQ-VS, respectively, and PFM function assessed by manometer (Camtech AS, Sandvika, Norway) were the main outcome measures.

Results

Participants

One hundred seventy-seven women were seen at 12 months postpartum (mean 12.9 months, SD 0.8). Eighty-eight women had been excluded according to the exclusion criteria, 71 because of participation in the PFMT group in the RCT, 12 because of subsequent pregnancies, 3 because of stillbirth, and 2 because of premature delivery. Thirty-five women were lost to follow up throughout the study period (11.6%) (Figure 1). Background characteristics for the total study sample at 12 months postpartum and for differences between women with no vaginal symptoms, with vaginal symptoms, with and vaginal symptoms interfering with sexual life are presented in Table 1. Part of these data has been presented by members in our study group, as described in the Materials and Methods section [13]. Our study sample was comparable with the total population of nulliparous women scheduled for delivery at Akershus University Hospital during the inclusion period (n = 2,621) with respect to age and marital or cohabitation status, but more women in our sample had university or college education (75.3% compared with 50.8%, $P < 0.001$). No significant difference was found for women lost to follow up and those excluded, or for the women recruited to PFMT in the RCT compared with the women participating in the study at 12 months postpartum with regard to age, education, and relationship status.

Coital Incontinence and Level of Bother

Data on coital incontinence and level of bother are presented in Table 2. Two (1.2%) out of the 166 women having sexual intercourse complained of coital incontinence. Because of low numbers, no further analysis was done.

Vaginal Symptoms and Level of Bother

Overall, 73.4% (130) of all participants reported at least one vaginal symptom, whereas 34.5% (61) reported at least one vaginal symptom interfering with sexual life (Table 1). At 12 months postpartum, 166 (93.8%) women had sexual intercourse. Of those 11 not having sexual intercourse at the time, 2 were because of vaginal symptoms and 9 were because of "other reasons," as defined under the question "Do you have a sex life at present?" using the ICIQ-VS. Data on vaginal symptoms, severity of symptoms, sexual matters, and bother are presented in Table 2. Symptoms of "vagina feels dry" were most prevalent (41.2%) followed by "vagina feels sore" (26%) and "vagina feels loose or lax" (26%). Thirty-two percent reported that the vaginal symptoms gave worries about the symptoms affecting their sexual life and 23% reported that the relationship with their partner was affected as a result of the vaginal symptoms. The overall bother given by the question "How much do you feel that your sex life has been spoilt by vaginal symptoms?" was low (1.4 out of 10 SD 2.5).

Women breastfeeding had more symptoms of "vagina feels dry" and "vagina feels sore" at 12 months postpartum as compared with women not breastfeeding: 33 (51.6%) vs. 40 (35.4%) ($P = 0.05$) and 24 (37.5%) vs. 22 (19.5%) ($P = 0.01$), respectively. No difference was found for women using hormonal contraceptives or not on either symptom: 30 (39.1%) vs. 43 (43%) ($P = 0.71$) and 16 (20.8%) vs. 30 (30%) ($P = 0.23$), respectively.

Vaginal Symptoms and PFM Function

No difference in PFM function was found between women with no vaginal symptoms, with vaginal symptoms, and with vaginal symptoms interfering with sexual life (Table 1). Among the vaginal symptoms listed in the questionnaire, we found a significant difference in VRP, PFM strength, and

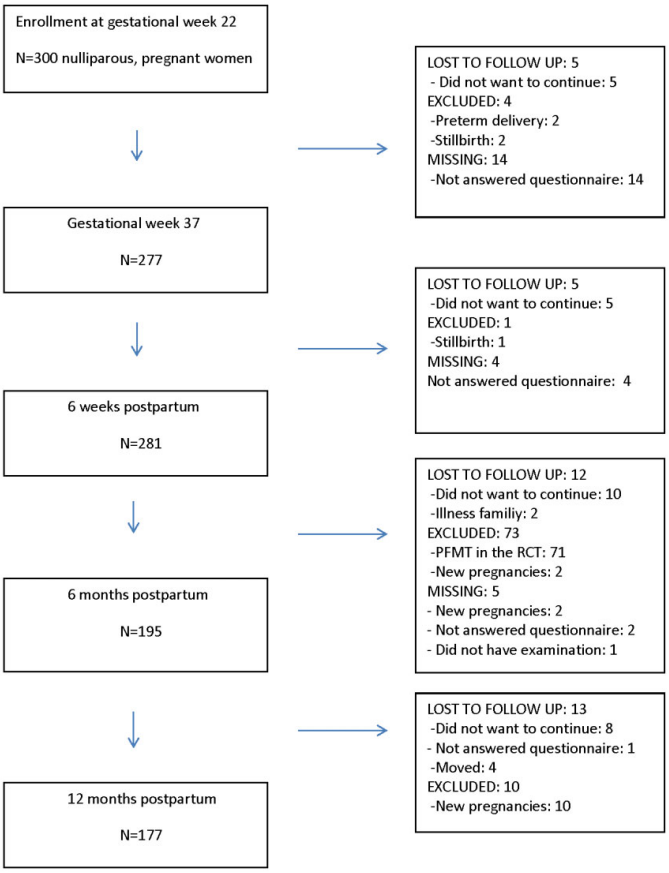

Figure 1 Flowchart of participants in the cohort study with women eligible for assessment at 12 months postpartum

endurance for women reporting "vagina feels loose or lax" compared with women with no such symptoms at 12 months postpartum (Table 3). Low VRP and weaker PFM strength and endurance were associated with symptoms of "vagina feels loose or lax": VRP: $r_s = -0.16$, $P = 0.03$; PFM strength: $r_s = -0.20$, $P = 0.007$; and endurance: $r_s = -0.21$, $P = 0.005$. The mean difference for women with and without the symptom was 3.6 cmH_2O (95% confidence interval [CI] 0.7, 6.6) for VRP, 9.0 cmH_2O (95% CI 2.6, 15.4) for PFM strength, and 80.0 cmH_2Osec (95% CI 32.6, 127.5) for PFM endurance.

Vaginal Symptoms and Delivery Mode

Information on delivery mode is presented in Table 1. There was no difference between women with no vaginal symptoms, with vaginal symptoms, and with vaginal symptoms interfering with sexual life when grouped by delivery outcomes. Looking at each vaginal symptom separately, "vagina feels loose or lax" was the only symptom associated with delivery mode. Eighty out of 131 (61.1%) women with no symptoms vs. 37/46 (80.4%) with the symptom had had a normal vaginal delivery. Furthermore, women with no symptoms had had caesarean section in 32/131 (24.4%) of the cases vs. 2/46 (4.3%) for the women with the symptom. For instrumental deliveries, the numbers were 7/46 (15.2%) vs. 19/131 (14.5%) for women with and without symptoms, respectively. $P = 0.02$ reflects the difference between symptomatic and asymptomatic women on caesarean section.

Table 1 Background variables of primiparous women and differences between groups at 12 months postpartum: no vaginal symptoms, vaginal symptoms, and vaginal symptoms interfering with sexual life

	Total study population n = 177	No vaginal symptoms N = 47	Vaginal symptoms N = 130	Vaginal symptoms interfering with sexual life n = 61	No vaginal symptoms vs. vaginal symptoms	No vaginal symptoms vs. vaginal symptoms interfering with sexual life
Age (years)	28.7 (SD 4.3)	28.7 (SD 4.7)	28.7 (SD 4.0)	28.8 (SD 3.7)	0.97	0.93
BMI (kg/m^2)	24.7 (SD 4.3)	25.7 (SD 4.8)	24.4 (SD 4.0)	24.4 (SD 4.2)	0.1	0.15
Civil status						
Married/cohabitant	287 (95.7%)	46 (97.9%)	127 (97.7%)	61 (100%)	1.0	0.9
Living alone	13 (4.3%)	1 (2.1%)	3 (2.3%)	0 (0%)		
Educational level						
College/university	226 (75.3%)	32 (68.1%)	105 (80.8%)	47 (77.0%)	0.11	0.41
Primary/high school/other	74 (24.7%)	15 (31.9%)	25 (19.2%)	14 (23.0%)		
Smoking	21 (11.9%)	6 (12.8%)	15 (11.3%)	6 (9.8%)	0.89	0.89
Breastfeeding						
1 to ≥ 3 times daily	61 (34.5%)	20 (42.6%)	41 (31.5%)	23 (37.7%)	0.24	0.76
< once daily	116 (65.5%)	27 (57.4%)	89 (68.5%)	38 (62.3%)		
Hormonal contraceptives	77 (43.5%)	21 (44.7%)	56 (43.1%)	26 (42.6%)	0.99	0.99
Sexually active	166 (93.8%)	44 (93.6%)	122 (93.8%)	59 (96.7%)	1.0	0.77
PFM function						
VRP (cmH_2O)	35.2 (SD 8.8)	36.9 (SD 9.2)	34.6 (SD 8.6)	35.2 (SD 9.1)	0.11	0.33
PFM strength (cmH_2O)	34.6 (SD 19.3)	36.6 (SD 19.2)	33.9 (SD 19.4)	34.3 (SD 19.1)	0.41	0.52
Endurance (cmH_2Osec)	276.5 (SD 166.5)	296.0 (SD 158.4)	269.4 (SD 169.4)	268.0 (SD 160.7)	0.41	0.37
Delivery mode						
NVD	117 (66.1%)	24 (51.1%)	93 (71.5%)	42 (68.9%)	0.07	0.3
Vacuum/forceps	26 (14.7%)	10 (21.3%)	16 (12.3%)	8 (13.1%)		
Pre-labor caesarean section	16 (9%)	7 (14.9%)	9 (6.9%)	5 (8.2%)		
Caesarean section during labour	18 (10.2%)	6 (13.1%)	12 (9.2%)	6 (9.8%)		

Vaginal symptoms are women answering one or more vaginal symptoms from the questionnaire ICIQ-VS. Vaginal symptoms interfering with sexual life is whether the reported vaginal symptom is associated with one or more of the sexual matters questions. Continuous variables are given as means with standard deviation (SD) and the difference between groups as mean differences with 95% confidence interval (CI). Categorical variables are given as frequencies with percentages (%) and the difference between groups as *P* values

BMI = body mass index; ICIQ-VS = International Consultation on Incontinence Modular Questionnaire Vaginal Symptoms Questionnaire; NVD = normal vaginal delivery; PFM = pelvic floor muscle; VRP = vaginal resting pressure

Table 2 Prevalence of coital incontinence, vaginal symptoms, and sexual matters with severity of symptoms and bother at 12 months postpartum (n = 177)

	Symptoms	No symptoms	Severe symptoms	Bother (0–10)
Coital incontinence*	2 (1.2%)	164 (98.8%)	0	4.5 (SD0.7)
Dragging pain in lower abdomen	45 (25.4%)	132 (74.6%)	0	3.3 (SD1.8)
Vagina feels sore	46 (26.0%)	131 (74.0%)	8 (4.5%)	5.0 (SD2.8)
Reduced sensation in vagina	20 (11.3%)	157 (88.7%)	0	4.1 (SD2.3)
Vagina feels loose or lax	46 (26.0%)	131 (74.0%)	2 (4.3%)	4.3 (SD2.4)
Bulge coming down in the vagina	32 (18.1%)	145 (81.9%)	11 (6.2%)	3.3 (SD2.0)
Bulge coming out of the vagina	5 (2.8%)	172 (97.2%)	1 (0.6%)	2.8 (SD0.8)
Vagina feels dry	73 (41.2%)	104 (58.8%)	12 (6.7%)	4.4 (SD2.6)
Support of finger in vagina when emptying bowel	13 (7.3%)	164 (92.7%)	1 (0.6%)	4.9 (SD3.0)
Vagina feels too tight	31 (17.5%)	146 (82.5%)	5 (2.8%)	4.5 (SD3.1)
Worries about vaginal symptoms affecting sexual life†	52/161 (32.3%)	109/161 (67.7%)	11 (6.8%)	6.3 (SD2.8)
Relationship with partner affected†	37/160 (23.1%)	123/160 (76.9%)	4 (2.5%)	7.2 (SD2.6)

*Women having sexual intercourse, n = 166 at 12 months postpartum
†Numbers reflecting women answering the question "Do you have a sex life at present?" using the ICIQ-VS
Continuous variables are given as means with standard deviation (SD). Categorical variables are given as frequencies with percentages (%). Severe symptoms are referred to as symptoms defined as "a lot" or as symptoms present "most of the time" and/or "all of the time." Percentages are calculated from the total of 177 women
ICIQ-VS = International Consultation on Incontinence Modular Questionnaire Vaginal Symptoms Questionnaire

Discussion

Main Findings

Coital incontinence was rare at 12 months postpartum, whereas there was a prevalence of 34.5% with vaginal symptoms interfering with the sexual life of primiparous women. Of the symptoms investigated, "vagina feels dry," "vagina feels sore," and "vagina feels loose or lax" were most prevalent, but the overall bother on sexual life was low. Women reporting "vagina feels loose or lax" had lower VRP, PFM strength, and endurance when compared with women without the symptom. The results can partly reject the 0-hypothesis and claim that there are differences between women with and without vaginal symptoms at 12 months postpartum.

Interpretation

Our results on numbers of primiparous women with vaginal symptoms differ slightly from the study by Durnea et al. [6] where vaginal tightness (29%), together with dyspareunia, was the most frequently reported symptom. Previously, dyspareunia has been reported in 33% at 12 months postpartum from our population of primiparous women [9]. Unfortunately, we have no data on vaginal symptoms prior to pregnancy. Preexisting symptoms could therefore not be addressed in the analysis and our numbers most likely represent both incidence and prevalence. Durnea et al. [6] found that pre-pregnancy sexual dysfunctions constituted for 53% of the symptoms reported at 12 months postpartum.

The large majority of women had intercourse 12 months postpartum, and of the 11 women who did not have intercourse, only 2 of these were because of vaginal symptoms. The present study did not address frequency of intercourse, and there is a possibility of not detecting the women who had less frequent intercourse because of symptoms. However, the low overall impact on sexual life reported (mean 1.4) makes this less probable. Van Delft et al. [3], using the same questionnaire, found that the reported vaginal symptoms did not interfere with the women's sexual life in their study. These findings as ours highlight the importance of reporting bother in order to avoid over-reporting and over-treating [22]. Vaginal dryness and soreness were found to be associated with breastfeeding 12 months postpartum. This has been described as a result of low estrogen levels leading to reduced vaginal lubrication, but also as a result of low desire and arousal affecting vaginal lubrication [23]. However, there may also be an overlap of symptoms from the questionnaire ICIQ-VS, meaning that more symptoms may have similar explanations. No association has been found between PFM function and breastfeeding among the same women [9].

We found that women reporting "vagina feels loose or lax" also had lower VRP, PFM strength, and endurance. The difference was only minimal for VRP, whereas the difference for PFM strength was 9.0 cmH_2O and for PFM endurance it was 80 cmH_2Osec, which is thought to be clinically relevant. Search on PubMed found no other studies that are directly comparable with ours.

Table 3 Spearman's rank order correlation among vaginal symptoms and vaginal resting pressure (VRP), pelvic floor muscle (PFM) strength, and endurance at 12 months postpartum (n = 177)

		Dragging pain in lower abdomen	Vagina feels sore	Reduced sensation in vagina	Vagina feels loose/lax	Bulge coming down in the vagina	Bulge coming out of the vagina	Vagina feels dry	Support of finger in vagina when emptying bowel	Vagina feels too tight
VRP	Correlation coefficient	–0.060	0.089	–0.068	–0.163†	–0.118	–0.027	0.032	–0.086	0.120
	Significance (two-tailed)	0.430	0.238	0.366	0.030	0.118	0.717	0.669	0.255	0.113
	n	177	177	177	177	177	177	177	177	177
PFM strength	Correlation coefficient	0.045	0.063	0.085	–0.204*	0.013	0.085	0.021	0.003	0.056
	Significance (two-tailed)	0.549	0.408	0.259	0.007	0.861	0.262	0.786	0.964	0.461
	n	177	177	177	177	177	177	177	177	177
PFM endurance	Correlation coefficient	0.001	0.046	0.066	–0.212*	0.000	0.085	–0.003	0.035	0.040
	Significance (two-tailed)	0.993	0.540	0.383	0.005	1.000	0.258	0.964	0.648	0.597
	n	177	177	177	177	177	177	177	177	177

*Correlation is significant at the 0.01 level (two-tailed)
†Correlation is significant at the 0.05 level (two-tailed)

Most published studies have looked into sexual dysfunction and vaginal symptoms in relation to delivery mode and levator ani muscle avulsion and not in relation to PFM function [4–6]. Our results indicate that vaginal laxity is associated with delivery mode and that more women without the symptom had had caesarean section compared with women with the symptom. Delivery mode has been previously shown to be associated with PFM function in this sample of primiparous women [10], and it might be that delivery mode in this present study can partly explain the relationship with vaginal laxity and weaker PFM. However, our data on PFM function give a description of the current status, and we believe this information could be of great value. The potential for PFMT to improve the symptom remains to be investigated. We cannot answer if this specific symptom affects the sexual life of the participating women because of the context in which the question was asked and unfortunately, the partners' perspective on this symptom was not covered in the questionnaire. Addition of such questions may have added to the understanding related to sexual dysfunction.

The present study found that the number of women with coital incontinence was 1.2%. This is a lower number than the few previous studies investigating coital incontinence postpartum [6,24–26]. Durnea et al. [6] found a prevalence of coital incontinence in 5% 12 months postpartum, while Dolan et al. [24] found 6.4% at 3 months postpartum. Ege et al. [25] reported symptoms in 7.3% at 12 months postpartum, whereas Serati et al. [26] found de novo symptoms of coital incontinence in 3% at 6 months postpartum. However, different design of the above studies makes it difficult to make direct comparisons. The link to PFM function in women with coital incontinence is largely unknown, especially among postpartum women, but two RCTs on PFMT have found statistically significant improvement of women's sexuality and a reduction of episodes of coital incontinence among adult women with mixed parity [27,28]. There is a need for further epidemiological studies in this area and questions covering de novo symptoms of sexual dysfunction after childbirth in addition to treatment studies.

Strengths and Limitations

Strength of the present study was inclusion of several questions related to the pelvic floor and symptoms that may be associated with sexual

dysfunction using validated questionnaires. Although there are other pelvic floor dysfunctions that may give sexual problems, e.g., overactive bladder and anorectal dysfunction, the questions used were thought to be most relevant for this group of women. Even if the questionnaire ICIQ-VS has not undergone linguistic validation, these questions were relatively easy to understand and we believe this did not affect our study results to a great extent. Relatively few cases were lost to follow up, although 71 women were excluded from the cohort because of participation in PFMT in the RCT. No differences were found for the women participating in the study at 12 months postpartum vs. the ones lost to follow up or excluded. The present study used a responsive, reliable, and valid tool to assess PFM strength [17,19]. However, measurements of VRP may be inherently problematic because of a variety of potential sources of error, but has shown good reliability values in bent-knee lying position [29]. Lastly, another strength of the study was blinding of investigators on questionnaire data when performing PFM assessment.

A limitation is that there was no a priori power calculation for questions on coital incontinence, vaginal symptoms, or sexual matters as the cohort aimed to look into several pelvic floor dysfunctions during pregnancy and postpartum. Our results may therefore be influenced by type II error. The questionnaire used to cover questions on coital incontinence does not discriminate between the leakage that could arise during intercourse and that during orgasm, which is a major limitation to this question. Nevertheless, we chose to include this question in order to report prevalence as there are only few studies published. We refrained from further analysis because of only two women reporting coital incontinence. A more comprehensive understanding of female sexual dysfunction may have been present if we had included information on closely linked factors to sexuality such as desire, arousal, orgasm, satisfaction [30], and reasons for not being sexually active (mood, motivation, partner) beyond that of not having a sex life "because of my vaginal symptoms." Such factors may also have added to our understanding of the lack of association between vaginal symptoms other than vaginal laxity and PFM function in this study. Because the present study was a planned part of a cohort covering several questions related to pelvic floor dysfunction, the questions related to sexual dysfunction were the ones most suitable when this study was planned. The present study approached all nulliparous women scheduled for delivery at Akershus University Hospital. Women in this cohort differ from the general population as they had a higher level of education. Further, we excluded those not being able to speak or understand Scandinavian languages. This makes generalization to the total population and other language groups impossible.

Conclusions

Coital incontinence was rare at 12 months postpartum, whereas there was a prevalence of 34.5% of vaginal symptoms interfering with the sexual life of primiparous women. However, the large majority of women in our study had sexual intercourse at 12 months postpartum and the reported overall bother on sexual life was low. Women reporting vaginal laxity had lower VRP, PFM strength, and endurance compared with the women without the symptom.

Acknowledgments

We thank midwife Tone Breines Simonsen and physical therapist Kristin Gjestland for excellent work with recruiting participants, clinical testing, and data entering. The original cohort study was funded by the South-Eastern Norway Regional Health Authority and the Norwegian Research Council. This present project on sexual dysfunction and the pelvic floor is funded through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

Corresponding Author: Merete Kolberg Tennfjord, Msc, Department of Sports Medicine, Norwegian School of Sport Sciences, PO Box 4014 Ullevål stadion, Oslo 0806, Norway. Tel: +47 23262020; Fax: +47 22234220; E-mail: merete.kolberg@gmail.com

Conflict of Interest: The authors report no conflicts of interest.

Statement of Authorship

Category 1

(a) Conception and Design
Merete Kolberg Tennfjord; Gunvor Hilde; Jette Stær-Jensen; Franziska Siafarikas; Marie Ellström Engh; Kari Bø

(b) Acquisition of Data
Jette Stær-Jensen; Gunvor Hilde; Franziska Siafarikas

(c) Analysis and Interpretation of Data
Merete Kolberg Tennfjord; Kari Bø

Category 2

(a) Drafting the Article
Merete Kolberg Tennfjord; Marie Ellström Engh; Kari Bø

(b) Revising It for Intellectual Content
Merete Kolberg Tennfjord; Gunvor Hilde; Jette Stær-Jensen; Franziska Siafarikas; Marie Ellström Engh; Kari Bø

Category 3

(a) Final Approval of the Completed Article
Merete Kolberg Tennfjord; Gunvor Hilde; Jette Stær-Jensen; Franziska Siafarikas; Marie Ellström Engh; Kari Bø

References

1 Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J 2010;21:5–26.

2 Sievert KDAB, Toomey PA, Robinson D, Milsom I, Koelbl H, Abrams P, Cardozo L, Wein A, Smith AL, Newman DK. Can we prevent incontinence? ICI-RS 2011. Neurourol Urodyn 2012;31:390–9.

3 van Delft K, Sultan A, Thakar R, Schwertner-Tiepelmann N, Kluivers K. The relationship between postpartum levator ani muscle avulsion and signs and symptoms of pelvic floor dysfunction. BJOG 2014;121:1164–71.

4 Thibault-Gagnon S, Yusuf S, Langer S, Wong V, Shek KL, Martin A, Dietz HP. Do women notice the impact of childbirth-related levator trauma on pelvic floor and sexual function? Results of an observational ultrasound study. Int Urogynecol J 2014;25:1389–98.

5 Laterza RM, Schrutka L, Umek W, Albrich S, Koelbl H. Pelvic floor dysfunction after levator trauma 1-year postpartum: A prospective case-control study. Int Urogynecol J 2014;26:41–7.

6 Durnea CM, Khashan AS, Kenny LC, Tabirca SS, O'Reilly BA. The role of prepregnancy pelvic floor dysfunction in postnatal pelvic morbidity in primiparous women. Int Urogynecol J 2014;25:1363–74.

7 Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: A retrospective cohort study of primiparous women. Am J Obstet Gynecol 2001;184:881–90.

8 Yeniel AO, Petri E. Pregnancy, childbirth, and sexual function: Perceptions and facts. Int Urogynecol J 2014;25:5–14.

9 Tennfjord MK, Hilde G, Staer-Jensen J, Ellstrom Engh M, Bo K. Dyspareunia and pelvic floor muscle function before and during pregnancy and after childbirth. Int Urogynecol J 2014;59:1227–35.

10 Hilde G, Staer-Jensen J, Siafarikas F, Engh ME, Braekken IH, Bo K. Impact of childbirth and mode of delivery on vaginal resting pressure and on pelvic floor muscle strength and endurance. Am J Obstet Gynecol 2013;208:51–7.

11 Elenskaia K, Thakar R, Sultan AH, Scheer I, Beggs A. The effect of pregnancy and childbirth on pelvic floor muscle function. Int Urogynecol J 2011;22:1421–7.

12 Lowenstein L, Gruenwald I, Gartman I, Vardi Y. Can stronger pelvic muscle floor improve sexual function? Int Urogynecol J 2010;21:553–6.

13 Hilde G, Staer-Jensen J, Ellstrom Engh M, Braekken IH, Bo K. Continence and pelvic floor status in nulliparous women at midterm pregnancy. Int Urogynecol J 2012;23:1257–63.

14 Abrams P, Avery K, Gardener N, Donovan J, Board IA. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol 2006;175:1063–6, discussion 66.

15 Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P. The Bristol Female Lower Urinary Tract Symptoms questionnaire: Development and psychometric testing. Br J Urol 1996;77:805–12.

16 Price NJS, Avery K, Brookes ST, Abrams P. Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: The ICIQ-VS. BJOG 2006;113:700–12.

17 Bo K, Hagen RR, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II. Validity of vaginal pressure measurements of pelvic muscle strength and the necessity of supplementary methods for control of correct contraction. Neurourol Urodyn 1990;9:479–87.

18 Kegel AH. Stress incontinence and genital relaxation; a nonsurgical method of increasing the tone of sphincters and their supporting structures. Ciba Clin Symp 1952;4:35–51.

19 Bo K, Hagen R, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic muscle strength. Neurourol Urodyn 1990;9:471–7.

20 Bo K. Pressure measurements during pelvic floor muscle contractions: The effect of different positions of the vaginal measuring device. Neurourol Urodyn 1992;11:107–13.

21 Braekken IH, Majida M, Ellstrom Engh M, Holme IM, Bo K. Pelvic floor function is independently associated with pelvic organ prolapse. BJOG 2009;116:1706–14.

22 Roos AM, Sultan AH, Thakar R. Sexual problems in the gynecology clinic: Are we making a mountain out of a molehill? Int Urogynecol J 2012;23:145–52.

23 Leeman LM, Rogers RG. Sex after childbirth: Postpartum sexual function. Obstet Gynecol 2012;119:647–55.

24 Dolan LM, Walsh D, Hamilton S, Marshall K, Thompson K, Ashe RG. A study of quality of life in primigravidae with urinary incontinence. Int Urogynecol J 2004;15:160–4.

25 Ege E, Akin B, Altuntug K, Benli SAA. Prevalence of urinary incontinence in the 12-months postpartum period and related risk factors in Turkey. Urol Int 2008;80:355–61.

26 Serati M, Salvatore S, Khullar V, Uccella S, Bertelli E, Ghezzi F, Bolis P. Prospective study to assess risk factors for pelvic floor dysfunction after delivery. Acta Obstet Gynecol Scand 2008;87:313–8.

27 Zahariou AG, Karamouti MV, Papaioannou PD. Pelvic floor muscle training improves sexual function of women with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:401–6.

28 Bo K, Talseth T, Vinsnes A. Randomized controlled trial on the effect of pelvic floor muscle training on quality of life and sexual problems in genuine stress incontinent women. Acta Obstet Gynecol Scand 2000;79:598–603.

29 Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn 2006;25:236–42.

30 Basson R, Wierman ME, Van Lankveld J, Brotto L. Summary of the recommendations on sexual dysfunctions in women. J Sex Med 2010;7:314–26.

Paper III

DOI: 10.1111/1471-0528.13823
www.bjog.org

Effect of postpartum pelvic floor muscle training on vaginal symptoms and sexual dysfunction—secondary analysis of a randomised trial

M Kolberg Tennfjord,[a,b] G Hilde,[b] J Stær-Jensen,[b] F Siafarikas,[b,c] M Ellström Engh,[b,c] K Bø[a]

[a] Department of Sports Medicine, Norwegian School of Sport Sciences, Oslo, Norway [b] Department of Obstetrics and Gynaecology, Akershus University Hospital, Lørenskog, Norway [c] Institute of Clinical Medicine, University of Oslo, Oslo, Norway
Correspondence: M Kolberg Tennfjord, Department of Sports Medicine, Norwegian School of Sport Sciences, PO Box 4014, Ullevål stadion, 0806 Oslo, Norway. Email merete.kolberg@gmail.com

Accepted 7 October 2015. Published online 22 December 2015.

Objective Evaluate effect of pelvic floor muscle training (PFMT) on vaginal symptoms and sexual matters, dyspareunia and coital incontinence in primiparous women stratified by major or no defects of the levator ani muscle.

Design Randomised controlled trial (RCT).

Setting Akershus University Hospital, Norway.

Sample About 175 primiparous women with a singleton vaginal delivery.

Methods Two-armed assessor blinded parallel group RCT from 6 weeks to 6 months postpartum comparing effect of PFMT versus control.

Main outcome measures International Consultation on Incontinence Modular Questionnaire—vaginal symptoms questionnaire (ICIQ-VS) and ICIQ sexual matters module (ICIQ-FLUTSsex).

Results Overall, analysis (n = 175) showed no difference between training and control groups in women having vaginal symptoms or symptoms related to sexual dysfunction 6 months postpartum. The majority of women (88%) had intercourse and there was no difference between groups. Unadjusted subgroup analysis of women with a major defect of the levator ani muscle (n = 55) showed that women in the training group had 45% less risk of having the symptom 'vagina feels loose or lax' compared with the control group (relative risk 0.55, 95% confidence interval 0.31, 0.95; P = 0.03).

Conclusions Unadjusted analysis showed that in women with major defect of the levator ani muscle, significantly fewer in the training group had the symptom 'vagina feels loose or lax' compared with the control group. No difference was found between groups for symptoms related to sexual dysfunction. More studies are needed to explore effect of PFMT on vaginal symptoms and sexual dysfunction.

Keywords Pelvic floor muscle function, pelvic floor muscle training, postpartum, sexual dysfunction, vaginal symptoms.

Tweetable abstract Unadjusted analysis shows that PFMT might prevent symptoms of 'vagina feels loose or lax'.

Please cite this paper as: Kolberg Tennfjord M, Hilde G, Stær-Jensen J, Siafarikas F, Ellström Engh M, Bø K. Effect of postpartum pelvic floor muscle training on vaginal symptoms and sexual dysfunction—secondary analysis of a randomised trial. BJOG 2015; DOI: 10.1111/1471-0528.13823.

Introduction

Symptoms of female sexual dysfunction (FSD) is defined as 'a departure from normal sensation and/or function experienced by a woman during sexual activity'[1] and has been classified as sexual interest /arousal disorder, orgasmic disorder and genito-pelvic pain/penetration disorder.[2]

Between 10 and 30% in the general female population experience FSD.[3] In primiparous women, 1 year postpartum, a prevalence of pelvic floor disorders (PFD) associated with FSD has been found in up to 58%, with the main complaints being: not sufficient lubrication, abnormal vaginal sensation, vaginal laxity, vaginal tightness, dyspareunia and coital incontinence.[4]

It has been postulated that the pelvic floor muscle (PFM) tone, strength and ability to contract are important factors for vaginal receptivity and responsiveness, for pleasure during intercourse for both partners, and for the orgasmic muscular response.[5] Some studies have shown that strong PFM may be associated with better orgasmic and arousal potentials, desire, excitement and vaginal lubrication,[6,7] in addition to improved vaginal sensation and

Clinical trial registration: ClinicalTrials.gov, NCT01069484.

tightness.[8] However, contradictory results have also been found.[9–10]

To date, there is international consensus that pelvic floor muscle training (PFMT) should to be the first-line treatment for stress urinary incontinence (SUI)[11–12] and pelvic organ prolapse (POP).[13] There is, however, no consensus on either prevention or treatment of symptoms related to FSD. A systematic literature search on the effect of PFMT on FSD revealed, in all, 12 randomised controlled trials (RCT) in postpartum women,[14–16] women with POP,[8,17–19] women with SUI,[20,21] women with orgasmic disorders[22,23] and gynecological cancer patients.[24] There are some promising results to suggest that PFMT may have an effect on symptoms related to FSD, but the heterogeneity of those trials makes these data inconclusive.

Thus the aims of this present RCT were to:

- Evaluate the effect of PFMT on vaginal symptoms and sexual matters, dyspareunia and coital incontinence in primiparous women stratified by major or no defects of the levator ani muscle.
- Investigate whether a possible effect of PFMT was associated with a change in vaginal resting pressure, PFM strength and endurance.

Methods

This is a planned secondary analysis of a two-armed assessor blinded parallel group RCT with the primary aim to evaluate the effect of PFMT on urinary incontinence.[25] The present study assessed the effect of PFMT on vaginal symptoms and sexual matters, dyspareunia and coital incontinence. The participating women were stratified by major defects of the levator ani muscle verified by transperineal ultrasound. The RCT was conducted for 16 weeks at Akershus University Hospital, Norway, from February 2010 to May 2012, starting 6 weeks postpartum. The study was approved by the Regional Medical Ethics Committee (REK South East 2009/289a), Data Protect Officer (2799004), and registered at ClinicalTrials.gov (NCT01069484). All subjects gave written informed consent before entering the study and the study followed the Consort reporting guidelines. Terminology was followed as recommended by Haylen et al.[1]

Power calculation was done for the primary analyses on urinary incontinence and was based on the results from a former study.[26] A sample size of 80 per group was assessed to be required; no specific power calculation was done for the present analysis but the trial aimed to include as many women as possible beyond that number. The small number of RCTs, variations in sample size and the effect of PFMT on FSD in postpartum women,[14–16] made it difficult to make direct comparisons with the present study during planning of the trial.

In all, 175 primiparous women were included. Of these, 139 women were recruited from a cohort study following nulliparous pregnant women from gestational week 21 until 1 year postpartum[27] and 36 women were recruited at 6 weeks postpartum from the maternity ward at Akershus University Hospital, Norway, or from the community primary health care clinics within the geographical area of the hospital.[28]

Inclusion criteria were: vaginal delivery to a singleton infant after more than 32 weeks of gestation including normal or instrumental deliveries [20% (35/175), 33 women with vacuum and two with forceps] and the ability to understand Scandinavian languages. Exclusion criteria were: caesarean section, 3b, 3c and 4th degree perineal tears, and serious illness of mother or child. At the project hospital, women with 3rd and 4th degree perineal tears are routinely referred for physical therapy for PFMT and ethically could not be allocated to a control group. Intrauterine fetal deaths/stillborns were also excluded.

The participating women answered an electronic questionnaire and were assessed by ultrasonography and manometer at 6 weeks (baseline) and 6 months postpartum (post intervention). Before inclusion in the study, all participants received the customary written leaflet from the postnatal ward before discharge which includes information about performing PFMT on a regular basis. At baseline the women in both arms of the RCT were taught by two trained physical therapists how to contract the PFM correctly before the clinical measurements were undertaken. A correct PFM contraction was defined as an inward movement of the perineum and a squeeze around the pelvic openings, assessed by observation and vaginal palpation.[29] All clinical measurements were performed with the participants in a standardised crook lying position.

Two trained gynaecologists stratified the women by major defects of the levator ani muscle using three- and four-dimensional transperineal ultrasound (GE Kretz Voluson E8 - RAB4-8) after voiding. Major defects of the levator ani muscle were diagnosed using tomographic ultrasound imaging of the axial plane at maximal PFM contraction as described by Dietz et al.[30,31] The method has shown good intra- and inter-rater reliability 6 weeks after childbirth.[32] All investigators were blinded to the participants' answers on the questionnaire when performing the clinical measurements. They were also blinded as to group allocation when performing the clinical measurements.

The participants were randomised in blocks of ten to either PFMT or control with usual care after being stratified according to major or no defects of the levator ani muscle at the very end of the baseline assessment. The randomisation sequence was computer-generated and opaque, sealed envelopes were used. The allocation of participants

into the PFMT or control group was performed outside the assessment room by a project midwife who was not involved in the assessment or the teaching of PFMT to the participating women.

The training group attended a weekly PFMT class led by one of three trained physical therapists at three different locations for 4 months, starting 6 weeks postpartum. In addition, the intervention group was told to perform three sets of 8–12 close to maximum PFM contractions daily at home. The exercise protocol has been described previously by Bø et al.[33] and Mørkved and Bø.[26] Participants recorded adherence to the home program in a training diary, and the physical therapists registered class participation. The control group received no intervention beyond the written information received at discharge from the hospital containing information about postpartum PFMT and the individual assessment of how to perform a correct PFM contraction.

An electronic questionnaire, International Consultation on Incontinence Modular Questionnaire—Vaginal symptoms questionnaire (ICIQ-VS), was used for questions on vaginal symptoms and sexual matters with answers given as an average over the last 4 weeks.[34] Seven questions were used for vaginal symptoms. The questions concerning POP (5a and 6a) have been published by members in our study group and were therefore excluded from the present study.[35] Sexual matters included the following questions: 'Do worries about your vagina interfere with your sex life?'; 'Do you feel that your relationship with your partner is affected by vaginal symptoms?'; 'How much do you feel that your sex life has been spoilt by vaginal symptoms?' The term 'sexual matters' will be used throughout this article to refer to the above questions. All answers were dichotomised into having the symptom or not having the symptom, except for the last question, which was presented as a scale (0 being no problem, 10 being major problem). For questions on vaginal symptoms the answers were given regardless of women having intercourse. For questions on sexual matters, the answers given reflected women's experiences during intercourse and for these questions, women who were sexually inactive due to 'vaginal symptoms' or 'other reasons' were excluded from the analysis of effect of PFMT.

Dyspareunia and coital incontinence were assessed by the Norwegian version of the validated ICIQ sexual matters module (ICIQ-FLUTSsex).[36,37] Answers were given as an average over the last 4 weeks and the results were dichotomised into having the symptom or not having the symptom. The answers given reflected women's experiences during intercourse and women who answered 'not having sexual intercourse' were excluded from the analysis of effect of PFMT. The answers from the last question were used for comparisons between groups at baseline and post intervention.

Vaginal resting pressure, PFM strength and endurance were assessed using a high precision pressure transducer connected to a vaginal balloon catheter (Camtech AS, Sandvika, Norway). The middle of the balloon was placed 3.5 cm inside the vaginal introitus.[38] Vaginal resting pressure was measured with no voluntary activity of the PFM, PFM strength was reported as the mean of three maximum voluntary contractions, and endurance was defined as a sustained maximum contraction and was quantified as the area under the curve over 10 seconds, measured during one attempt. Vaginal resting pressure and PFM strength were registered as cmH_2O and PFM endurance as cmH_2O/second.[39] The method has demonstrated good reliability and validity for measurement of PFM strength and vaginal resting pressure.[29,40,41]

Data were analysed using SPSS, version 15, and REVIEW MANAGER 5.3 (SPSS, Inc., Armonk, NY, USA). Background variables were reported as numbers with percentages and means with standard deviations (SD). Data was analysed as intention-to-treat. In principle, when there were missing values post intervention, the method of last observation carried forward was used for categorical data. If not having sexual intercourse at baseline, the observation was excluded from the analysis of effect of PFMT. For continuous data the baseline value plus the added average change observed in the corresponding control group was used. Assumptions using intention-to-treat were explored through sensitivity analysis. An additional per protocol analysis was performed based on women completing the trial and adhering to more than 80% of the prescribed training sessions (at home and during group training) who did not have a new pregnancy post intervention at 6 months postpartum.

Between-group comparisons on categorical data for vaginal symptoms, sexual matters, coital incontinence and dyspareunia were analysed by chi-square and the Mantel−Haenszel risk ratio (relative risk, RR). For continuous data, an independent sample *t*-test was used. No within-group analysis was done.

Former reported data on improvement in PFM strength, in favour of the training group, has previously been published for this group of women.[35] A sub-analysis was performed using multiple regression analysis on the effect of PFMT (a difference in symptoms between training and control group seen at post intervention), which could be related to a change in PFM variables (assessed as the change in vaginal resting pressure, PFM strength or endurance from 6 weeks to 6 months postpartum). An interaction effect was tested across stratum groups, symptom variables, and between training and control groups. The treatment effect was estimated using an independent sample *t*-test. Level of significance was set at $P < 0.05$.

Results

Of the 175 primiparous women included in this study at 6 weeks postpartum (mean 6.1 weeks, SD 0.9, range 3.9–8.7 weeks), 55 women were diagnosed with major levator ani muscle defect and 120 women with no defect of the levator ani muscle.[25,35] The number of women randomised to PFMT or the control group, and participant flow throughout the study are shown in Figure 1. Baseline characteristics are presented in Table 1. Women in the control group had a significantly higher education than women in the training group ($P = 0.01$). There was no association between education and any of the outcome variables of interest, so no further analyses were performed to adjust for this discrepancy at baseline. No other differences in demographic variables were seen between groups at inclusion.

Of the 75 women in the training group, 96% ($n = 72$) adhered to 80% of the required attendance both for class sessions and for daily home training. Two women from the control group were pregnant with their second child at 6 months postpartum. Fifteen (8.6%) women were lost to

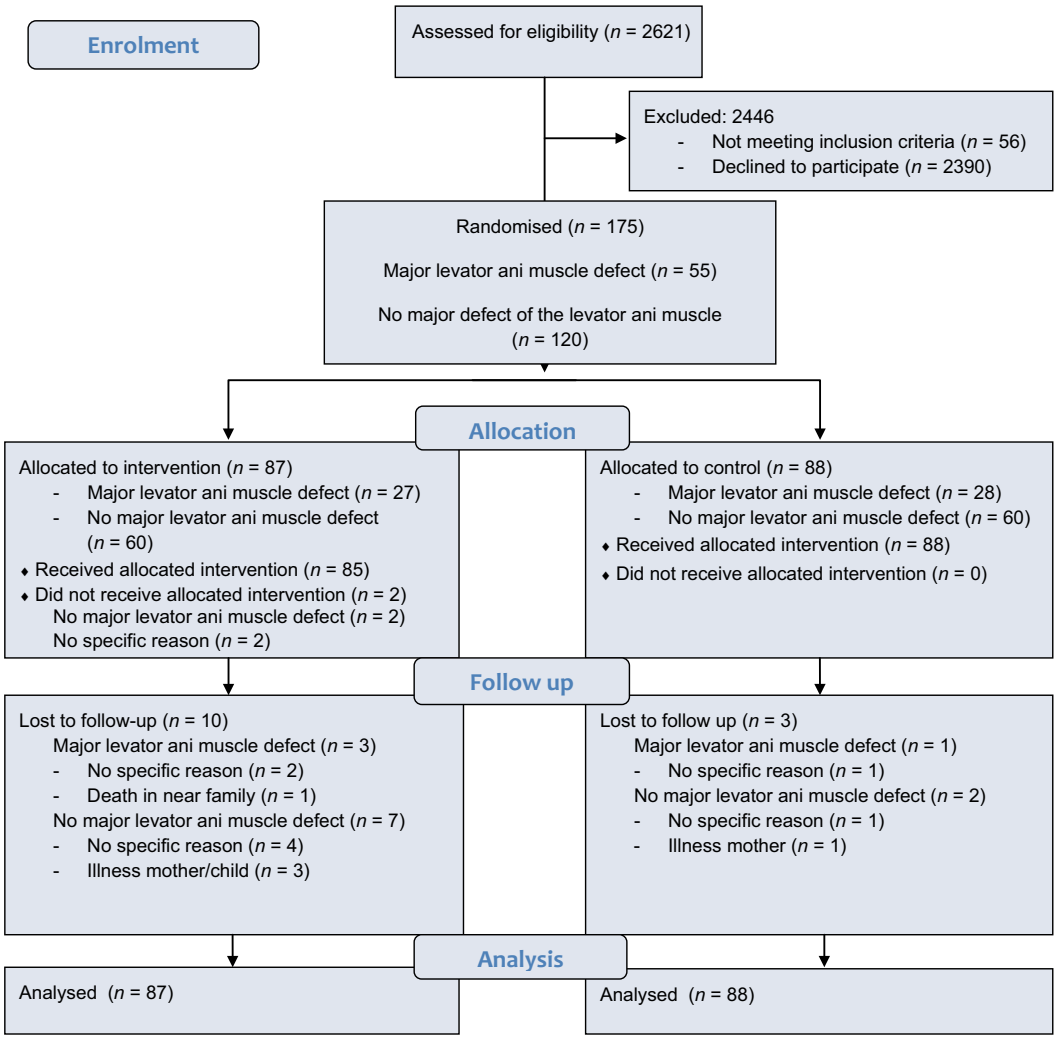

Figure 1. CONSORT 2010 Transparent Reporting of Trials: Flow Diagram.

follow up during the RCT, 12 (13.8%) from the PFMT group and three (3.4%) from the control group (Figure 1). There were no reports of any adverse effects in the PFMT group. Among the 15 women lost to follow up, a higher percentage with a lower educational level (46.7%) was found when compared with the 160 women completing the trial (15.6%; $P = 0.01$).[25]

There were no differences between groups at baseline regarding the outcome variables for vaginal symptoms, sexual matters, dyspareunia and coital incontinence, except for 'vagina feels sore': 14 (23.3%) versus 25 (41.7%) for the training group and control group, respectively (RR: 0.56, 95% CI 0.32, 0.97, $P = 0.04$). Between-group comparisons post intervention for these outcomes are shown in Supporting Information Table S1. There was no significant difference between groups for the total study sample ($n = 175$) or in the stratum with no defects ($n = 120$). In the stratum with major defects ($n = 55$) at post intervention significantly fewer women in the training group had symptoms of 'vagina feels loose or lax' than the control group (RR 0.55, 95% CI 0.31, 0.95, $P = 0.03$) (Figure 2). For the question 'how much do you feel that your sex life has been spoilt by vaginal symptoms?' there was no difference between the training ($n = 61$) and control groups ($n = 64$): respectively, mean 1.3 (SD 2.4) versus 1.1 (SD 2.1) (95% CI–1.0, 0.6, $P = 0.59$). Similar results were found for all outcomes when performing a per protocol analysis. There was no difference between groups in number of women not having intercourse at 6 months postpartum: 9/72 (12.5%) versus 10/83 (12%) ($P = 0.81$) for the training group and control group, respectively.

In women with the symptom 'vagina feels loose or lax' there was a significant increase in PFM strength and endurance in favour of the training group in the total study sample, whereas there was no difference in the two stratum groups with and without major defects of the levator ani muscle. Change in vaginal resting pressure did not differ between training and control (Table 2). In women without the symptom 'vagina feels loose or lax' (data not shown) a slight increase in PFM strength and endurance in the total study group and in the stratum groups was seen in favour of the training group, but these findings did not reach between-group significance. Results from the multiple regression analysis showed that the effect of PFMT on the symptom 'vagina feels loose or lax' in the stratum with major defects was not related to changes in PFM variables between training and control groups.

Table 1. Baseline characteristics of the training and control groups at baseline (6 weeks postpartum). $n = 175$

	PFMT $n = 87$	Control group $n = 88$	*P*-value
Age, years at delivery	29.5 (SD 4.3)	30.1 (SD 4.0)	0.38
BMI (kg/m^2)	26.0 (SD 4.1)	25.3 (SD 3.9)	0.26
Numbers married/cohabitant	80 (92.0%)	86.0 (97.7%)	0.10
Numbers with college/university degree	64 (73.6%)	79 (89.8%)	0.01
Numbers smoking*	2 (2.4%)	4 (4.5%)	0.71
Numbers breastfeeding ≥3 times daily*	80 (94.1%)	76 (86.4%)	0.15
Numbers using hormonal contraceptives*	5 (5.9%)	5 (5.7%)	1.00
Numbers doing PFMT >3 times/week*	26 (30.6%)	37 (42.0%)	0.16
Numbers being physically active ≥3 times/week*	4 (4.6%)	3 (3.4%)	0.96
Major levator ani muscle defects	27 (31.0%)	28 (31.8%)	1.00
Women not having sexual intercourse*,**	56 (65.9%)	56 (63.6%)	0.23

Continuous variables are given as means with standard deviation (SD) and 95% CI. Categorical variables are given as frequencies with percentages (%) and *P*-value. BMI, body mass index; PFMT, pelvic floor muscle training.
*Total $n = 173$; two missing from PFMT group.
**International Consultation on Incontinence Modular Questionnaire —sexual matters module.

Discussion

Main findings

Overall analysis showed no difference between groups after PFMT on vaginal symptoms or symptoms related to sexual dysfunction in primiparous women 6 months postpartum. The majority (88%) had intercourse and there was no difference between groups in women having sexual intercourse. The effect of problems with vaginal symptoms on sexual life was low and did not differ between groups. Unadjusted stratified analysis of women with major defect of the levator ani muscle showed that women in the training group had 45% less chance of having the symptom 'vagina feels loose or lax' compared with the control group. No association with this symptom and change in PFM variables was found.

Strengths and limitations

Strengths of the present study were the RCT design, blinding of assessors, supervised group training, high adherence to the training protocol, and the use of reliable and valid outcome measures. Limitations were some loss to follow up and a small sample size in some of the symptom groups.

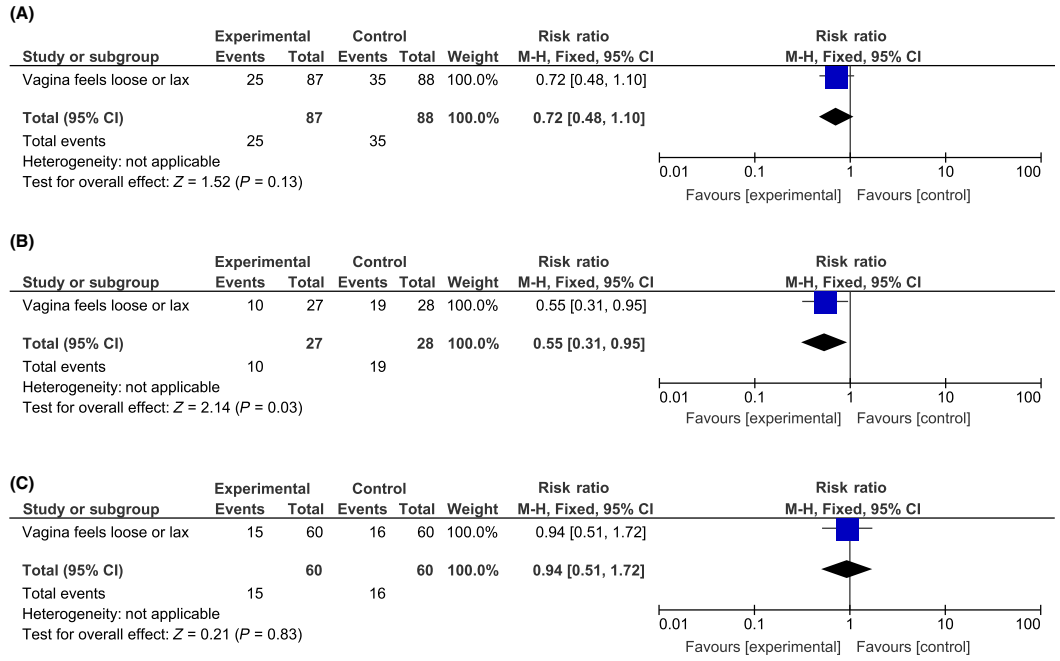

Figure 2. Forest plots showing effect of pelvic floor muscle training on 'vagina feels loose or lax' in primiparous women 6 months postpartum. (A) Total study sample (n =175). (B) Women with major defects of the levator ani muscle (n = 55). (C) Women with no major defect of the levator ani muscle (n = 120). Data analysed by REVIEW MANAGER 5.3 (SPSS, Inc., Armonk, NY, USA) and presented with numbers and risk ratio with 95% confidence intervals and P-values.

Intention-to-treat analysis was used, which could be a limitation. However, relatively few women were lost to follow up. Both intention-to-treat and per protocol analysis gave the same results and we could therefore be fairly confident that the non-completers did not differ from the women completing the trial. There was no *a priori* power calculation for this specific study and we cannot rule out a type II error. On the other hand, these data are the result of secondary analysis and the findings of effect of PFMT are unadjusted and should be seen as exploratory. The questionnaires used have not been validated in postpartum women, and a more comprehensive questionnaire related to orgasm, arousal and interest[2] could have contributed to a better understanding of the effect of PFMT on FSD. Questions relating to satisfaction with sexual life and the partner's satisfaction could also have given more information. To assess whether women who are sexually inactive at 6 weeks postpartum would benefit from PFMT is difficult, as we have no data on why the women did not have intercourse at this stage. Women may have several reasons for engaging in sex at 6 months postpartum and these may not be due solely to effect of PFMT. The imbalance at baseline related to the control group having a higher education than the training group may have meant that our findings are underestimations. However, there was no difference between groups on symptom variables when stratifying on high or low education. A limitation for generalisability of our overall analyses (n = 175) could be that more women had a higher education when compared with the general primiparous population and that the participants had to be able to understand and speak Scandinavian languages.

Interpretation

A systematic literature search revealed 12 RCTs on the effect of PFMT on FSD. Three studies were conducted in postpartum women, showing contradictory effects.[14–16] Due to differences in study design, outcome measures and content of the intervention, direct comparisons with these studies are limited. The present study found that women in the training group with major levator ani defects had significantly fewer symptoms of 'vagina feels loose or lax' compared with the control group. Newly published data has shown that primiparous women with this symptom had lower vaginal resting pressure, PFM strength and endurance than women without the symptom and perhaps a potential for effect.[42] No association between this symptom and change in PFM variables was found. A significantly larger change in PFM strength and

Table 2. Change in vaginal resting pressure, pelvic floor muscle strength and endurance from 6 weeks to 6 months postpartum between training and control group in women with the symptom 'vagina feels loose or lax'

	Total study sample (n = 60)				Major levator ani defects (n = 29)				Without major levator ani defects (n = 31)			
	Training (n = 25)	Control (n = 35)	Mean difference (95% CI)	P-value	Training (n = 10)	Control (n = 19)	Mean difference (95% CI)	P-value	Training (n = 15)	Control (n = 16)	Mean difference (95% CI)	P-value
Change VRP	2.4 (7.3)	3.4 (5.3)	1.1 (–2.2, 4.4)	0.51	0.6 (4.5)	1.9 (4.2)	1.4 (–2.1, 4.8)	0.43	3.5 (8.7)	5.2 (6.0)	1.7 (–3.7, 7.1)	0.54
Change PFM strength	14.8 (8.5)	9.6 (8.3)	5.2 (0.8, 9.6)	0.02	13.6 (9.6)	8.3 (5.1)	5.3 (–1.8, 12.5)	0.13	15.6 (8.0)	11.1 (10.9)	4.4 (–2.6, 11.5)	0.21
Change endurance	138.3 (91.5)	86.2 (79.8)	52.1 (7.6, 96.5)	0.02	130.6 (103.7)	67.6 (48.2)	63.0 (–13.1, 139.1)	0.10	143 (85.9)	108.4 (103.3)	35.0 (–35.0, 105.1)	0.32

CI, 95% confidence interval; PFM, pelvic floor muscle; VRP, vaginal resting pressure. Values given as n (%) with mean difference between groups at post intervention analysed using independent sample t-test.

endurance from 6 weeks to 6 months postpartum in favour of the training group has been found,[35] but this change may have been too small to be clinically relevant. There is probably a natural remission as both training and control group improved their PFM strength and endurance.[25,43] As the effect of PFMT was seen in one stratum, reduced statistical power may explain the lack of association. On the other hand, our results indicate that symptoms worsened in the control group but did not change in the training group. This could be interpreted as PFMT possibly having a preventative effect. Women may also experience their vaginal symptoms differently depending on whether they have intercourse or not, which may be reflected in the answers given in the questionnaire at both time points. Lastly, the reported problems reflected in the question 'how much do you feel that your sex life has been spoilt by vaginal symptoms' were low, indicating that this symptom may play less of a role during intercourse. Although the PFM has been postulated to be an important factor for different aspects of female sexual function,[5] there may be a potential psychosocial effect of PFMT, for example improved self-acceptance, body awareness and satisfaction[8].

Other vaginal symptoms and symptoms related to sexual dysfunction did not differ between groups. There may be several explanations for this. First, our study started at 6 weeks postpartum, which may have been too early taking into consideration that only 35% of the women had intercourse at that time. Citak et al.[14] studied 75 women starting in the 16th postpartum week and found a positive effect on arousal, lubrication and orgasm. Mørkved et al.[16] followed 188 women during pregnancy and found improved satisfaction with sexual life 6 years after PFMT. Wilson and Herbison[15] did not find any effect of PFMT on sexual dysfunction after a training period of 9 months, starting 3 months postpartum. However, that study had several methodological limitations and a high dropout rate (>50%), especially in the training group. Although the above studies reported the effect of the intervention, no report of effect size was given. Secondly, the possible natural remission of symptoms during the intervention period may blur the between-group difference. The negative findings related to sexual matters from ICIQ-VS could perhaps reflect the irrelevance of some of the vaginal symptoms in relation to intercourse. The majority of women in our study had intercourse and there was no difference between groups. We did not register frequency of intercourse, and therefore risk not detecting those having less frequent intercourse possible due to symptoms. No effect on dyspareunia was found, which is in accordance with other studies.[14,15] Due to the nature and complexity of this symptom,[5] PFMT alone may not be appropriate.

None of the RCTs included questions related to coital incontinence, but one non-randomised trial found effect

of PFMT combined with either biofeedback or electro stimulation.[44] Our negative finding is limited because there were only six women with this symptom.

Conclusion

The overall analysis showed no difference between training and control group after PFMT on vaginal symptoms or symptoms related to sexual dysfunction in primiparous women 6 months postpartum. The majority of women had intercourse and the overall problems of vaginal symptoms affecting sexual life were low and did not differ between groups. Unadjusted analysis of women with major defect of the levator ani muscle showed that significantly fewer women in the training group had symptoms of 'vagina feels loose or lax' compared with the control group, but whether this symptom is related to sexual dysfunction is not clear. This indicates that PFMT might prevent symptoms of 'vagina feels loose or lax' but these findings need to be explored in future studies with vaginal symptoms and sexual dysfunction as primary outcomes.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting Information.

Contribution to authorship

MKT, GH, JSJ, FS, MEE, KB took part in the conception and design. GH, JSJ, FS were responsible for acquisition of data. MKT and KB analysed and interpreted the data. MKT MEE, KB drafted the article. MKT, GH, JSJ, FS, MEE, KB revised it for intellectual content and contributed to the final approval of the completed article.

Details of ethics approval

The study was approved by the Regional Medical Ethics Committee (REK South East 2009/289a, date of approval: 2 December 2009), Data Protect Officer (2799004), and registered at ClinicalTrials.gov (NCT01069484).

Funding

We acknowledge the South-Eastern Norway Regional Health Authority and the Norwegian Research Council for financing the original study. We also gratefully acknowledge financial funding for the present project on pelvic floor muscle training and vaginal symptoms and sexual dysfunction through the EXTRA funds from the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

Acknowledgements

The authors thank midwife Tone Breines Simonsen for recruiting participants and administering clinical appointments and electronic questionnaires; physical therapist Kristin Gjestland for clinical testing and data entering; physical therapists Ingeborg Hoff Brækken, Vigdis Skøld and Ingvild Sandholt for supervising the interventional group training sessions; Cathrine Reimers for data cleaning and entry; and Professor Ingar Holme, PhD, for statistical advice.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Effect of pelvic floor muscle training 6 months postpartum on vaginal symptoms, sexual matters, coital incontinence and dyspareunia. ■

References

1 Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J* 2010;21:5–26.

2 Ishak WW, Tobia G. DSM-5 Changes in Diagnostic Criteria of Sexual Dysfunctions. *Reprod Sys Sexual Disorders* 2013;2:122.

3 Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States: prevalence and predictors. *JAMA* 1999;281:537–44.

4 Durnea CM, Khashan AS, Kenny LC, Tabirca SS, O'Reilly BA. The role of prepregnancy pelvic floor dysfunction in postnatal pelvic morbidity in primiparous women. *Int Urogynecol J* 2014;25:1363–74.

5 Graziottin A. Female sexual dysfunction. In: Bø K, Berghmans B, Mørkved S, Van KM, editors. *Evidence Based Physical Therapy for the Pelvic Floor. Bridging Science and Clinical Practice*, 2nd edn. Philadelphia: Churchill Livingstone Elsevier; 2015. pp. 243–70.

6 Martinez CS, Ferreira FV, Castro AAM, Gomide LB. Women with greater pelvic floor muscle strength have better sexual function. *Acta Obstet Gynecol Scand* 2014;93:457–502.

7 Lowenstein L, Gruenwald I, Gartman I, Vardi Y. Can stronger pelvic muscle floor improve sexual function? *Int Urogynecol J* 2010;21:553–6.

8 Braekken IH, Majida M, Ellstrom EM, Bo K. Can pelvic floor muscle training improve sexual function in women with pelvic organ prolapse? A randomized controlled trial *J Sex Med* 2015;12:470–80.

9 Chambless DL, Stern T, Sultan FE, Williams AJ, Goldstein AJ, Lineberger MH, et al. The pubococcygens and female orgasm: a correlational study with normal subjects. *Arch Sex Behav* 1982;11:479–90.

10 Baytur YB, Deveci A, Uyar Y, Ozcakir HT, Kizilkaya S, Caglar H. Mode of delivery and pelvic floor muscle strength and sexual function after childbirth. *Int J Gynaecol Obstet* 2005;88:276–80.

11 Hay-Smith EJ, Herderschee R, Dumoulin C, Herbison GP. Comparisons of approaches to pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev* 2011:CD009508.

12 Boyle R, Hay-Smith EJ, Cody JD, Morkved S. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. *Cochrane Database Syst Rev* 2012:CD007471.

13 Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. *Cochrane Database Syst Rev* 2011:CD003882.

14 Citak N, Cam C, Arslan H, Karateke A, Tug N, Ayaz R, et al. Postpartum sexual function of women and the effects of early pelvic floor muscle exercises. *Acta Obstet Gynecol Scand* 2010;89:817–22.

15 Wilson PD, Herbison GP. A randomized controlled trial of pelvic floor muscle exercises to treat postnatal urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998;9:257–64.

16 Morkved S, Rommen K, Schei B, Salvesen KA, Bo K. No difference in urinary incontinence between training and control group six years after cessation of a randomized controlled trial, but improved sexual satisfaction in the training group. *Neurourol Urodyn* 2007;26:667.

17 Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, et al. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. *Lancet* 2014;383:796–806.

18 Eftekhar T, Sohrabi M, Haghollahi F, Shariat M, Miri E. Comparison effect of physiotherapy with surgery on sexual function in patients with pelvic floor disorder: a randomized clinical trial. *Iran J Reprod Med* 2014;12:7–14.

19 Wiegersma M, Panman CM, Kollen BJ, Berger MY, Lisman-Van LY, Dekker JH. Effect of pelvic floor muscle training compared with watchful waiting in older women with symptomatic mild pelvic organ prolapse: randomised controlled trial in primary care. *BMJ* 2014;349:g7378.

20 Bo K, Talseth T, Vinsnes A. Randomized controlled trial on the effect of pelvic floor muscle training on quality of life and sexual problems in genuine stress incontinent women. *Acta Obstet Gynecol Scand* 2000;79:598–603.

21 Liebergall-Wischnitzer M, Paltiel O, Hochner Celnikier D, Lavy Y, Manor O, Woloski Wruble AC. Sexual function and quality of life of women with stress urinary incontinence: a randomized controlled trial comparing the Paula method (circular muscle exercises) to pelvic floor muscle training (PFMT) exercises. *J Sex Med* 2012;9:1613–23.

22 Chambless DL, Sultan FE, Stern TE, O'Neill C, Garrison S, Jackson A. Effect of pubococcygeal exercise on coital orgasm in women. *J Consult Clin Psychol* 1984;52:114–8.

23 Trudel G, Saint-Laurent S. A comparison between the effects of Kegel's exercises and a combination of sexual awareness relaxation and breathing on situational orgasmic dysfunction in women. *J Sex Marital Ther* 1983;9:204–9.

24 Yang EJ, Lim JY, Rah UW, Kim YB. Effect of a pelvic floor muscle training program on gynecologic cancer survivors with pelvic floor dysfunction: a randomized controlled trial. *Gynecol Oncol* 2012;125:705–11.

25 Hilde G, Staer-Jensen J, Siafarikas F, Ellstrom EM, Bo K. Postpartum pelvic floor muscle training and urinary incontinence: a randomized controlled trial. *Obstet Gynecol* 2013;122:1231–8.

26 Morkved S, Bo K. The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1997;8:217–22.

27 Hilde G, Staer-Jensen J, Ellstrom EM, Braekken IH, Bo K. Continence and pelvic floor status in nulliparous women at midterm pregnancy. *Int Urogynecol J* 2012;23:1257–63.

28 Hilde G, Staer-Jensen J, Siafarikas F, Gjestland K, Ellstrom EM, Bo K. How well can pelvic floor muscles with major defects contract? A cross-sectional comparative study 6 weeks after delivery using transperineal 3D/4D ultrasound and manometer *BJOG* 2013;120:1423–9.

29 Bo K, Hagen RR, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II. Validity of vaginal pressure measurements of pelvic muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourol Urodyn* 1990;9:479–87.

30 Dietz HP, Bernardo MJ, Kirby A, Shek KL. Minimal criteria for the diagnosis of avulsion of the puborectalis muscle by tomographic ultrasound. *Int Urogynecol J* 2011;22:699–704.

31 Dietz HP, Shek KL. Tomographic ultrasound imaging of the pelvic floor: which levels matter most? *Ultrasound Obstet Gynecol* 2009;33:698–703.

32 Staer-Jensen J, Siafarikas F, Hilde G, Braekken IH, Bo K, Engh ME. Pelvic floor muscle injuries 6 weeks post partum-an intra- and inter-rater study. *Neurourol Urodyn* 2013;32:993–7.

33 Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. III. Effects of two different degrees of pelvic floor muscle exercises. *Neurourol Urodyn* 1990;9:489–502.

34 Price NJS, Avery K, Brookes ST, Abrams P. Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: the ICIQ-VS. *BJOG* 2006;113:700–12.

35 Bo K, Hilde G, Staer-Jensen J, Siafarikas F, Tennfjord MK, Engh ME. Postpartum pelvic floor muscle training and pelvic organ prolapse-a randomized trial of primiparous women. *Am J Obstet Gynecol* 2015;212:38.e1–7.

36 Abrams P, Avery K, Gardener N, Donovan J, Board IA. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. *J Urol* 2006;175:1063–6; discussion 6.

37 Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P. The Bristol Female Lower Urinary Tract Symptoms questionnaire: development and psychometric testing. *Br J Urol* 1996;77:805–12.

38 Bo K. Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. *Neurourol Urodyn* 1992;11:107–13.

39 Braekken IH, Majida M, Ellstrom EM, Holme IM, Bo K. Pelvic floor function is independently associated with pelvic organ prolapse. *BJOG* 2009;116:1706–14.

40 Bo K, Hagen R, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic muscle strength. *Neurourol Urodyn* 1990;9:471–7.

41 Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourol Urodyn* 2006;25:236–42.

42 Tennfjord MK, Hilde G, Staer-Jensen J, Siafarikas F, Engh ME, Bo K. Coital incontinence and vaginal symptoms and the relationship to pelvic floor muscle function in primiparous women at 12 months postpartum: a cross-sectional study. *J Sex Med* 2015;12:994–1003.

43 Staer-Jensen J, Siafarikas F, Hilde G, Benth JS, Bo K, Engh ME. Postpartum recovery of levator hiatus and bladder neck mobility in relation to pregnancy. *Obstet Gynecol* 2015;125:531–9.

44 Beji NK, Yalcin O, Erkan HA. The effect of pelvic floor training on sexual function of treated patients. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:234–8; discussion 8.

Paper IV

Int Urogynecol J
DOI 10.1007/s00192-017-3290-y

ORIGINAL ARTICLE

An intra- and interrater reliability and agreement study of vaginal resting pressure, pelvic floor muscle strength, and muscular endurance using a manometer

Merete Kolberg Tennfjord[1,2] · **Marie Ellström Engh**[2,3] · **Kari Bø**[1]

Received: 6 December 2016 / Accepted: 2 February 2017

Abstract
Introduction and hypothesis Manometry is commonly used to assess pelvic floor muscle (PFM) function. Aims of the study were to assess intra- and interrater reliability and agreement of vaginal resting pressure, PFM strength, and muscular endurance using a high-precision pressure transducer.
Methods A convenient sample of 23 women was included. The participants were tested twice by two examiners on day 1 and retested after 1 week by one examiner. Vaginal resting pressure, PFM strength, and muscular endurance were measured by manometer (Camtech AS). Intraclass correlation coefficient (ICC) and Bland–Altman plots were used to analyze reliability and agreement respectively. Results are presented with mean differences (bias) and minimal detectable change.
Results Twenty participants completed the tests (mean age 55.8 years [27–71], mean parity 1.7 [range 0–3], and mean body mass index 23.7 [range 18.4–27.2, SD 2.4]). ICC values were very good (ICC >0.90) for all measurements. Considerable intervariation of scores, and outliers were seen for measurements representing the highest values. Agreement with mean differences (bias) and minimal detectable change for the intrarater assessment was for vaginal resting pressure: -2.44 ± 8.7 cmH_2O, for PFM strength -0.22 ± 7.6 cmH_2O, and for muscular endurance 0.75 ± 59.5 cmH_2O/s. The interrater agreement for vaginal resting pressure was: 1.36 ± 9.0 cmH_2O, for PFM strength 2.24 ± 9.0 cmH_2O, and for muscular endurance 15.89 ± 69.7 cmH_2O/s.
Conclusions Manometry (Camtech AS) seems less accurate for the strongest women. In clinical practice, significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement.

Keywords Pelvic floor · Reliability · Manometer · Vaginal resting pressure · Pelvic floor muscle strength · Muscular endurance

Introduction

A correct, voluntary pelvic floor muscle (PFM) contraction has been described as an elevation and a squeeze around the pelvic openings [1]. The levator ani muscle is primarily responsible for this function. Furthermore, at rest, the levator ani muscle keeps constant tone to keep the urogenital hiatus of the levator ani closed [2]. Vaginal resting pressure, PFM strength, and muscular endurance may be assessed in several ways: visual observation and palpation, electromyography, vaginal pressure measurements (manometry), dynamometry, and imaging, such as magnetic resonance imaging techniques and ultrasound [3, 4].

In physiotherapy practices, the manometer is the most common method of assessing PFM function [4]. In general, the manometer has been established as a reliable assessment method for PFM strength [5–7]. However, comparing results across studies using different devices is not possible [8]. To date, randomized controlled trials (RCT) have demonstrated significant improvements in PFM strength and endurance after pelvic floor muscle training (PFMT) using a manometer (Camtech AS, Sandvika, Norway) [9–11]. Observational

✉ Merete Kolberg Tennfjord
merete.kolberg@gmail.com

[1] Department of Sports Medicine, Norwegian School of Sport Sciences, PO Box 4014, Ullevål stadion, 0806 Oslo, Norway

[2] Department of Obstetrics and Gynecology, Akershus University Hospital, Lørenskog, Norway

[3] Institute of Clinical Medicine, University of Oslo, Oslo, Norway

Published online: 16 March 2017

studies have also shown statistically significant differences in vaginal resting pressure in symptomatic and asymptomatic women [12, 13]. Although good reliability and validity for PFM strength has been established [14, 15], the reliability and agreement of vaginal resting pressure and muscular endurance has not been assessed using Camtech AS, nor has interrater reliability and agreement for PFM strength been assessed.

The International Continence Society Clinical Assessment Group recommended studies on intra- and interrater variability for PFM function, voluntary contraction, and relaxation [3]. Thus, the aims of the present study were to assess intra- and interrater reliability and agreement of vaginal resting pressure PFM strength and muscular endurance.

Materials and methods

Subjects and design

This study on intra- and interrater reliability and agreement was performed at a physiotherapy center in Sandvika, Norway, from March 2015 to April 2015. A convenient sample of 23 women was recruited to evaluate the intra- and interrater reliability and agreement of PFM function measured by manometer (Camtech AS). The sample of 23 women was based on previous reliability studies in the field [5–7, 14]. The women received information through leaflets available in the reception area at the center or they were encouraged to participate in the study during general group fitness classes. The inclusion criterion was the ability to contract the PFM correctly, defined as an inward movement and squeeze around the pelvic openings assessed by observation and palpation [1, 15]. No grading of PFM strength was done for inclusion purposes. Exclusion criterion was the inability to understand instructions given in any of the Scandinavian languages. To avoid a possible effect of training/detraining, the participants were asked not to change PFMT habits between testing days. To maintain anonymity, the participants received a unique ID number, which was the only link between the examination and the woman. The Regional Medical Ethics Committee (2014/1768) approved the study and the Data Protection Officer at Akershus University hospital (15–018) was informed about the study. All participants gave written informed consent to participate. The study procedures were in accordance with the World Medical Association, Helsinki Declaration (2013) [16]. The applied terminology follows recommendations from the clinical assessment group of the International Continence Society, except where specifically noted [3]. The Guidelines for Reporting Reliability and Agreement Studies (GRRAS) studies were followed [17].

Procedure and apparatus

Two women's health physiotherapists were involved in the study. Participants were tested twice on the same day by two independent physiotherapists. The order in which they were examined was random. One week later one physiotherapist, MKT, re-tested the same group of women at the same timepoint as test 1. The physiotherapists were blinded to each other's results and the results from test 1 were unavailable during test 2. Both physiotherapists had thorough training before conducting the study. The training included: positioning of the participant and assessor, verbal instructions, catheter placement, recording of measurements, and analysis. All participants answered a short questionnaire before the examination including: age, level of education, if they undertook strenuous physical work, weight, height, parity, and any symptoms from the pelvic floor (urinary and anal incontinence, pelvic organ prolapse [vaginal bulging, pelvic pressure], pelvic floor pain, other).

The procedures were recorded on a flat bench with a small pillow underneath the head. The physiotherapist was sitting at the examination table next to the woman supporting one leg, while the other leg of the woman was resting against a pillow to the wall. The participating women were given a short anatomy lecture and were taught how to perform a correct PFM contraction using observation and palpation [1, 15] before measurement was taken using the instructions: "*breathe slowly in and out*"; "*you are ready*"; "*lift and squeeze your pelvic floor —lift as hard as you can*"; "*let go and breathe out slowly*". The sequence for muscle testing was as follows: three repetitions of maximum voluntary contractions lasting approximately 3 s each with an approximately 6-s rest in between. Less than 1-min rest was allowed before muscular endurance was tested. PFM contraction without any movement of the pelvis or visible contraction of the glutei, hip or abdominal muscles was emphasized [14, 15].

Vaginal resting pressure, PFM strength, and muscular endurance were measured using a high-precision pressure transducer connected to a vaginal balloon (Camtech AS; Fig. 1). After compressing the balloon 10–20% to allow for air expansion at body temperature, the balloon catheter was connected to the fiber tip and calibrated in air. A lubricating gel was applied to the balloon catheter. The device was positioned with the middle of the balloon 3.5 cm internal to the introitus in the vaginal high pressure zone [18], a method found to be reliable and valid for the assessment of PFM strength, with simultaneous observation of an inward movement of the catheter and no use of extra-pelvic muscle contraction [14, 15]. To control placement and movement of the balloon, the physiotherapist held the catheter with the thumb and index finger before and during every measurement. The physiotherapist followed the movement of the catheter during contraction. The atmospheric pressure on the balloon was calibrated to

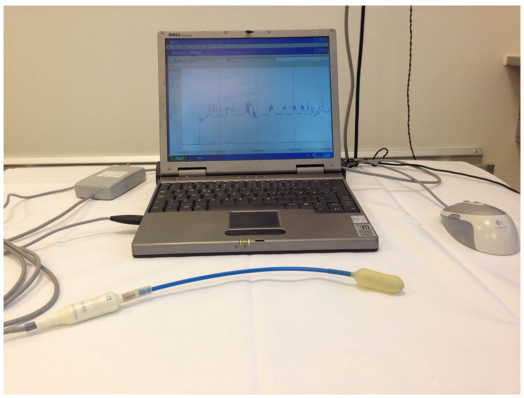

Fig. 1 High-precision pressure transducer connected to a vaginal balloon (Camtech AS, Sandvika, Norway)

0 cmH_2O for each woman before it was placed in the vagina. Vaginal resting pressure was measured as the difference between the atmospheric pressure and the vaginal high pressure zone at rest, with no voluntary PFM activity, and was registered as cmH_2O. The measurement was taken before the first contraction and registered as a flat curve after the woman was instructed to relax and given time to slowly breathe in and out. PFM strength was measured from the resting pressure line until the peak, not including the resting pressure, reported as the mean of three maximum voluntary contractions, and registered as cmH_2O. Local muscular endurance is the ability of a muscle to sustain near maximal or maximal force, assessed by the time a person is able to maintain a maximal static or isometric contraction [19], and was quantified as the area under the curve for 10 s, measured during one attempt and registered as cmH_2O/s (Fig. 2). Using the area under the curve includes the force applied during a specific time (10 s). To ensure maximal tension in the muscle, it is commonly recommended that the contraction is held for more than 6 s [20]. Local muscular endurance may also be defined as the ability to repeatedly develop near maximal or maximal force determined by the number of repetitions [19], but using time in seconds will not give details on the exact force.

Manometer analysis

Data showing pressure values and pressure curves were stored on the hard disk of the apparatus using the unique ID number for each woman. Each physiotherapist analyzed their own measurement.

Statistical analysis

Statistical analysis was performed using SPSS version 15. All parameters were measured once, except for PFM strength, where the mean of three contractions was used for analyses. Demographic data and results were given as mean values with standard deviations (SD), or, in the case of categorical data, as counts (%). Normality tests were performed. Intra- and interrater reliability were analyzed using the intraclass correlation coefficient (ICC, average measures) using a two-way mixed model for absolute agreement with the 95% confidence interval (CI). 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. One sample *t* test was used to calculate the mean difference (bias) between measurements and the corresponding SD and 95% CI. To assess agreement, the Bland–Altman approach was used [21]. This method assesses for systematic bias and random error using the mean difference and 95% limits of agreement (1.96 SD). Minimal detectable change was calculated to identify the smallest amount of change above the threshold of error using the SD of the mean difference (bias) multiplied by 1.96 SD [22].

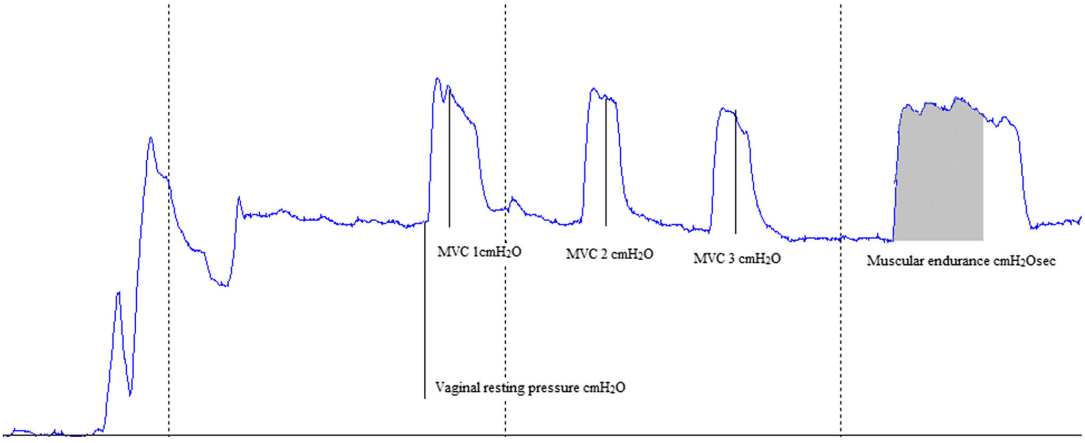

Fig. 2 Pressure curves from one participant showing vaginal resting pressure, pelvic floor muscle strength, and muscular endurance

Results

One woman was excluded because of her inability to insert the probe (owing to restricted vaginal opening) and one woman did not attend her scheduled appointment. Furthermore, one had to be excluded owing to poor image quality, leaving 20 women for analysis (mean age 55.8 (range 27–71), mean parity 1.7 (range 0–3), and mean body mass index 23.6 (range 18.4–27.2, SD 2.4). The majority, 17 (85%), had a college/university degree and 10 (50%) reported undergoing strenuous physical work. All participants knew of PFMT and they were all able to perform a correct PFM contraction after instructions. Fourteen (70%) reported that they sometimes experienced minor symptoms from the pelvic floor (urinary incontinence, vaginal dryness, and urinary tract infection). Two were pregnant with their second child, one was in the second and one in the third trimester. None of the above conditions interfered with the placement of the catheter or the procedure.

Intra- and interrater analysis are shown in Tables 1 and 2 respectively. There was considerable intervariation of scores as seen from the large SD in the first two rows. ICC values were very good for all measurements for both intra- and interrater assessments (ICC >0.90).

Results from the Bland–Altman plot are illustrated in Fig. 3, showing vaginal resting pressure (a, b), PFM strength (c, d), and muscular endurance (e, f). When looking at the dots on the plot, one can see that the distribution of scores was right-skewed, and that the limits of agreement were relatively wide. There was also a slight bias as the centre line deviated from zero (Fig. 3); vaginal resting pressure (mean difference −2.44 (95% CI −4.51, −0.36) in the intrarater assessment and PFM strength (mean difference 2.24 (95% CI 0.03, 4.45) in the interrater assessment (Tables 1, 2). Outliers were observed in all measurements, most of which represented the strongest women (Fig. 3).

Discussion

This intra- and interrater reliability and agreement study showed very good ICC values (>0.90) for vaginal resting pressure, PFM strength, and muscular endurance using a manometer. Agreement as seen in the Bland–Altman plot was poorer. The heterogeneity of the samples may explain these findings [21]. Systematic bias was statistically significant for two measurements. Visual inspection of the data showed a right-skewed distribution of scores and outliers representing the strongest women. Hence, the manometer used in this study seems less accurate for the strongest women and could potentially underestimate the highest scores and overestimate the lowest scores.

In a similar study by Bø et al. [14], test–retest on PFM strength using the same manometer was performed. The authors concluded that the test results were reproducible, but wide confidence intervals imply to some degree inaccuracy around their estimates. This is in line with findings from the present study and corresponds with previous studies using different types of manometers [5–7, 14]. However, results from the above cited studies are not directly comparable owing to the use of different measurement devices [8]. Measurements recorded for the strongest women were more problematic than those recorded for the weakest women. The vaginal probe may be pulled further inside the vagina during contraction, and may not have been in the high-pressure zone [23], a possible explanation for the outliers seen in our sample. For the probe to stay in the high-pressure zone [18], the assessors had to control the movement of the probe, which could yield a potential source of error. The use of dynamometry may be less sensitive to the movement of the apparatus during contraction, as the device is better fixed inside the vagina [24]. Dumoulin et al. [24] concluded that there was good reliability for PFM strength, but that with a coefficient of variation (CV%) of 21%, some degree of random error was present. We have not been able to find studies on muscular endurance using the same manometer as this present study.

Table 1 Intrarater reliability analysis for vaginal resting pressure (*VRP*), pelvic floor muscle (*PFM*) strength, and muscular endurance for assessor 1. *N* = 20

	Test 1 (SD)	Test 2 (SD)	ICC (95% CI)	Bias (95%CI)	SD	Limits of agreement		Minimal detectable change (cmH_2O)
						Lower	Upper	
VRP (cmH_2O)	24.36 (9.50)	21.93 (6.96)	0.91 (0.72, 0.97)	−2.44 (−4.51, −0.36)	4.44	−11.13	6.26	8.7
PFM strength (cmH_2O)	21.42 (13.19)	21.20 (13.80)	0.98 (0.95, 0.99)	−0.22 (−2.05, 1.60)	3.89	−7.86	7.41	7.6
Muscular endurance (cmH_2O/s)	144.30 (88.47)	145.05 (99.99)	0.98 (0.94, 0.99)	0.75 (−13.46,14.96)	30.35	−58.74	60.24	59.5

Bias = test 2 − test 1

Table 2 Interrater reliability analysis for VRP, PFM strength, and muscular endurance. $N = 20$

	Assessor 1 (SD)	Assessor 2	ICC (95%CI)	Bias (95%CI)	SD	Limits of agreement		Minimal detectable change (cmH_2O)
						Lower	Upper	
VRP (cmH_2O)[a]	24.13 (9.70)	25.49 (11.81)	0.95 (0.88, 0.98)	1.36 (−0.86, 3.58)	4.60	−7.66	10.38	9.0
PFM strength (cmH_2O)[a]	21.56 (13.54)	23.80 (13.18)	0.96 (0.90, 0.99)	2.24 (0.03, 4.45)	4.58	−6.74	11.22	9.0
Muscular endurance (cmH_2O/s)[a]	145.74 (90.65)	161.63 (92.98)	0.96 (0.88, 0.98)	15.89 (−1.26, 33.04)	35.58	−53.85	85.64	69.7

[a] n = one value missing for assessor 2. Assessor 1 being the first author (MKT)

Bias = assessor 2 – assessor 1

Therefore, direct comparisons of studies are challenging owing to different apparatus and methods of measurement [8]. Frawley et al. [6] measured multiple repeated muscle contractions (20 fast contractions) with the Peritron and concluded poor reliability (ICC 0.05-0.42) in lying positions. Poor reliability for muscular endurance, as measured as a 1-min maximum contraction was also found using a dynamometer (dependability indices of 0.10) [24].

Vaginal resting pressure was measured before PFM muscle contraction. This method was chosen as it has been used in previous studies using the same manometer [9, 12, 13]. Although no voluntary muscle contraction was seen (stable pressure values and a flat curve), outliers were also seen for this measurement. Using Peritron, Frawley et al. [6] found good reliability (ICC 0.74–0.77) for vaginal resting pressure in lying positions. The use of a dynamometer has also shown "enough" reliability for the passive properties of the PFM in postmenopausal women [25]. However, "enough" is hard to quantify as there is a lack of data on normal values for the resting condition of the PFM [3]. Although surface electromyography (EMG) is not recommended to assess function of the PFM, rather than the presence/absence of muscle activation, it could be that surface EMG might be a more reliable tool for assessing the resting condition of the PFM, as no voluntary muscle activation is present and the measurement would be less biased by cross-talks from nearby muscles at rest than during contraction [3, 26].

Previous randomized controlled trials on women with stress urinary incontinence and pelvic organ prolapse, using Camtech AS [9–11], have shown statistically significant improvement in PFM strength and muscular endurance after PFMT. These improvements have been close to or above what we found was the minimal detectable change for PFM strength: 8.2 cmH_2O ($p < 0.03$) and 15.5 cmH_2O ($p < 0.01$) respectively [10, 11], and 13.1 cmH_2O, and for muscular endurance 107 cmH_2O ($p < 0.001$) [9]. Two recent observational studies also found statistically significant differences for vaginal resting pressure of 3.6 cmH_2O (95% CI 0.7, 6.6) and 3.3 cmH_2O ($p = 0.02$) respectively [12, 13] in women with and without vaginal laxity and between women with provoked vestibulodynia and asymptomatic controls respectively. According to the results from this present study, differences of 3.6 and 3.3 cmH_2O may be the results of measurement error. However, although gain in PFM function may be low and clinically nonsignificant, women may still report significant improvement in symptoms after PFMT [27].

The heterogeneity of participants representing the clinical everyday life, the standardization of test procedures, and the use of recommended statistical methods are strengths of this study [15, 18, 22, 28]. The physiotherapists had been thoroughly trained by the supervisor of the project, KB, and had extensive experience in use of the method. All women in the sample knew of PFMT and were able to perform a correct contraction after receiving instructions. Although less likely, we cannot rule out a possible learning effect. The number of participants included may be another limitation. Regarding sample size, the number of women in this study was in line with previous studies in this field [5–7, 14]. However, including more women in the study may have given a better estimate of the limits of agreement [28], but would probably not have changed the overall outcome. Although we included a heterogeneous group of women, we could still question the generalizability of the results. Our results indicate that the apparatus seem less accurate for the strongest women in this sample. This means that the limits of agreement could be wider apart than they should for the lowest scores and narrower than they should for the highest scores [21]. Based on results from this present study, it is important for clinicians to be aware that to evaluate improvement over the error of measurement after conservative treatments, the gain should exceed the minimal detectable change.

The clinical relevance of using a manometer could be the visual biofeedback obtained during a PFM contraction giving extra motivation for maximum contraction. In addition, it may be motivating to follow the development of quantifiable data on PFM function throughout an exercise

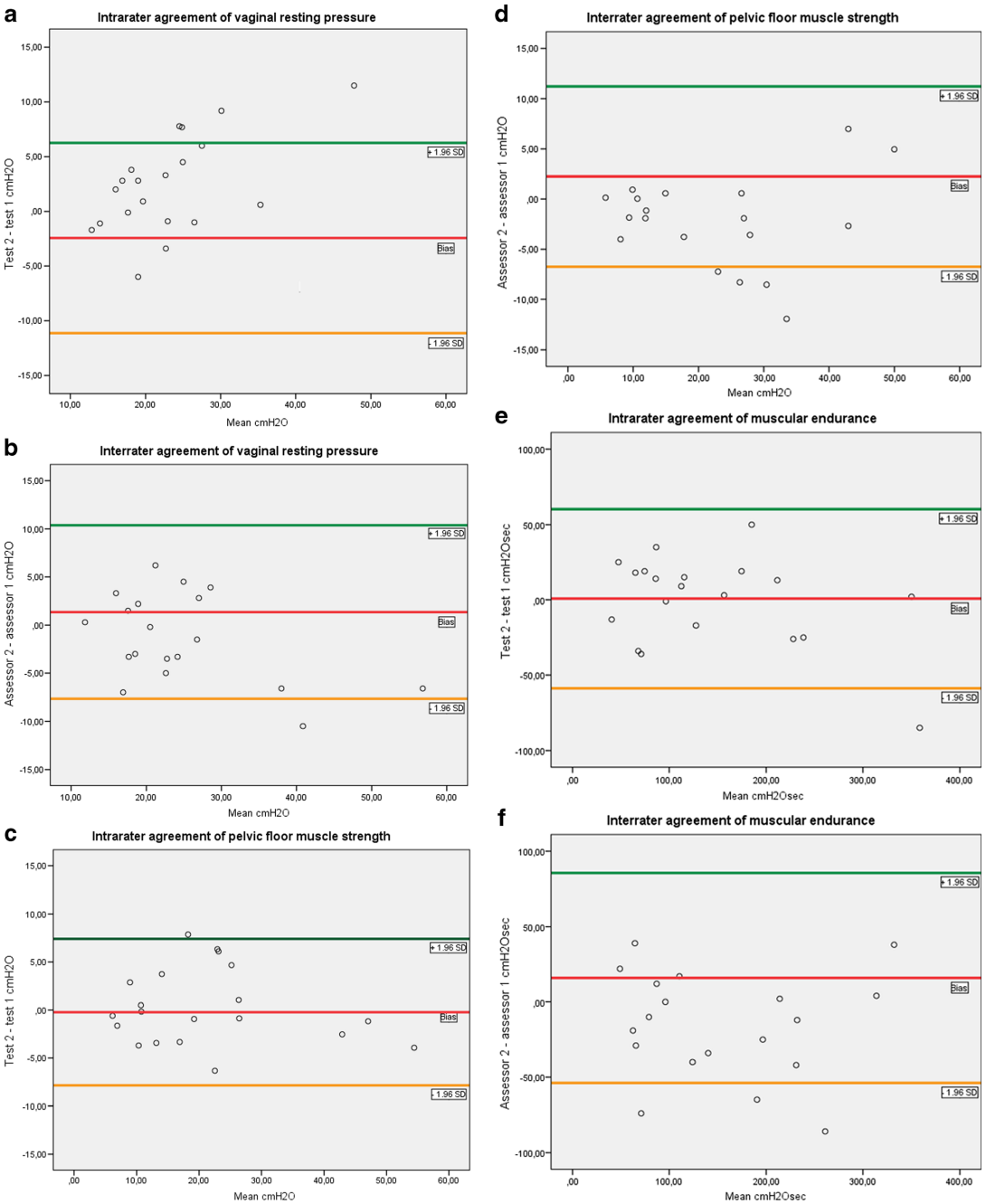

Fig. 3 Bland–Altman plot showing **a**, **b** vaginal resting pressure, **c**, **d** pelvic floor muscle strength, and **e**, **f** muscular endurance. The differences between the tests/assessors are plotted against each individual mean for the two tests. The bias line and random error lines forming the 95% limits of agreement are presented

period. However, in countries where such measurement tools are not available because of cost and feasibility, palpation should still be the core measurement. However, assessors need to be aware of the limitations of palpation and reported low interrater reliability [4, 29].

Conclusions

Compared with previous studies in this field, using the same device, this study presents new data on the reliability and agreement of vaginal resting pressure, PFM strength, and muscular endurance. Very good ICC values were found; however, agreement using the Bland–Altman approach was poorer. Outliers were women with the strongest PFM. Thus, Camtech AS seems less accurate for the strongest women and could potentially underestimate the highest scores and overestimate the lowest scores. For use in clinical practice, examiners must be aware that a significant improvement in PFM variables needs to exceed the minimal detectable change to be above the error of measurement.

Acknowledgements The authors thank physical therapist Vigdis Skøld for participating in data collection, physical therapist Hilde Løset Myrvang and Vest Helse for help with recruitment and location, Professor Ingar Holme (PhD) and Morten Wang Fagerland (PhD) for valuable statistical advice, and medical doctor Franziska Siafarikas (PhD) for valuable discussions and advice on the manuscript.

Compliance with ethical standards

Financial disclaimer None.

Conflicts of interest None.

Funding This project has been made possible by the Norwegian ExtraFoundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

References

1. Kegel AH. Stress incontinence and genital relaxation; a nonsurgical method of increasing the tone of sphincters and their supporting structures. Ciba Clin Symp. 1952;4:35–51.
2. Ashton-Miller JA, Delancey JOL. Functional anatomy of the female pelvic floor. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence-based physical therapy for the pelvic floor bridging science and clinical practice. 2nd ed. Philadelphia: Churchill Livingstone Elsevier; 2015. p. 19–34.
3. Messelink B, Benson T, Berghmans B, Bo K, Corcos J, Fowler C, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn. 2005;24:374–80.
4. Bø K, Sherburn M. Evaluation of female pelvic-floor muscle function and strength. Phys Ther. 2005;85:269–82.
5. Sigurdardottir T, Steingrimsdottir T, Arnason A, Bø K. Test-retest intra-rater reliability of vaginal measurement of pelvic floor muscle strength using myomed 932. Acta Obstet Gynecol Scand. 2009;88:939–43.
6. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bø K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn. 2006;25:236–42.
7. Ferreira CH, Barbosa PB, de Oliveira SF, Antonio FI, Franco MM, Bø K. Inter-rater reliability study of the modified Oxford Grading Scale and the Peritron manometer. Physiotherapy. 2011;97:132–8.
8. Bø K, Raastad R, Finckenhagen HB. Does the size of the vaginal probe affect measurement of pelvic floor muscle strength? Acta Obstet Gynecol Scand. 2005;84:129–33.
9. Brækken IH, Majida M, Engh ME, Bø K. Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial. Am J Obstet Gynecol. 2010;203:170.e1–7.
10. Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ. 1999;318:487–93.
11. Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. III. Effects of two different degrees of pelvic floor muscle exercises. Neurourol Urodyn. 1990;9:489–502.
12. Tennfjord MK, Hilde G, Staer-Jensen J, Siafarikas F, Engh ME, Bo K. Coital incontinence and vaginal symptoms and the relationship to pelvic floor muscle function in primiparous women at 12 months postpartum: a cross-sectional study. J Sex Med. 2015;12:994–1003.
13. Næss I, Bø K. Pelvic floor muscle function in women with provoked vestibulodynia and asymptomatic controls. Int Urogynecol J. 2015;26:1467–73.
14. Bø K, Hagen R, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic muscle strength. Neurourol Urodyn. 1990;9:471–7.
15. Bø K, Hagen RR, Kvarstein B, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II. Validity of vaginal pressure measurements of pelvic muscle strength and the necessity of supplementary methods for control of correct contraction. Neurourol Urodyn. 1990;9:479–87.
16. WMA. Declaration of Helsinki—ethical principles for medical research involving human subjects Fortaleza Brazil 2013. Accessed 30 September.2016. Available from: www.wma.net/en/30/publictions/10policies/b3/.
17. Kottner JA, Audige L, Brorson S, Donner A, Gajewski BJ, Hròbjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. Int J Nurs Stud. 2011;48:661–71.
18. Bø K. Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. Neurourol Urodyn. 1992;11:107–13.
19. Wilmore JH, Costill DL. Physiology of sport and exercise. 2nd ed. Leeds: Human Kinetics; 1999.
20. Åstrand PO, Rodahl K, Dahl HA. Textbook of work physiology; physiological basis of exercise. Champaign: Human Kinetics; 2003.
21. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;8:307–10.
22. Atkinson G, Nevill AM. Statistical methods for assessing measurement error (reliability) in variables relevant to sports medicine. Sports Med. 1998;26:217–38.
23. Guaderrama NM, Nager CW, Liu J, Pretorius DH, Mittal RK. The vaginal pressure profile. Neurourol Urodyn. 2005;24:243–7.

24. Dumoulin C, Gravel D, Bourbonnais D, Lemieux MC, Morin M. Reliability of dynamometric measurements of the pelvic floor musculature. Neurourol Urodyn. 2004;23:134–42.
25. Morin M, Gravel D, Bourbonnais D, Dumoulin C, Ouellet S. Reliability of dynamometric passive properties of the pelvic floor muscles in postmenopausal women with stress urinary incontinence. Neurourol Urodyn. 2008;27:819–25.
26. Vodusek DB. Electromyography. In: Bø K, Berghmans B, Mørkved S, Van Kampen M, editors. Evidence based physical therapy for the pelvic floor bridging science and clinical practice. 2nd ed. Philadelphia: Churchill Livingstone Elsevier; 2007. p. 56–63.
27. Tennfjord MK, Hilde G, Stær-Jensen J, Siafarikas F, Ellström Engh M, Bø K. Effect of postpartum pelvic floor muscle training on vaginal symptoms and sexual dysfunction—secondary analysis of a randomised trial. BJOG. 2016;123:634–42.
28. De Vet HCV, Terwee CB, Mokkink LB, Knol DL, editors. Measurement in medicine a practical guide. United States of America: Cambridge University Press; 2011.
29. Bø K, Finckenhagen HB. Vaginal palpation of pelvic floor muscle strength: inter-test reproducibility and comparison between palpation and vaginal squeeze pressure. Acta Obstet Gynecol Scand. 2001;80:883–7.

Appendix 1

Paper I and II

Letters of approval

Regional Committees for Medical Research Ethics

Data Protect Officer

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Dr. med. Marie Ellstrøm Engh
Akerhus universitetssykehus
Sykehusveien 31
1428 Lørenskog

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst D (REK Sør-Øst D)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 85 05 93
Telefaks: 22 85 05 90
E-post: i.m.middelthon@medisin.uio.no
Nettadresse:
http://helseforskning.etikkom.no/xnet/public

Dato: 04.08.09
Deres ref.:
Vår ref.: 2009/170

Vedr. svar på merknader for studien "Bekkenbunn skader ved fødsel målet med tre og fire-dimensjonalt ultralyd."

Vi viser til svar på merknader av 13.07.09. med følgende vedlegg: Revidert informasjonsskriv

Komiteen behandlet svar på merknader 04.08.09. Prosjektet er vurdert etter gjeldende regelverk med tilhørende forskrifter.

Komiteen finner at våre merknader er tilfredsstillende besvart. Komiteen kan imidlertid ikke ta standpunkt til spørsmålet om fremlegging er nødvendig for å foreta en ekstra undersøkelse uten å motta supplerende opplysninger. I praksis kan dette sannsynligvis håndteres som en enkel endringssøknad.

Vedtak:
Prosjektet godkjennes som nå fremlagt. Eventuell endring av prosjektet imøtesees i form av en endringssøknad.

REK har gått over til elektronisk saksbehandling og fått ny saksportal: http://helseforskning.etikkom.no. Vi ber om at svar på merknader og henvendelser til REK sendes inn via denne portalen eller på epost: post@helseforskning.etikkom.no. Vennligst oppgi REKs saksnummer.

Med vennlig hilsen

Stein A. Evensen (sign.)
Professor dr.med.
leder

Ingrid Middelthon
komitésekretær

Brevet er godkjent elektronisk

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Dr. med. Marie Ellstrøm Engh
Akerhus universitetssykehus
Sykehusveien 31
1428 Lørenskog

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst D (REK Sør-Øst D)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 85 05 93
Telefaks: 22 85 05 90
E-post: i.m.middelthon@medisin.uio.no
Nettadresse: www.etikkom.no

Dato: 13.10.2009
Deres ref.:
Vår ref.: 2009/170

Bekkenbunn skader ved fødsel målet med tre og fire-dimensjonalt ultralyd.

Vi viser til søknad av 25.09.2009 for det ovenfor nevnte forskningsprosjekt.

Prosjektleder er dr. med. Marie Ellstrøm Engh.

Forskningsansvarlig er Akershus Universitetssykehus.

Endringene innebærer:
Det søkes om å gjøre en ekstra undersøkelse av bekkenbunnen rundt 37. graviditetsuke hos de førstegangsfødende som allerede er rekruttert til studien.

Komiteen har vurdert endringssøknaden og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og oppdatert protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden må prosjektleder sende endringsmelding til REK. Vi gjør oppmerksom på at hvis endringene er vesentlige må prosjektleder sende ny søknad, eller REK kan pålegge at dette gjøres.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren», http://www.norsk-helsenett.no/informasjonssikkerhet/bransjenormen/Personvern%20og%20informasjonssikkerhet%20i%20forskningsprosjekter%20v1.pdf

Vedtak:
Prosjektet godkjennes slik det nå foreligger.

REK har gått over til elektronisk saksbehandling og fått ny saksportal: http://helseforskning.etikkom.no. Vi ber om at svar på merknader og henvendelser til REK

sendes inn via denne portalen eller på epost: post@helseforskning.etikkom.no. Vennligst oppgi REKs saksnummer.

Med vennlig hilsen

Stein A. Evensen (sign.)
Professor dr.med.
leder

Ingrid Middelthon (sign.)
komitésekretær

Brevet er godkjent elektronisk

<MELDESKJEMA[1] for forskningsstudier, kvalitetssikring og annen aktivitet som medfører behandling av personopplysninger som er melde- eller konsesjonspliktig i henhold til helseregisterloven og personopplysningsloven med forskrifter. Dette gjelder også bruk av biologisk materiale i forskning.

Utfylt skjema lagres på disk og sendes til ellef.mork@ahus.no som vedlegg til e-post sammen med eventuelt informasjonsskriv. Biobank: Ta kontakt med biobankkoordinator Randi Otterstad (epost: Randi.Otterstad@ahus.no).

1 INFORMASJON OM PROSJEKTANSVARLIG OG PROSJEKTLEDER (SØKEREN)	
A. PROSJEKTANSVARLIG (div direktør/klinikksjef):	
Navn og stilling: Pål Wiik	Klinikk/avdeling: Kirurgisk Divisjon
Telefonnummer: 67969099	E-postadresse: Pal.Wiik@ahus.no
B. PROSJEKTLEDER[2]	
Navn og stilling: Marie Ellstrøm Engh, første amenuensis, overlege KK Ahus	Klinikk/avdeling hvor prosjektet gjennomføres: Kvinneklinikken
Telefonnummer: 67964541	E-postadresse: m.e.engh@medisin.uio.no
C. MULTISENTERSTUDIE	
Er prosjektet en multisenterstudie? ☐ Ja x Nei Dersom **ja**, angi øvrige virksomheter som deltar: Skal noen av disse også ha kopi av elektronisk database/informasjon som etableres i prosjektet? ☐ Ja ☐ Nei	
D. ANNEN DATABEHANDLINGSANSVARLIG ENN AKERSHUS UNIVERSITETSSYKEHUS HF[3]	
Er prosjektet organisert fra et legemiddelfirma eller annen ekstern virksomhet? ☐ Ja x Nei Dersom **ja**, angi virksomhetens navn (Kopi av konsesjonen/godkjenning skal sendes personvernombudet, og prosjektet skal meldes til personvernombudet som meldepliktig prosjekt, dvs skjemaet fylles ut med unntak av punkt 5.4): Skal den eksterne også ha kodelisten/navnelisten over deltakere? ☐ Ja ☐ Nei	
2 PROSJEKTETS NAVN/TITTEL	
Bekkenbunnsskader ved graviditet og fødsel undersøkt ved 3 og 4 dimensjonal ultralyd	
3 Finansiering av prosjektet	
☐ Nei x Ja Hvis ja – hvor (NFR, HSØ etc): HSØ og NFR Prosjektnr/kostnadsted: 2799026/ 90002	
4 BESKRIV FORMÅLET MED BEHANDLINGEN/PROSJEKTET[4]	
Formålet er å beskrive de endringene som skjer med bekkenbunnen hos gravide dels i siste halvdel av graviditeten men også etter fødselen. Disse endriger ønsker vi å sette op mot fødselsforløp og mulige tiltak under fødselen. Vi vil studere om de anatomiske forhold i bekkenbunnen kan være prediktive for fødselsforløpet og for mulige skader. Vi ønsker derved å opnå å bli bedre til å forebygge skader ved fødselen.	

5 AVKLARING FOR KONSESJON ELLER MELDING[5]

a) Kobling

x Ja, det benyttes kobling mot forskriftsregulerte registre, som for eksempel fødselsregister, kreftregister eller dødsårsaksregister, eller interne konsesjonsbelagte registre.
Hvis **ja**, beskriv hvilke registre: DIPS og PARTUS

b) Store datasett

Angi totalt antall inkluderte: 200

☐ Ja, studien inkluderer et stort omfang av personer og/eller data – dvs mer enn 5000 og/eller opplysninger av svært inngripende karakter.

c) Varighet

Angi antall år opplysningene vil bli lagret, inkludert oppbevaring for etterprøving[6]: 50

6 RETTSLIG GRUNNLAG FOR BEHANDLING AV PERSONOPPLYSNINGENE[7]

6.1 Samtykke

Skal det innhentes skriftlig samtykke fra den registrerte?	x Ja	☐ Nei
Skal det innhentes skriftlig samtykke fra andre enn den registrerte?	☐ Ja	x Nei
Skal det søkes Helsedirektoratet om unntak fra taushetsplikten?	☐ Ja	x Nei

ELLER

6.2 Intern kvalitetssikring av pasientbehandling.[8]

☐ Ja, prosjektet oppfyller helsepersonelloven § 26. Opplysningene må være slettet eller anonymisert før eventuell publisering av resultater. Må publiseres som kvalitetssikring, ikke som forskning. Det kreves ikke samtykke (ref. punkt 5.1). Personopplysningsloven § 33 4. ledd gir unntak for konsesjon, men krever melding. Det er ikke krav til samtykke, men pasienter som har reservert seg mot slik bruk av opplysningene skal respekteres.

ELLER

6.3 Annet som hjemler melding, angi årsak/hjemmel:

6.4 Andre tillatelser

X Fremleggingsplikt for De regionale komiteer for medisinsk forskningsetikk[9]

☐ Søknadsplikt til Statens legemiddelverk

☐ Bioteknologiloven kommer til anvendelse (det utføres genetiske undersøkelser hvor deltakeren gis tilbakemelding om resultatet)[10]

7 PROSJEKTPERIODE

Studiestart (dd.mm.åååå):	Studieslutt(dd.mm.åååå)[11]:	Sletting/anonymisering av data (dd.mm.åååå) 01092059
01092009	31122015	Beskriv hvordan data vil bli slettet/anonymisert: HØKH vil stå ansvarlig for sletting av Data. Projektansvarlig vil bli kontaktet før sletting av data.

8 HUMANT, BIOLOGISK MATERIALE

Medfører prosjektet bruk av humant, biologisk materiale som tas kun for denne studien eller fra en diagnostisk biobank? ☐ Ja x Nei

Dersom ja:

,

Opprettes forskningsbiobanken fra en eksisterende biobank? ☐ Ja ☐ Nei

Hvis ja, navn på biobank: Biobankregisternr.:

Opprettes forskningbiobanken som en ny biobank ? ☐ Ja ☐ Nei

Ansvarshavende person for biobanken (Biobankloven §7)[12]:

Forskningsbiobankens navn:

Forskningsbiobankens innhold (vev, blod og lignende):

Skal biologisk materiale til forskning utleveres fra Ahus til en ekstern biobankansvarlig institusjon

Dersom ja: Kontakt biobankkoordinator

Ved avsluttet prosjekt:

Hva skjer med biobankmaterialet?: ☐ Materialet destrueres ☐ Materialet føres tilbake til eksisterende biobank Annet:

Hva skjer med forskningsdata utledet av biobankmaterialet?:

9 DETALJER OM PROSJEKTETS INFORMASJONSBEHANDLING

9.1 Type personopplysninger behandlingen skal omfatte:

9.1.1 Ikke-sensitive personopplysninger

Identifikasjonsopplysninger
- X Navn, adresse, fødselsdato
- X Fødselsnummer (11 siffer)
- ☐ Fingeravtrykk, iris
- ☐ Annet:

Opplysninger om tredjepersoner
- ☐ Navn, adresse, fødselsdato
- ☐ Fødselsnummer (11 siffer)
- ☐ Annet:

9.1.2 Sensitive personopplysninger (jf. personopplysningsloven § 2 nr. 8)

Prosjektet omfatter opplysninger om
- x rasemessig eller etnisk bakgrunn, eller politisk, filosofisk eller religiøs oppfatning
- ☐ at en person har vært mistenkt, siktet, tiltalt eller dømt for en straffbar handling
- X helseforhold
- X seksuelle forhold

Presiser nærmere:

Rasemessig bakgrunn vil bli registrert, da dette kan ha betydning for elastisitet i bekkenleddene og bekkenbunnen og for organmobilitet i bekkenet.

Helseopplysninger vil omfatte: Sosial status, utdanning, inntekt, type yrke og grad av belastning i yrke, røykeadferd, fysisk aktivitetsnivå, BMI, gynekologiskt status inkludert gradering av prolaps (POPQ), ultralyd data av bekkenbunnsmorfologi, styrkemåling av bekkenbunnmuskultatur, subjektive symptomer fra ulike validerte spørreskjema på dysfunksjon i bekkebunnen. I tillegg vil relevante journaldata fra DIPS/PARTUS bli innhentet (f.eks. lengde på fødselsforløp, barnets hodeomkrets, eventuell instrumentell fødsel, skade i bekkenbunnen). Eksklusjonskriterier i studien er prematur fødsel (< 32 uker), alvorlig sykdom hos mor eller barn. Disse opplysningene innhentes også fra DIPS / PARTUS ved Ahus.

Seksuelle forhold: Dysfunksjon i bekkenbunnen (for eksempel inkoninens og prolaps) som følge av graviditet og fødsel kan få følger for seksualfunksjon. Standardiserte internasjonale spørreskjema vil bli benyttet for å innhente opplysninger om dette.

9.2 Utvalg

Behandlingen omfatter opplysninger om (beskriv også eventuell kontrollgruppe):

☐ Ansatte i egen virksomhet ☐ Elever/studenter/ barnehagebarn ☐ Pasienter ☐ Tilfeldig utvalgte

☐ Adgangskontrollerte ☐ Medlemmer ☐ Kunder/klienter/brukere X Seleksjonsutvalgte

☐ Friske frivillige Dersom det skal gis godtgjørelse, beskriv nærmere:

Inkluderer utvalget personer med begrenset samtykkekompetanse, eks mindreårige, demente eller annet? ☐ Ja x Nei

Dersom **ja**, forklar:

9.3 Innsamling av opplysningene

Hvordan samles personopplysningene inn?

X Manuelt x Elektronisk (bilde og tekst) ☐ Videoopptak ☐ Lydopptak ☐ Annet (beskriv hvordan):

Hvor innhentes personopplysningene fra? X Fra den registrerte selv x Annet (beskriv hvor fra): DIPS og PARTUS

Hvis uttrekk av forskningsdata, hvem er ansvarlig for uttrekk og anonymisering/avidentifisering av data:

X HØKH ☐ SEIM x Andre – oppgi hvem: Projektkoordinator, jordmor Tone Breines Simonsen

9.4 Utlevering av opplysningene

Blir personopplysningene gjort tilgjengelige/utlevert til andre? ☐ Ja x Nei

Dersom **ja**, oppgi mottakeres navn og adresse, samt hvilken rolle mottakeren har i prosjektet:

Dersom mottaker skal være databehandler må det inngås databehandleravtale.
Er det inngått slik avtale? Dersom **ja**, legg ved avtale. ☐ Ja ☐ Nei

Hva blir overført?

☐ Informasjon med navn, personnummer eller annet som entydig angir det enkelte individ

☐ Anonymisert informasjon

☐ Avidentifisert informasjon. Forklar i så fall hvordan kryssreferanseliste beskyttes dersom dette ikke er likt som i pkt 8.6:

Hvordan oversendes informasjonen?

☐ Personlig overlevering

☐ CD sendt med rekommandert post

☐ Registreres på sikret web-side hos mottaker

☐ Legges ut på sikret område for nedlasting av mottaker

☐ Annet. Nærmere beskrivelse:

9.5 Lagring og behandling av opplysninger

Hvordan lagres opplysningene?

X Elektronisk:

- X Egen forskningsserver ved Ahus
- X Lokal PC
- ☐ Annen virksomhet – oppgi hvem
- ☐ Forskningsserver ved UiO
- ☐ Annet[13]. Angi navn på server:

x På papir. Forklar hvordan dette sikres mot uvedkommende: I låst skab på Tone Breines Simonsen sit kontor

☐ På video, tape eller annet opptak. Beskriv hvordan dette er sikret og om personen kan identifiseres:

☐ Annet. Forklar:

9.6 Gjenfinning av opplysningene

Hvordan gjenfinnes opplysningene? (Bruk av direkte identifisering som personnummer og navn skal forsøkes unngått)

☐ Opplysningene lagres med navn, personnummer eller annet som entydig angir det enkelte individ

X Opplysningene lagres avidentifisert (ved bruk av krysslister, kodelister, løpenummer eller lignende)

Hvordan er krysslister/kodelister beskyttet/lagret? Forklar: Kun autorisert personell knyttet til prosjektet (Tone Breines Simonsen) har adgang til navneliste med kodenøkkel som gjør det mulig å finne tilbake til deltagere i prosjektet. Liste med navn, adresse, personnummer og mobilnummer,samt løpenummer i studien oppbevares elektronisk på HØKH sitt forskernett. Samtykke-erklæringene inkl. ark med personopplysninger oppbevares i låst skap på Tone sitt kontor

10 DATO FOR UTFYLLING

Meldeskjemaet er forelagt divisjonsdir/ klinikk-/ forskningsansvarlig x Ja

Sted og dato	**Utfylt av:**
Akershus Universitetets Sykehus, 24.09.09	Jette Stær-Jensen

11 BEHANDLING AV PERSONVERNOMBUD	
Skal det sendes søknad om konsesjon til Datatilsynet?	
Ja, det må sendes søknad om konsesjon til Datatilsynet. Jfr POL §33) ☐	
Nei, ikke nødvendig – oppgi begrunnelse: ☒ PROSJEKT GODKJENT AV REK.	
Sted og dato: AHUS 28.09.09	Navn personvernombud:

12 GODKJENNING FOR OPPRETTELSE AV REGISTER/PROSJEKT (fylles ut av direktør ved Forskningssenteret)	
Anmodning om opprettelse av forskningsregister er:	
Godkjent (skjema sendes personvernombud) ☒	
Avslått (skjema returneres avsender) ☐	
Sted og dato: Nordbyhagen 300909	Navn forskningsdirektør:

Aktuelle rutiner og retningslinjer for Forskning ved Ahus er tilgjengelig via EQS – Forskning og utvikling.

Merknader

[1] Tilpasset fra Datatilsynets meldeskjema

[2] Prosjektleder er ansvarlig for at studien formaliseres i henhold til gjeldende lovbestemmelser. Hvis prosjektleder ikke er ansatt ved Akershus universitetssykehus HF (Ahus) må det oppgis navn på den Ahus-ansatte som er ansvarlig for at studien formaliseres korrekt.

[3] For alle studier som startes i regi av Ahus og som bruker pasientdata som utgår fra Ahus vil normalt databehandlingsansvarlig være Forskingsdirektør ved Ahus. Hvis det foretas en utlevering av data til ekstern institusjon, skal navnet på denne virksomheten skrives her.

[4] Behovet for konsesjon/melding er knyttet opp til hvilket formål man har med behandlingen av personopplysningene. Pasientjournalsystemet er meldt i sin helhet, og har lovhjemlet formål. Når informasjon i journalsystemet skal benyttes til andre formål må konsesjon eller alternativt ny melding vurderes og man må angi formålet med den nye bruken/behandlingen av personopplysningene. Formulering av formålet er derfor viktig. Tilsvarende gjelder for annen innsamling og behandling av pasient-/personopplysninger. Formålet må samsvare med det som beskrives i samtykket fra hver enkelt person som deltar i studien.

[5] Ett av de tre hovedpunktene under må være oppfylt for at studien skal være meldepliktig, og unntatt fra konsesjon:

1. Prosjektet er omfattet av personopplysningsforskriften §7-27. (Punkt a må være oppfylt, samt enten b eller c)
   a) Prosjektet er tilrådd av personvernombud. For prosjekter med medisinsk eller helsefaglig forskning skal prosjektet i tillegg være godkjent av REK.
   b) Ikke stort omfang, men lang varighet og identifiserbart, eller
   c) store datasett og tilfredsstillende avidentifisert eller pseudonymisert.
2. Prosjektet/behandlingen har hjemmel i lov og utføres i regi av organ i stat eller kommune (eks. kvalitetssikring etter helsepersonellovens § 26) – se personopplysningsloven § 33, fjerde ledd.
3. Prosjektet er regulert i forskrift som spesielt angir at det er unntatt fra konsesjonsplikt eller underlag meldeplikt (f.eks. de sentrale helseregisterforskriftene)

Frafallsanalyser (analyser av fordelinger over utdanning, inntekt og ytelser m.m. blant fremmøtte og ikke-fremmøtte for å beregne betydningen av frafallet) er også unntatt dersom de er basert på samtykke.

[6] Data skal lagres i en viss tid etter at prosjektet er ferdigstilt (analyse er gjennomført) for mulig etterprøving. I forskningsstudier skal data lagres 5 år (Norsk Lægemiddelforening) etter publisering, og for klinisk utprøving skal data lagres i minst 15 år etter innsendt sluttrapport til SLV. Enkelte større tidsskrifter krever 10 års oppbevaring for etterprøving. Data kan ikke oppbevares etter prosjektslutt for kvalitetssikring. Dersom forskningsprosjektet er finansiert av Norges forskningsråd, skal sluttrapport og prosjektdata arkiveres på betryggende måte i minimum 10 år etter avslutning av prosjektet (se punkt 5.3 i Norges forskningsråds generelle kontraktsvilkår).

[7] Som hovedregel skal skriftlig informert samtykke innhentes.

[8] Kvalitetssikring er intern kvalitetskontroll av diagnostiske og behandlingsmessige metoder som har som formål å forbedre diagnostiseringen og behandlingen av pasientene ved sykehuset.

[9] Samtlige biomedisinske forskningsprosjekter hvor det inngår forsøk på mennesker, og som ikke er av en slik art at det regnes som en del av vanlig etablert behandlingsprosedyre. Det gjelder både terapeutisk og ikke-terapeutisk forskning på pasienter og friske forsøkspersoner. Det skal foreligge en hypotese og en protokoll.

[10] Når det skal gis tilbakemelding om genetiske resultater skal deltagerne informeres før, under og etter det utføres genetiske analyser. Det er ikke aktuelt å gi tilbakemelding til barn.

[11] Når prosjektet er ferdigstilt. Dette inkluderer innsamling, analyse/vurdering, artikkelskriving/konklusjon.
[12] Hver biobank skal ha en ansvarshavende person med medisinsk eller biologisk utdannelse av høyere grad. Dette vil normalt være klinikksjef eller prosjektleder .
[13] Krever gjennomføring og godkjenning av risikovurdering

Appendix 2

Paper III

Letters of approval

Regional Committees for Medical Research Ethics

Data Protect Officer

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Professor dr.scient Kari Bø
Norges idrettshøgskole
Postboks 4014 Ullevål Stadion
0806 Oslo

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst A (REK Sør-Øst A)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 84 46 66
Telefaks: 22 85 05 90
E-post: jorgen.hardang@medisin.uio.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 29.09.09
Deres ref.:
Vår ref.: 2009/289a

2009/289a Effekt av bekkenbunnstrening etter fødsel

Vi viser til epost av 24.09.2009 vedlagt revidert informasjonsskriv samt epost av 28.09.2009 fra Gunnvor Hilde vedlagt svar på komiteens merknader.

Komiteen har ingen merknader til revidert informasjonsskriv.

Komiteen tar til orientering at vilkår for godkjenning er oppfylt

Med vennlig hilsen

Gunnar Nicolaysen (sign)
Professor
Leder

Jørgen Hardang
Komitésekretær

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Professor dr.scient Kari Bø
Norges idrettshøgskole
Postboks 4014 Ullevål Stadion
0806 Oslo

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst A (REK Sør-Øst A)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 84 46 66
Telefaks: 22 85 05 90
E-post: post@helseforskning.etikkom.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 02.12.09
Deres ref.:
Vår ref.: 2009/289a

2009/289a Effekt av bekkenbunnstrening etter fødsel

Vi viser til viser til innsendte endringer per e-post for ovennevnte studie, mottatt 19.11.2009; samt e-post mottatt 26.11.2009. Vedlagt følger også en forespørsel om deltakelse i forskningsprosjektene.

Prosjektleder er Kari Bø.

Det forutsettes at forskningsansvarlig er Norges idrettshøgskole. Komiteen gjør oppmerksom på at forskningsansvarlig etter helseforskningsloven § 4 er institusjon eller annen juridisk eller fysisk person som har det overordnede ansvaret for forskningsprosjektet, og som har de nødvendige forutsetninger for å kunne oppfylle den forskningsansvarliges plikter etter denne loven.

Endringene innebærer følgende:
Endret intervensjonsvarighet fra 3 til 4 måneder, bruk av tradisjonell treningsdagbok i stedet for bruk av SMS trac, bruk av ICIQ spørreskjema i stedet for bruk av Mouritsen, i tillegg til innføringen av en PAD test.

Komiteen har vurdert endringssøknaden og har ingen forskningsetiske innvendinger mot endringen av prosjektet. Komiteen godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriftens kap. 2, og Helsedirektoratets veileder for "Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren" (http://www.helsedirektoratet.no/samspill/informasjonssikkerhet/norm_for_informasjonssikkerhet_i_helsesektoren_232354).

Tillatelsen gjelder til 01.05.2013. Prosjektet skal sende sluttmelding på eget skjema (se helseforskningsloven § 12) senest et halvt år etter prosjektslutt.

Med vennlig hilsen

Gunnar Nicolaysen (sign.)
Professor
Leder REK sør-øst A

Øyvind Grønnie Olsen
Jurist/rådgiver REK sør-øst
Fungerende komitésekretær

MELDESKJEMA[1] for forskningsstudier, kvalitetssikring og annen aktivitet som medfører behandling av personopplysninger som er melde- eller konsesjonspliktig i henhold til helseregisterloven og personopplysningsloven med forskrifter. Dette gjelder også bruk av biologisk materiale i forskning.

Utfylt skjema lagres på disk og sendes til ellef.mork@ahus.no som vedlegg til e-post sammen med eventuelt informasjonsskriv. Biobank: Ta kontakt med biobankkoordinator Randi Otterstad (epost: Randi.Otterstad@ahus.no).

1 INFORMASJON OM PROSJEKTANSVARLIG OG PROSJEKTLEDER (SØKEREN)

A. PROSJEKTANSVARLIG (div direktør/klinikksjef):

Navn og stilling:	Klinikk/avdeling:
Pål Wiik	Kirurgisk Divisjon
Telefonnummer:	E-postadresse:
67969099	pal.wiik@ahus.no

B. PROSJEKTLEDER[2]

Navn og stilling:	Klinikk/avdeling hvor prosjektet gjennomføres:
Kari Bø, professor, dr. scient, fysioterapeut	Kvinneklinikken
Telefonnummer:	E-postadresse:
23 26 20 09	kari.bo@nih.no

C. MULTISENTERSTUDIE

Er prosjektet en multisenterstudie? ☐ Ja xNei

Dersom **ja**, angi øvrige virksomheter som deltar:

Skal noen av disse også ha kopi av elektronisk database/informasjon som etableres i prosjektet? ☐ Ja ☐ Nei

D. ANNEN DATABEHANDLINGSANSVARLIG ENN AKERSHUS UNIVERSITETSSYKEHUS HF[3]

Er prosjektet organisert fra et legemiddelfirma eller annen ekstern virksomhet? ☐ Ja x Nei

Dersom **ja**, angi virksomhetens navn (Kopi av konsesjonen/godkjenning skal sendes personvernombudet, og prosjektet skal meldes til personvernombudet som meldepliktig prosjekt, dvs skjemaet fylles ut med unntak av punkt 5.4):

Skal den eksterne også ha kodelisten/navnelisten over deltakere? ☐ Ja ☐ Nei

2 PROSJEKTETS NAVN/TITTEL

Effekt av bekkenbunnstrening etter fødsel for kvinner med og uten skade i bekkenbunnsmuskulatur

3 Finansiering av prosjektet

☐ Nei x Ja Hvis ja – hvor (NFR, HSØ etc):

Prosjektnr/kostnadsted: 2799004 / 90005

4 BESKRIV FORMÅLET MED BEHANDLINGEN/PROSJEKTET[4]

Hensikten med denne randomiserte kontrollerte studien er å evaluere effekt av bekkenbunnstrening etter fødsel hos førstegangsfødende med og uten skade i bekkenbunn. Forekomst av inkontinens, underlivsprolaps, styrke og skadetilheling av bekkenbunnsmuskulatur er valgte effektmål.

5 AVKLARING FOR KONSESJON ELLER MELDING[5]

a) Kobling

x Ja, det benyttes kobling mot forskriftsregulerte registre, som for eksempel fødselsregister, kreftregister eller dødsårsaksregister, eller interne konsesjonsbelagte registre.
Hvis **ja**, beskriv hvilke registre: PARTUS, Dips

b) Store datasett

Angi totalt antall inkluderte: 200

☐ Ja, studien inkluderer et stort omfang av personer og/eller data – dvs mer enn 5000 og/eller opplysninger av svært inngripende karakter.

c) Varighet

Angi antall år opplysningene vil bli lagret, inkludert oppbevaring for etterprøving[6]: 50

6 RETTSLIG GRUNNLAG FOR BEHANDLING AV PERSONOPPLYSNINGENE[7]

6.1 Samtykke

Skal det innhentes skriftlig samtykke fra den registrerte?	x Ja	☐ Nei
Skal det innhentes skriftlig samtykke fra andre enn den registrerte?	☐ Ja	x Nei
Skal det søkes Helsedirektoratet om unntak fra taushetsplikten?	☐ Ja	x Nei

ELLER

6.2 Intern kvalitetssikring av pasientbehandling.[8]

☐ Ja, prosjektet oppfyller helsepersonelloven § 26. Opplysningene må være slettet eller anonymisert før eventuell publisering av resultater. Må publiseres som kvalitetssikring, ikke som forskning. Det kreves ikke samtykke (ref. punkt 5.1). Personopplysningsloven § 33 4. ledd gir unntak for konsesjon, men krever melding. Det er ikke krav til samtykke, men pasienter som har reservert seg mot slik bruk av opplysningene skal respekteres.

ELLER

6.3 Annet som hjemler melding, angi årsak/hjemmel:

6.4 Andre tillatelser

x Fremleggingsplikt for De regionale komiteer for medisinsk forskningsetikk[9]

☐ Søknadsplikt til Statens legemiddelverk

☐ Bioteknologiloven kommer til anvendelse (det utføres genetiske undersøkelser hvor deltakeren gis tilbakemelding om resultatet)[10]

7 PROSJEKTPERIODE

Studiestart (dd.mm.åååå):	Studieslutt(dd.mm.åååå)[11]:	Sletting/anonymisering av data (dd.mm.åååå): 01092059
01.09.2009	31.12.2015	Beskriv hvordan data vil bli slettet/anonymisert: HØKH vil stå ansvarlig for sletting av Data. Projektansvarlig vil bli kontaktet før sletting av data.

8 HUMANT, BIOLOGISK MATERIALE

Medfører prosjektet bruk av humant, biologisk materiale som tas kun for denne studien eller fra en diagnostisk biobank? ☐ Ja x Nei

Dersom ja:

,

Opprettes forskningsbiobanken fra en eksisterende biobank? ☐ Ja ☐ Nei

Hvis **ja**, navn på biobank: Biobankregisternr.:

Opprettes forskningbiobanken som en ny biobank ? ☐ Ja ☐ Nei

Ansvarshavende person for biobanken (Biobankloven §7)[12]:

Forskningsbiobankens navn:

Forskningsbiobankens innhold (vev, blod og lignende):

Skal biologisk materiale til forskning utleveres fra Ahus til en ekstern biobankansvarlig institusjon

Dersom ja: Kontakt biobankkoordinator

Ved avsluttet prosjekt:

Hva skjer med biobankmaterialet?: ☐ Materialet destrueres ☐ Materialet føres tilbake til eksisterende biobank Annet:

Hva skjer med forskningsdata utledet av biobankmaterialet?:

9 DETALJER OM PROSJEKTETS INFORMASJONSBEHANDLING

9.1 Type personopplysninger behandlingen skal omfatte:

9.1.1 Ikke-sensitive personopplysninger

Identifikasjonsopplysninger
- xNavn, adresse, fødselsdato
- x Fødselsnummer (11 siffer)
- ☐ Fingeravtrykk, iris
- ☐ Annet:

Opplysninger om tredjepersoner
- ☐ Navn, adresse, fødselsdato
- ☐ Fødselsnummer (11 siffer)
- ☐ Annet:

9.1.2 Sensitive personopplysninger (jf. personopplysningsloven § 2 nr. 8)

Prosjektet omfatter opplysninger om
- x rasemessig eller etnisk bakgrunn, eller politisk, filosofisk eller religiøs oppfatning
- ☐ at en person har vært mistenkt, siktet, tiltalt eller dømt for en straffbar handling
- x helseforhold
- x seksuelle forhold

Presiser nærmere:

Rasemessig bakgrunn vil bli registrert, da dette kan ha betydning for elastisitet i bekkenleddene og bekkenbunnen og for organmobilitet i bekkenet.

Helseopplysninger vil omfatte: Sosial status, utdanning, inntekt, type yrke og grad av belastning i yrke, røykeadferd, fysisk aktivitetsnivå, BMI, gynekologiskt status inkludert gradering av prolaps (POPQ), ultralyd data av bekkenbunnsmorfologi, styrkemåling av bekkenbunnmuskultatur, subjektive symptomer fra ulike validerte spørreskjema på dysfunksjon i bekkebunnen. I tillegg vil relevante journaldata fra DIPS/PARTUS bli innhentet (f.eks. lengde på fødselsforløp, barnets hodeomkrets, eventuell instrumentell fødsel, skade i bekkenbunnen). Eksklusjonskriterier i studien er prematur fødsel (< 32 uker), keisersnitt, alvorlig sykdom hos mor eller barn. Disse opplysningene innhentes også fra DIPS / PARTUS ved Ahus.

Seksuelle forhold: Dysfunksjon i bekkenbunnen (for eksempel inkoninens og prolaps) som følge av graviditet og fødsel kan få følger for seksualfunksjon. Standardiserte internasjonale spørreskjema vil bli benyttet for å innhente opplysninger om dette (ICIQ-Group: http://www.iciq.net/)

9.2 Utvalg

Behandlingen omfatter opplysninger om (beskriv også eventuell kontrollgruppe):

☐ Ansatte i egen virksomhet ☐ Elever/studenter/ barnehagebarn ☐ Pasienter ☐ Tilfeldig utvalgte

☐ Adgangskontrollerte ☐ Medlemmer ☐ Kunder/klienter/brukere x Seleksjonsutvalgte

☐ Friske frivillige Dersom det skal gis godtgjørelse, beskriv nærmere:

Inkluderer utvalget personer med begrenset samtykkekompetanse, eks mindreårige, demente eller annet? ☐ Ja x Nei

Dersom **ja**, forklar:

9.3 Innsamling av opplysningene

Hvordan samles personopplysningene inn?

x Manuelt x Elektronisk (bilde og tekst) ☐ Videoopptak ☐ Lydopptak ☐ Annet (beskriv hvordan):

Hvor innhentes personopplysningene fra? x Fra den registrerte selv x Annet (beskriv hvor fra): DIPS og PARTUS

Hvis uttrekk av forskningsdata, hvem er ansvarlig for uttrekk og anonymisering/avidentifisering av data:

xHØKH ☐ SEIM x Andre – oppgi hvem: Prosjektkoordinator Tone Breines Simonsen, jordmor, prosketkoordinator

9.4 Utlevering av opplysningene

Blir personopplysningene gjort tilgjengelige/utlevert til andre? ☐ Ja x Nei

Dersom **ja**, oppgi mottakeres navn og adresse, samt hvilken rolle mottakeren har i prosjektet:

Mottaker:

Dersom mottaker skal være databehandler må det inngås databehandleravtale.
Er det inngått slik avtale? Dersom **ja**, legg ved avtale. ☐ Ja ☐ Nei

Hva blir overført?

☐ Informasjon med navn, personnummer eller annet som entydig angir det enkelte individ

☐ Anonymisert informasjon

☐ Avidentifisert informasjon. Forklar i så fall hvordan kryssreferanseliste beskyttes dersom dette ikke er likt som i pkt 8.6:

Hvordan oversendes informasjonen? –

☐ Personlig overlevering

☐ CD sendt med rekommandert post

☐ Registreres på sikret web-side hos mottaker

☐ Legges ut på sikret område for nedlasting av mottaker

☐ Annet. Nærmere beskrivelse:

9.5 Lagring og behandling av opplysninger

Hvordan lagres opplysningene?

x Elektronisk:

- x Egen forskningsserver ved Ahus
- x Lokal PC
- ☐ Annen virksomhet – oppgi hvem
- ☐ Forskningsserver ved UiO
- ☐ Annet[13]. Angi navn på server:

x På papir. Forklar hvordan dette sikres mot uvedkommende: I låst skap (Tone Breines Simonsen sitt kontor?)

☐ På video, tape eller annet opptak. Beskriv hvordan dette er sikret og om personen kan identifiseres:

☐ Annet. Forklar:

9.6 Gjenfinning av opplysningene

Hvordan gjenfinnes opplysningene? (Bruk av direkte identifisering som personnummer og navn skal forsøkes unngått)

☐ Opplysningene lagres med navn, personnummer eller annet som entydig angir det enkelte individ

x Opplysningene lagres avidentifisert (ved bruk av krysslister, kodelister, løpenummer eller lignende)

Hvordan er krysslister/kodelister beskyttet/lagret? Kun autorisert personell knyttet til prosjektet (Tone Breines Simonsen) har adgang til navneliste med kodenøkkel som gjør det mulig å finne tilbake til deltagere i prosjektet. Liste med navn, adresse, personnummer og mobilnummer,samt løpenummer i studien oppbevares elektronisk på HØKH sitt forskernett. Samtykke-erklæringene inkl. ark med personopplysninger oppbevares i låst skap på Tone sitt kontor.

10 DATO FOR UTFYLLING

Meldeskjemaet er forelagt divisjonsdir/ klinikk-/ forskningsansvarlig x Ja

Sted og dato	**Utfylt av:**
Akershus Universitetssykehus, 24.09.09	Gunvor Hilde

11 BEHANDLING AV PERSONVERNOMBUD	
Skal det sendes søknad om konsesjon til Datatilsynet?	
Ja, det må sendes søknad om konsesjon til Datatilsynet. Jfr POL §33) ☐	
Nei, ikke nødvendig – oppgi begrunnelse: ☐ X **Med hjemmel i personopplysningsforskr § 7-12 og helseregisterloven § 36 har Datatilsynet ved oppnevning av personvernombud ved Ahus fritatt sykehuset for meldeplikten.**	
Sted og dato 20.11.2009	**Navn personvernombud:**
12 GODKJENNING FOR OPPRETTELSE AV REGISTER/PROSJEKT (fylles ut av direktør ved Forskningssenteret)	
Anmodning om opprettelse av forskningsregister er:	
Godkjent (skjema sendes personvernombud) ☒	
Avslått (skjema returneres avsender) ☐	
Sted og dato 23/09	**Navn forskningsdirektør:**

Aktuelle rutiner og retningslinjer for Forskning ved Ahus er tilgjengelig via EQS – Forskning og utvikling.

Merknader

[1] Tilpasset fra Datatilsynets meldeskjema

[2] Prosjektleder er ansvarlig for at studien formaliseres i henhold til gjeldende lovbestemmelser. Hvis prosjektleder ikke er ansatt ved Akershus universitetssykehus HF (Ahus) må det oppgis navn på den Ahus-ansatte som er ansvarlig for at studien formaliseres korrekt.

[3] For alle studier som startes i regi av Ahus og som bruker pasientdata som utgår fra Ahus vil normalt databehandlingsansvarlig være Forskingsdirektør ved Ahus. Hvis det foretas en utlevering av data til ekstern institusjon, skal navnet på denne virksomheten skrives her.

[4] Behovet for konsesjon/melding er knyttet opp til hvilket formål man har med behandlingen av personopplysningene. Pasientjournalsystemet er meldt i sin helhet, og har lovhjemlet formål. Når informasjon i journalsystemet skal benyttes til andre formål må konsesjon eller alternativt ny melding vurderes og man må angi formålet med den nye bruken/behandlingen av personopplysningene. Formulering av formålet er derfor viktig. Tilsvarende gjelder for annen innsamling og behandling av pasient-/personopplysninger. Formålet må samsvare med det som beskrives i samtykket fra hver enkelt person som deltar i studien.

[5] Ett av de tre hovedpunktene under må være oppfylt for at studien skal være meldepliktig, og unntatt fra konsesjon:

1. Prosjektet er omfattet av personopplysningsforskriften §7-27. (Punkt a må være oppfylt, samt enten b eller c)
   a) Prosjektet er tilrådd av personvernombud. For prosjekter med medisinsk eller helsefaglig forskning skal prosjektet i tillegg være godkjent av REK.
   b) Ikke stort omfang, men lang varighet og identifiserbart, eller
   c) store datasett og tilfredsstillende avidentifisert eller pseudonymisert.
2. Prosjektet/behandlingen har hjemmel i lov og utføres i regi av organ i stat eller kommune (eks. kvalitetssikring etter helsepersonellovens § 26) – se personopplysningsloven § 33, fjerde ledd.
3. Prosjektet er regulert i forskrift som spesielt angir at det er unntatt fra konsesjonsplikt eller underlag meldeplikt (f.eks. de sentrale helseregisterforskriftene)

Frafallsanalyser (analyser av fordelinger over utdanning, inntekt og ytelser m.m. blant fremmøtte og ikke-fremmøtte for å beregne betydningen av frafallet) er også unntatt dersom de er basert på samtykke.

[6] Data skal lagres i en viss tid etter at prosjektet er ferdigstilt (analyse er gjennomført) for mulig etterprøving. I forskningsstudier skal data lagres 5 år (Norsk Lægemiddelforening) etter publisering, og for klinisk utprøving skal data lagres i minst 15 år etter innsendt sluttrapport til SLV. Enkelte større tidsskrifter krever 10 års oppbevaring for etterprøving. Data kan ikke oppbevares etter prosjektslutt for kvalitetssikring. Dersom forskningsprosjektet er finansiert av Norges forskningsråd, skal sluttrapport og prosjektdata arkiveres på betryggende måte i minimum 10 år etter avslutning av prosjektet (se punkt 5.3 i Norges forskningsråds generelle kontraktsvilkår).

[7] Som hovedregel skal skriftlig informert samtykke innhentes.

[8] Kvalitetssikring er intern kvalitetskontroll av diagnostiske og behandlingsmessige metoder som har som formål å forbedre diagnostiseringen og behandlingen av pasientene ved sykehuset.

[9] Samtlige biomedisinske forskningsprosjekter hvor det inngår forsøk på mennesker, og som ikke er av en slik art at det regnes som en del av vanlig etablert behandlingsprosedyre. Det gjelder både terapeutisk og ikke-terapeutisk forskning på pasienter og friske forsøkspersoner. Det skal foreligge en hypotese og en protokoll.

Appendix 3

Paper I-III

Study information and consent form

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTENE:

Kartlegging av hvordan bekkenbunnen påvirkes av graviditet og fødsel ved hjelp av ultralyd
&
Effekt av bekkebunnstrening etter fødsel

Bakgrunn og hensikt
Dette er et spørsmål om du som er førstegangsfødende vil delta i forskningsprosjekter for å kartlegge endringer i bekkenbunnen under graviditet, fødsel og barseltid, og videre undersøke effekt av bekkenbunnstrening etter fødsel.

Svangerskap og fødsel er først og fremst forbundet med positive forventninger og glede, men utgjør også risiko for skader i bekkenbunnen. Man vet at fødselen påvirker bekkenbunnen, men nyere undersøkelser kan tyde på at en del av forandringene også skjer i løpet av graviditeten. Ved bruk av ultralyd og måling av styrke kan man kartlegge endringer i bekkenbunnen som følge av mekanisk belasting og hormonell påvirkning. Skader i bekkenbunnen kan føre til urinlekkasje, avføringslekkasje, smerter og underlivsprolaps (fremfall/nedsynking av underlivet). Heldigvis går flesteparten av disse skadene over av seg selv, men det antas at bekkenbunnstrening kan forebygge og behandle dette ytterligere. Hensikten med studiene er:

Kartleggingsstudien: Kartlegge endringer i bekkenbunnen for å kunne forebygge og behandle skader i forbindelse med svangerskap og fødsel
Treningsstudien: Undersøke om bekkenbunnstrening kan gi bedre skadetilheling, forebygge og behandle urinlekkasje, avføringslekkasje og underlivsprolaps.

I forbindelse med rutinemessig ultralydundersøkelse i uke 18-20 vil vi spørre om du vil delta i disse studiene. Du kan velge å delta i en eller begge. Dersom du vil delta, blir du bedt om å fylle ut et spørreskjema. Dette tar ca 20 minutter.

Hva innebærer kartleggingsstudien: Vi ønsker å inkludere 200 førstegangsfødende kvinner. Første undersøkelse foregår i graviditetsuke 20-22 med oppfølgningsundersøkelser i graviditetsuke 37, 6 uker, 6 og 12 mnd etter fødsel. Undersøkelsene foregår ved gynekologisk poliklinikk på Ahus og tar ca 1 t. Du blir instruert i riktig bekkenbunnssammentrekning av fysioterapeut, som undersøker om du gjør dette riktig ved å kjenne i ytre del av skjeden. Muskelstyrke i bekkenbunnen måles ved vaginal trykkmåling.
Deretter vil gynekologen foreta en ultralydundersøkelse av bekkenbunnen der ultralydapparatet tas utvendig mot underlivet. I tillegg foretas en gynekologisk undersøkelse.

Hva innebærer treningsstudien: 200 førstegangsfødende som har født vaginalt med og uten skader i bekkenbunnen vil bli spurt om å delta. Du blir ved loddtrekning trukket ut til å være med i enten en treningsgruppe eller en kontrollgruppe. Studien innebærer de samme undersøkelsene som i kartleggingsstudien. I tillegg inngår en stresstest for urinlekkasje (PAD test). Blir du trukket ut til treningsgruppen vil du få veiledet trening i gruppe hos fysioterapeut 1 gang i uken og ellers gjennomføre daglig egentrening. Hjemmetreningen tar ca 15 min. Treningen starter 6-8 uker etter fødsel og varer i 4 måneder. Registrering av hjemmetreningen gjøres via treningsdagbok. De som kommer i kontrollgruppen vil få samme oppfølging som barselkvinner får i dag, dvs. skriftlig informasjon om bekkenbunnstrening. Gynekolog og fysioterapeut ved Ahus skal ikke vite om du er med i trenings- eller kontrollgruppen.

Mulige fordeler og ulemper: Som deltager i disse studiene vil du få en grundigere undersøkelse av bekkenbunnen og eventuelle skader enn det som er vanlig i dag. Hvis ønskelig kan du få utført rutinekontrollene i graviditetsuke 37 og 6 uker etter fødsel ved Ahus i stedet for hos jordmor / fastlege. Helsepersonell med spesialkompetanse innen kvinnehelse foretar undersøkelsene og svarer på eventuelle spørsmål. Alle vil bli instruert i riktig bekkenbunnsammentrekning. De undersøkelsene som inngår i studiene er ikke forbundet med risiko for skade eller bivirkninger hverken hos deg eller det ufødte barnet. Som deltager må du møte til flere undersøkelser enn det som er vanlig, og treningsgruppen må investere noe mer tid til trening.

Hva skjer med informasjonen om deg: Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studiene. Behandlere og undersøkere har taushetsplikt. Alle opplysningene vil bli oppbevart avidentifisert og behandles uten navn, fødselsnummer eller andre direkte gjenkjennende opplysninger. Kun autorisert personell knyttet til prosjektet har adgang til navneliste med kodenøkkel som gjør det mulig å finne tilbake til deg. Det vil ikke være mulig å identifisere deg når studienes resultater publiseres.

I tillegg til data fra undersøkelsene hos gynekolog, fysioterapeut og spørreskjema vil vi innhente relevante journaldata (f.eks. lengde på fødselsforløp, eventuell instrumentell fødsel, barnets hodeomkrets).

Sier du ja til å delta i studiene, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har rett til å få korrigert eventuelle feil. Når studiene er avsluttet vil opplysningene bli oppbevart i en avidentifisert database i 50 år for videre oppfølgning dersom du gir tillatelse til dette. Opplysningene kan kun hentes ut hvis det blir aktuelt med en oppfølgningsstudie, i så fall vil du få en ny henvendelse om samtykke til dette.

Frivillig deltakelse: Dersom du ønsker å delta, undertegner du samtykkeerklæring (siste 2 sider). Du kan når som helst og uten å oppgi noen grunn trekke deg fra studiene. Dette vil ikke få konsekvenser for din videre behandling. Ønske du å trekke deg kontakter du Tone Breines Simonsen, jordmor ved Ahus og koordinator for studiene Kontor: 67 96 85 16, mobil: 900 68 626, e-post: tosi@ahus.no

Ansvar og finansiering. Studiene gjøres i samarbeid mellom Akershus Universitetssykehus og Norges idrettshøgskole. Studiene finansieres helt av uavhengige forskningsmidler fra Norges Forskningsråd og Helse Sør Øst. Studiene er godkjent av Regional komité for medisinsk forskningsetikk, og meldt til Personvernombudet ved Akershus Universitetssykehus.

Hovedansvarlig for kartleggingsstudien er Marie Ellstrøm Engh, dr.med., førsteamanuensis, overlege ved Kvinneklinikken Ahus. For mer informasjon om denne studien kan du kontakte Jette Stær-Jensen, gynekolog, doktorgradsstudent ved Kvinneklinikken Ahus. Mobil 41 14 00 32, e-post: jett@ahus

Hovedansvarlig for treningsstudien er Kari Bø, dr.scient, fysioterapeut, professor ved Norges idrettshøgskole, seksjon for idrettsmedisin. For mer informasjon om denne studien kan du kontakte Gunvor Hilde, fysioterapeut, doktorgradsstudent ved Norges idrettshøgskole, seksjon for idrettsmedisinske fag. Mobil 41 36 60 45, e-post: gunvor.hilde@nih.no

Marie Ellström Engh
Dr. med, førsteamanuensis, overlege
Kvinneklinikken

Kari Bø
Professor, dr. scient,
fysioterapeut

Jette Stær- Jensen
Doktorgradsstudent
gynekolog

Gunvor Hilde
Doktorgradsstudent,
fysioterapeut

Franziska Richter
Doktorgradsstudent
gynekolog

Akershus universitetssykehus

NORGES IDRETTSHØGSKOLE

Samtykkeerklæring – Kartleggingsstudie

Jeg har mottatt skriftlig og muntlig informasjon og er villig til å delta i studien ” *Kartlegging av hvordan bekkenbunnen påvirkes av graviditet og fødsel ved hjelp av ultralyd”.*

Jeg er innforstått med at undersøkelsesdata oppbevares anonymisert i en database for fremtidig forskning

Navn…… Dato……..

Appendix 4

Paper IV

Letters of approval

Regional Committees for Medical Research Ethics

Data Protect Officer

Study information and consent form

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Jakob Elster	22845530	18.12.2014	2014/1768 REK sør-øst B
			Deres dato:	**Deres referanse:**
			23.09.2014	

Vår referanse må oppgis ved alle henvendelser

Marie Ellström Engh
Akershus universitetssykehus HF

2014/1768 Måling av funksjon i bekkenbunnsmusklene hos kvinner

Forskningsansvarlig: Akershus universitetssykehus HF
Prosjektleder: Marie Ellström Engh

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 26.11.2014. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Det er av stor betydning å ha gode måleinstrumenter til klinisk bruk og ved forskning for å kunne undersøke og identifisere kvinner med bekkenbunnsplager. Vi ønsker å se på overenstemmelse av vaginal trykkmåling mellom testere og ved samme tester ved at to erfarne kvinnelige fysioterapeuter med felles opplæring gjør undersøkelsen etter hverandre på samme dag for så å gjøre en tredje undersøkelse uken etter av samme fysioterapeut. Dette er ikke blitt gjort blant gravide eller førstegangsfødende kvinner og det er kun vurdert styrke, ikke hvilefunksjon eller utholdenhet av muskulaturen. Vi ønsker å rekruttere kvinner i fertil alder over 18 år med og uten barn fra ansatte og pasienter på Akershus Universitetssykehus. Undersøkelsene er standard fysioterapi praksis i Norge og det ikke er rapportert ubehag eller smerte ved undersøkelsen. Kvinnene vil få mulighet til å se resultatene etter avsluttet testing og få tilbakemelding og eventuelle råd og tips om videre oppfølging.

Komiteens vurdering
Prosjektet er en tilleggsstudie til en allerede gjennomført studie (vår ref 2009/170), som har som målsetting å undersøke bekkenbunnsfunksjon og symptomer knyttet til seksuell dysfunksjon i bekkenbunnen hos gravide og hos kvinner etter fødsel. Studien har benyttet et vaginalt måleapparat (manometer) for å måle hviletrykk, styrke og utholdenhet i bekkenbunnsmusklene. Det er dette måleapparatet man nå skal gjøre en reliabilitetsstudie av.

Undersøkelsen innebærer at hvilefunksjon, styrke og utholdenhet i bekkenbunnen måles ved vaginal trykkmåling, et lite ballongkateter som innføres i ytre del av skjeden. Hvilefunksjonen måles uten sammentrekning av bekkenbunnen, styrke som gjennomsnitt av 3 maksimale sammentrekninger og utholdenhet som en maksimal sammentrekning over 10 sekunder.

Komiteen har ingen forskningsetiske innvendinger til at prosjektet gjennomføres.

Komiteen har imidlertid en merknad til informasjonsskrivet. I søknadsskjemaet står det at undersøkelsen kan oppleves ubehagelig for noen, selv om den er mindre invasiv og av mindre omfang enn en gynekologisk

undersøkelse. Komiteen mener at det bør komme tydeligere frem i informasjonsskrivet at undersøkelsen kan være forbundet med ubehag.

Utfra dette setter komiteen følgende vilkår for godkjenning:

- Informasjonsskrivet revideres i henhold til ovenstående merknader. Revidert informasjonsskriv sendes komiteen til orientering.

Vedtak
Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33 under forutsetning av at ovennevnte vilkår oppfylles.

I tillegg til ovennevnte vilkår, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden.

Tillatelsen gjelder til 01.09.2016. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 01.09.2021. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder *"Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren"*.

Sluttmelding og søknad om prosjektendring
Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK. Prosjektet skal sende sluttmelding på eget skjema, se helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Klageadgang
Komiteens vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Komiteens avgjørelse var enstemmig.

Med vennlig hilsen

Geir Olav Hjortland
nestleder REK sør-øst B

Jakob Elster
Seniorrådgiver

Kopi til: *Akershus universitetssykehus HF ved øverste administrative ledelse*

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Hege Holde Andersson	22845514	16.09.2016	2014/1768/REK sør-øst B
			Deres dato:	**Deres referanse:**
			08.09.2016	

Vår referanse må oppgis ved alle henvendelser

Til Marie Ellström Engh
Akershus universitets sykehus

2014/1768 Måling av funksjon i bekkenbunnsmusklene hos kvinner

Forskningsansvarlig: Akershus universitets sykehus
Prosjektleder: Marie Ellström Engh

Vi viser til søknad om prosjektendring datert 08.09.2016 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

De omsøkte endringene er beskrevet i skjema for prosjektendringer og dreier seg om at man ved prosjektstart startet rekruttering av prosjektdeltakere fra Ahus. Denne rekrutteringen gikk sent og det var vanskelig å få nok deltakere. En prosjektmedarbeider kontaktet en fysioterapi kollega ved Vest Helse i Sandvika og fikk der hjelp til rekruttering ved å annonsere på gruppetimer og i behandlingssammenheng med informasjonsskrivet som prosjektet fikk godkjent i første runde. Rekrutteringen var den samme gruppen deltakere, men annen lokasjon. Det ble ikke sendt endringsmelding til REK på dette.

Komiteens vurdering
Komiteen vil innledningsvis bemerke at søknad om endringer i prosjektet skal sendes REK i forkant. Det påligger prosjektleder og forskningsansvarlig å påse at prosjektet gjennomføres i tråd med godkjenning som er gitt. Helseforskningslovens § 6 stiller krav til organiseringen av et medisinsk og helsefaglig forskningsprosjekt; disse kravene inkluderer et krav til internkontroll. Kravene til organisering av forskning, og hvilke plikter prosjektleder og forskningsansvarlig har i så henseende, utdypes i forskrift om organisering av medisinsk og helsefaglig forskning.

Komiteen mener imidlertid det er positivt at prosjektleder selv tar kontakt med REK når feilen oppdages. Etter en helhetlig vurdering har komiteen kommet til at endringsmeldingen kan ettergodkjennes. Komiteen har lagt avgjørende vekt på at det kun er gjort endring i lokasjon og ikke endring i sammensetning av deltakere, inklusjon eller eksklusjon eller selve undersøkelsen. Deltakere er gitt informasjon om prosjektet, de var informert om frivillig deltakelse og om mulighet til å trekke seg ut av prosjektet etter eget ønske.

Vedtak
Komiteen har vurdert endringsmeldingen og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i endringsmeldingen.

Klageadgang
Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. Forvaltningslovens § 28 flg. Eventuell klage sendes til REK Sør-øst. Klagefristen er tre uker fra mottak av dette brevet.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no

Med vennlig hilsen

Grete Dyb
professor, dr. med.
leder REK sør-øst B

Hege Holde Andersson
komitésekretær

Kopi til: *m.e.engh@medisin.uio.no; Akershus universitetssykehus HF ved øverste administrative ledelse: hilde.luras@ahus.no*

Akershus universitetssykehus

Akershus universitetssykehus HF

Postadresse:
Postboks 95
1478 Lørenskog

Sentralbord:
02900

Org.nr:
NO 983 971 636 MVA

www.ahus.no

PERSONVERNOMBUDETS UTTALELSE

Til:	Marie Elstrøm Engh, og Merete Kolberg Tennfjord
Kopi:	Hege Lundring
Fra:	Personvernombudet ved Akershus universitetssykehus
Saksbehandler:	Marianne B Blair
Dato:	9.2. 2015
Offentlighet:	Ikke unntatt offentlighet
Sak:	Personvernombudets uttalelse til innsamling og behandling av personopplysninger
Saksnummer/ Personvernnummer:	15-018

Personvernombudets uttalelse til innsamling og behandling av personopplysninger for forskning i prosjektet " *Måling av funksjon i bekkenbunnsmusklene hos kvinner*

Prosjektbeskrivelse:

Det er av stor betydning å ha gode måleinstrumenter til klinisk bruk og ved forskning for å kunne undersøke og identifisere kvinner med bekkenbunnsplager. Vi ønsker å se på overenstemmelse av vaginal trykkmåling mellom testere og ved samme tester ved at to erfarne kvinnelige fysioterapeuter med felles opplæring gjør undersøkelsen etter hverandre på samme dag for så å gjøre en tredje undersøkelse uken etter av samme fysioterapeut. Dette er ikke blitt gjort blant gravide eller førstegangsfødende kvinner og det er kun vurdert styrke, ikke hvilefunksjon eller utholdenhet av muskulaturen. Vi ønsker å rekruttere kvinner i fertil alder over 18 år med og uten barn fra ansatte og pasienter på Akershus Universitetssykehus. Undersøkelsene er standard fysioterapi praksis i Norge og det ikke er rapportert ubehag eller smerte ved undersøkelsen. Kvinnene vil få mulighet til å se resultatene etter avsluttet testing og få tilbakemelding og eventuelle råd og tips om videre oppfølging.

Viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Det følgende er et formelt svar på meldingen. Forutsetningene nedenfor må være oppfylt før rekruttering av pasienter til studien kan starte.

Personvernombudet har vurdert det til at den planlagte databehandlingen av personopplysninger / helseopplysninger tilfredsstiller de krav som stilles i helse- og personvernlovgivningen. Personvernombudet har ingen innvendinger til at den planlagte databehandlingen av personopplysninger / helseopplysninger kan igangsettes under forutsetning av følgende:

1. Databehandlingsansvarlig er Akershus universitetssykehus HF ved adm. direktør.
2. Avdelingsleder og forskningsansvarlig i divisjonen/klinikken har godkjent gjennomføringen av prosjektet.
3. Behandling av personopplysningene / helseopplysninger i prosjektet skjer i samsvar med og innenfor det formål som er oppgitt i meldingen.

4. Studien er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk (REK), og eventuelle merknader må følges.
5. Vedlagte samtykke benyttes, inklusive markerte tillegg og forslag til endringer fremsatt av personvernombudet.
6. Data lagres som oppgitt i meldingen. Kodeliste som kobler avidentifiserte data med personopplysninger lagres som angitt i meldingen som separat fil på tilgangsstyrt prosjektområde på forskningsserver i sikker sone. Det høstes ikke opplysninger fra pasientjournal eller pasientadministrative systemer, men opplysninger nedtegnes i møte med prosjektdeltakerne og punsjes inn på prosjektområdet. Kontakt datafangstgruppen for opprettelse av prosjektområde på forskningsserver på datafangst@ahus.no
7. Prosjektslutt er 01.09.2016. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 01.09.2021, da skal data slettes eller anonymiseres ved at kodelisten slettes og eventuelle andre identifikasjonsmuligheter i databasen fjernes.
8. Dersom formålet, utvalget av inkluderte eller databehandlingen endres må personvernombudet gis forhåndsinformasjon om dette.

Studien er registrert i sykehusets offentlig tilgjengelig database over forsknings- og kvalitetsstudier.

Lykke til med studien!

Med vennlig hilsen
for Personvernombudet

Marianne B Blair
Personvernombud
Akershus universitetssykehus HF

Epost: personvern@ahus.no
Web: www.ahus.no