Pelvic floor muscle function, vaginal symptoms and symptoms of sexual dysfunction in first time mothers: a cohort and a randomised controlled trial
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Oslo, June 2017
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List of papers

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


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 tieller 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 muskler utholdenhet enn kvinner uten symptomet; gjennomsnittsforskjell 3.6 cmH₂O (95 % KI 0.7, 6.6), 9.0 cmH₂O (95 % KI 2.6, 15.4) og 80.0 cmH₂Osek (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 intervension 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 cmH₂O, for bekkenbunnsstyrke -0.22 ±7.6 cmH₂O og for muskler utholdenhet 0.75 ±59.49 cmH₂Osek (intrarater). Bias og minste reelle endring for vaginalt hviletrykk var 1.36 ±9.0 cmH₂O, for bekkenbunnsstyrke 2.24 ±9.0 cmH₂O og for muskler utholdenhet 15.89 ±69.7 cmH₂Osek (interrater). Camtech AS virker mindre sikkert for de sterkeste kvinnene. En statistisk signifikant forbedring i bekkenbunnsvariabler må overstige den minste reelle forskjell.

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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 \cite{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 \cite{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 \cite{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 \cite{15}.

Pelvic floor muscles

The PFM are regular skeletal muscles \cite{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 \cite{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 \cite{12}. The levator ani muscle consists of three parts: the pubococcygeus, the puborectalis, and the iliococcygeus muscles \cite{19}. The pubococcygeus muscle can further be divided into the puboanal, puboperineal and the pubovaginal muscle \cite{19}. Some authors are in favour of the term puboviseralis for this portion of the muscle \cite{20-22} (Figure 1). Different muscle fibre directions, origins and insertions makes up the subdivisions of the levator ani muscle \cite{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 \cite{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 eitoris\(^{(26-28)}\). 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\(^{(29)}\).

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**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.


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**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\(^{(23,30,31)}\). 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 pubovisceral muscle and the puborectal muscle) that are primarily responsible for this squeeze and lift function.\cite{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.\cite{39} The iliococcygeus muscle acts in a similar manner as the pubovisceral muscle.\cite{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.\cite{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)\cite{35}. During a PFM contraction it has also been shown that mean incremental increase in maximum urethral closure pressure may range from 8\cite{40} to 23.2 (SD 8.4)\cite{41} to 47.3 cmH$_2$O.\cite{42}

A PFM contraction of the levator ani has been found upon clitoral and cervical stimulation.\cite{6} This contraction is thought to be mediated through the vaginolevator reflex.\cite{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.\cite{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.\cite{5} The involuntary contractions has been described as a product of spinal cord reflex mechanisms,\cite{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\cite{6} equivalent to the penile erection, intensifying orgasm. The increased blood flow to the clitoris, vagina and labia leads to engorgement of these organs.\cite{6,29,43}

**Examination of pelvic floor muscle function**

Vaginal resting pressure is the resting condition of the muscle with no voluntary muscle contraction.\cite{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.\cite{14} 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 \[31, 40\].

### 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 \[10\], 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. Poorer intrarater reliability has been found for muscular endurance (dependability indices of 0.10). However, the device is not commercially available and its use is restricted to research purposes.

**Imaging**

MRI is capable of providing anatomical details of the pelvic floor, both normal anatomy and levator trauma, but due to cost, access and contraindications the adoption into clinical practice has been difficult. 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. 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. The method has been tested showing good reliability for assessment of pelvic floor anatomy and function, and for diagnosis of major levator ani muscle defects, and has also shown to be able to quantify squeeze and lift during a PFM contraction and may be used as biofeedback during teaching and training and as an outcome measure after PFMT and rehabilitation.

**Manometer**

In physiotherapy practices, manometer is the most common method of assessing PFM function; vaginal resting pressure, PFM strength and muscular endurance. There is a variety of devices in use, but they all measure squeeze pressure in either mmHg, hPa or cmH₂O. In general, manometer has been established as a reliable assessment method for PFM strength if there is a simultaneous inward movement of the perineum seen by observation and palpation. 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). Due to different manometers being tested with different measurement properties, comparing results across studies are difficult. While good reliability and validity for PFM strength has been concluded using Camtech AS, 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. However, some authors do not acknowledge symptoms of...
sexual dysfunction and pelvic pain as part of PFD \cite{83,84}. Most common in clinical practice and clinically definable conditions are urinary incontinence, anal incontinence and pelvic organ prolapse \cite{83}.

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 \cite{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 \cite{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) \cite{86}.

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**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)


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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. 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. Sexual History Form 12 (SHF-12) is a short version of a 24 item questionnaire. 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. 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. 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 PFD. 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. International Consultation on Incontinence Questionnaire FLUTSsex (ICIQ-FLUTSex) has been established as a reliable, valid and responsive assessment tool to address sexual issues in women with urinary symptoms/incontinence. Questionnaires assessing sexual function and pelvic organ prolapse are that developed by Mouritsen et al., the original long form of the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ) and the validated short form of the PISQ (PISQ-12). 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. 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.
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 [1,108-113], 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% [1,108-111]. 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 [1,114]. 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 [8,116]. Few studies have confirmed this [108], whereas women seven months after delivery reported high pain levels as compared to early pregnancy (p-value <0.01) [118]. 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 [100,106,107], with a risk of underreported numbers [103,107,117].

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. Serati et al 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. Symptoms of sexual dysfunction, however, have found to decrease with increasing age and the aetiology is often more diverse and complex than that of urinary incontinence and pelvic organ prolapse. Further, having one or more PFD, not being in a relationship and having lower education have increased odds of experiencing symptoms of sexual dysfunction, such as dyspareunia. Symptoms of sexual dysfunction may be an end-product of a vicious circle and reveal little about the cause or pathophysiology.

**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. 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. Physiological changes with increases in hiatal dimensions and bladder neck mobility has also been demonstrated by our study group.

A review on female sexual function during pregnancy concluded that sexual function had a significant global decline during pregnancy, particularly in the third trimester. 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. Vaginal discomfort and dryness were significantly higher at the 3rd trimester compared to earlier in pregnancy in another study. 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).
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 [1, 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, with some studies finding an association with mode of delivery/delivery variables [106, 111, 112, 129-131] and others 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 [106, 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 [1]. 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 [1, 127]. Plausible, it may be that breastfeeding also indirectly affect PFM function [1]. 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 [106].

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 [23, 130], Elenskaia et al [148] 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 \([9]\). 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 \([30, 31, 122, 123]\). 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 \[16\].

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 [31, 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 [86].

There is a significant interplay between neural and muscular adaptations during strength and power training [168]. 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 Bo 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 \[4,149\]. 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 spoil 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 \[188\]. 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>
<thead>
<tr>
<th>Author/year</th>
<th>Design</th>
<th>Study population</th>
<th>Intervention period</th>
<th>Dosage</th>
<th>Follow-up</th>
<th>Loss to follow up</th>
<th>Outcome measures</th>
<th>Results</th>
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<td>During pregnancy and after childbirth</td>
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<tr>
<td>Citak et al, 2010</td>
<td>Single blinded RCT</td>
<td>118 primiparous women (mean age 22.6)</td>
<td>4th-7th month postpartum</td>
<td>PFMT: 10 reps increasing to 15 reps daily, 2 sec contraction increasing to 5 and 10 sec Control: no treatment</td>
<td>PFMT: Telephone and meeting with nurse twice in the first month and once in the following months</td>
<td>Total: 43 (36.4%) Training: 21 (17.8%) Control: 22 (18.6%)</td>
<td>FSFI. PFM strength assessed by digital palpation and manometer</td>
<td>Positive effect in favor of training group on arousal, lubrication and orgasm. Improvement in PFM strength</td>
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<td>Wilson and Herbison, 1998</td>
<td>RCT</td>
<td>230 incontinent primi/multi-parous women (mean age 28.4)</td>
<td>3-12 months postpartum</td>
<td>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</td>
<td>PFMT and cones: PT meeting 3, 4, 6 and 9 months after delivery</td>
<td>Total: 85 (36.9%) Intervention: 59 (25.7%) Control: 26 (11.3%)</td>
<td>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</td>
<td>No between group difference</td>
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<td>Study (Year)</td>
<td>Type</td>
<td>Participants</td>
<td>Study Group</td>
<td>Follow Up Program</td>
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<td>Total Improvement</td>
<td>Questionnaire After Delivery</td>
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<tr>
<td>Mørkved et al 2007</td>
<td>Single blind RCT (Abstract)</td>
<td>280 primiparous women with and without UI followed up after 6 years (mean age at inclusion 27.5)</td>
<td>Btw 20th and 36th months of pregnancy for 12 weeks</td>
<td>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 reps x 2 daily</td>
<td>Control: no treatment</td>
<td>PFMT: Weekly group training led by PT</td>
<td>Total: 106 (38%) Postal questionnaire: satisfaction with sex after delivery</td>
<td>Improved satisfaction in favor of training group</td>
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<td>General female population</td>
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<td>Bø et al 2000</td>
<td>RCT</td>
<td>59 women with SUI (mean age 50.7)</td>
<td>6 months</td>
<td>PFMT: 8–12 x 3 daily (near maximum PFM contractions)</td>
<td>Control: no treatment</td>
<td>PFMT: Weekly group training with PT</td>
<td>Total: 4 (6.8%) Training: 4 (6.8%) Control: 0</td>
<td>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</td>
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<tr>
<td>Brækken et al 2014</td>
<td>Partially blinded RCT</td>
<td>109 women with POP (mean age 48.9)</td>
<td>6 months</td>
<td>PFMT: 8–12 x 3 daily (near maximum PFM contractions)</td>
<td>Control: no</td>
<td>PFMT: Individual training weekly/every other week with PT</td>
<td>Total: 2 (1.8%) Training: 1 (0.9%)</td>
<td>POP-specific questionnaire, semi-structured interview, PFM function assessed Improvement in sexual function in favor of training group. Improved PFM strength and</td>
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<td>Study</td>
<td>Design</td>
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<td>Liebergall-Wischnitzer et al, 2012</td>
<td>RCT</td>
<td>187 women with SUI (mean age 46.7)</td>
<td>PFMT: 25 min exercises daily, rapid/prolonged/graded contractions</td>
<td>Control: 1 (0.9%)</td>
<td>by manometer.</td>
<td>endurance, not vaginal resting pressure</td>
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<td>Paula method: 45 min exercises daily</td>
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<td>PFMT: 6 group sessions with PT</td>
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<td>Paula method: Weekly private session with instructor</td>
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<td>PFM strength assessed with perineometer</td>
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<td>Improved sexual function, numbers being sexually active and PFM strength</td>
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<td>increased in favor of the training group.</td>
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<td>Improved PFM strength</td>
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<td>Yang et al 2012</td>
<td>RCT (pilot)</td>
<td>34 women with gynecological cancer (mean age 52.4)</td>
<td>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</td>
<td>Training: 5 (14.7%)</td>
<td>Australian Pelvic floor questionnaire on sexual function.</td>
<td>Improved sexual function, numbers being sexually active and PFM strength increased in favor of the training group. Improved PFM strength</td>
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<td>Biofeedback: 45-min exercise session and a 30-min counseling session per week for 4 weeks led by PT</td>
<td>Control: 5 (14.7%)</td>
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<td>PFM strength assessed with perineometer</td>
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<tr>
<td>Hagen et al 2014</td>
<td>parallel-group, multicenter</td>
<td>477 women with symptomatic POP (mean age 56.8)</td>
<td>PFMT: Individualized: 10 sec maximum hold x 10</td>
<td>PFMT: 5 individualized</td>
<td>6 months: PISQ-12</td>
<td>Sexual scores (interference of prolapse symptoms)</td>
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<td>Treatment Details</td>
<td>Sessions Led By PT</td>
<td>Training:</td>
<td>Control:</td>
<td>12 Months:</td>
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<tr>
<td>Eftekhar et al 2014</td>
<td>RCT</td>
<td>90 women with grade &lt;3 POP (mean age 36.5 years)</td>
<td>8 weeks</td>
<td>Treatment: Vaginal and anal biofeedback, infrared, 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</td>
<td>sessions led by PT</td>
<td>Training: 36 (16%)</td>
<td>Control: 36 (16%)</td>
<td>Training: 75 (33.3%)</td>
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<tr>
<td>Study Authors</td>
<td>Study Type</td>
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<td>Duration</td>
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<td>Control</td>
<td>Total Phase 1</td>
<td>Total Phase 2</td>
<td>Main Outcome Measures</td>
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<tr>
<td>Wiegersma et al 2014</td>
<td>RCT</td>
<td>287 women with symptomatic, mild POP (mean age 64.3 years)</td>
<td>3 months</td>
<td>Treatment: PFMT, myofeedback, electrical stimulation, the knack, lifestyle advice (diet, body weight, toilet habits), FFM relaxation and general relaxation. PFMT: 2-3 times daily, 3-5 x per week.</td>
<td>Control: no treatment.</td>
<td>48 (16.7%)</td>
<td>31 (10.8%)</td>
<td>PISQ 12 (PFM function measured by digital palpation)</td>
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<tr>
<td>Chambless et al 1984</td>
<td>RCT</td>
<td>36 women with orgasmic disorder (mean age 27.4 years)</td>
<td>6 weeks</td>
<td>PFMT: 10 min daily. Placebo: 10 nonsexual images concerning vaginal sensations 10 min daily.</td>
<td>Control: no treatment.</td>
<td>21 (58.3%)</td>
<td>8 (22.2%)</td>
<td>SAI-E (arousal, anxiety, satisfaction), WSQ (orgasmic responsiveness, frequency of orgasm, stimulation) and expectancy due to treatment or assessment only.</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Intervention</td>
<td>Control: 3 (8.3%)</td>
<td>Outcome measures</td>
<td>Results</td>
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<tr>
<td>Trudel and Saint-Laurent 1983</td>
<td>RCT</td>
<td>12 women with orgasmic disorder (mean age not stated)</td>
<td>PFMT: 3 sec contract and 3 sec relax with increasing intensity for 20 min daily&lt;br&gt;Sexual awareness, relaxation, breathing (SARB): different exercises for 20 min daily</td>
<td>Both groups: Home training with weekly phone contact with experimenter</td>
<td>0% SAI, SII, clinical questionnaire (sexual reactions, stimuli needed to reach orgasm)</td>
<td>No effect in main outcome: orgasmic responsivity between groups. Higher scores for SARB group on sexual satisfaction, self-acceptance and perceptual accuracy scale, but no between group differences</td>
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<tr>
<td>Handa et al 2011</td>
<td>RCT</td>
<td>445 women with SUI, mean age 49.8 years</td>
<td>Group 1: continence pessary&lt;br&gt;Group 2: behavioral therapy (pelvic floor muscle training and continence strategies)&lt;br&gt;Group 3: combination therapy</td>
<td>Group 1: pessary fitted and used as desire to decrease UI&lt;br&gt;Group 2 and 3: four visits over 8 weeks + home training with increasing difficulty over time</td>
<td>Total: 100 (22.5%)&lt;br&gt;Personal Experiences Questionnaire (SPEQ) (libido, arousal and dyspareunia)&lt;br&gt;Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire</td>
<td>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</td>
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PFM function measured with palpation 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.

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<td>Allocation Concealment</td>
<td>Baseline Similarity</td>
<td>Blinding</td>
<td>Therapist Administering Treatment</td>
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<td>Statistical Comparison</td>
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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-assessors 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 manometer (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 \([123, 193]\). 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 $\geq$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 $\geq$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
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 \[23,195\].

**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 \cite{197} and was based on the results from a former study \cite{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 \cite{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 \cite{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 \cite{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 \cite{38,199}, a method 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 \cite{78,80}. The atmospheric pressure on the balloon was calibrated to zero cmH\textsubscript{2}O 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\textsubscript{2}O. 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\textsubscript{2}O. Local muscular endurance was defined as a sustained maximum contraction \cite{45}, and was quantified as the area...
under the curve during ten seconds, measured during one attempt and registered as cmH₂Osec  (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.

![Image of manometer](image-url)


**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. & Bo, 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 Bo et al [90]. ICIQ-VS has shown good validity, reliability and is sensitivity to change [96], 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. ICIQ-FLUTSex has been established as a reliable, valid and responsive assessment tool to address sexual issues.

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-S) in a standardized lithotomy position after voiding. 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. 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, described by Dietz et al 2005. 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. 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. The method has shown very good intra- and inter-rater reliability six weeks after childbirth.

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.\(^{116,207}\) 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 papers the level of significance was set to \(\leq 0.05\). 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”.

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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$_2$O (95%CI 0.7, 6.6) for vaginal resting pressure, 9.0 cmH$_2$O (95%CI 2.6, 15.4) for PFM strength and 80.0 cmH$_2$Osec (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>
<thead>
<tr>
<th></th>
<th>No loose or lax</th>
<th>Loose or lax</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVD</td>
<td>80 (68.4%)</td>
<td>37 (31.6%)</td>
<td>117</td>
</tr>
<tr>
<td>IVD</td>
<td>19 (73.1%)</td>
<td>7 (26.9%)</td>
<td>26</td>
</tr>
<tr>
<td>CS</td>
<td>32 (94.1%)</td>
<td>2 (5.9%)</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>131</td>
<td>46</td>
<td>177</td>
</tr>
</tbody>
</table>

Table 3. Distribution of symptom (“vagina feels loose or lax”) with delivery mode.
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). 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. 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.
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 cmH2O, PFM strength -0.22 ±7.6 cmH2O and muscular endurance 0.75 ±59.49 cmH2Osec. Interrater agreement for vaginal resting pressure was: 1.36 ±9.0 cmH2O, for PFM strength 2.24 ±9.0 cmH2O and for muscular endurance 15.89 ±69.7 cmH2Osec.
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 cmH₂O, PFM strength -0.22 ± 7.6 cmH₂O and muscular endurance 0.75 ± 59.49 cmH₂Osec (Intrarater). Interrater agreement for vaginal resting pressure was: 1.36 ± 9.0 cmH₂O, for PFM strength 2.24 ± 9.0 cmH₂O and for muscular endurance 15.89 ± 69.7 cmH₂Osec. 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 Bo 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 [213].

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 [214]. 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 \(^76,78,79\). Bo 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 \(^178\). 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 Bo 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 [219]. 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 [81, 11].

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 [234]. 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 [199, 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 [106, 110, 111] and not finding this association [113, 115, 113].

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. Operative vaginal deliveries has been found to be associated with dyspareunia in large studies on postnatal women. However, conflicting results exists. 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, and others don’t. Since dyspareunia is a symptom it may be an end-product of a complex circle and reveal little about the cause or pathophysiology.

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. 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. A few other studies have been published since then, assessing vaginal symptoms 12 months after delivery. 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 as well as previous reviews have concluded with lack of studies addressing bother in relation to symptoms of sexual dysfunction. Roos et al 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. 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 [6], affecting negatively on vaginal lubrication [6, 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 cmH₂O and 80.0 cmH₂O/sec, respectively). Differences in vaginal resting pressure was however low (3.6 cmH₂O). From clinical experience and previous research [249] 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 [249]. 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\textsuperscript{143, 156-160, 247, 250} and vaginal laxity\textsuperscript{143, 244, 245}. Although diagnosing major levator ani defects has shown good reliability\textsuperscript{72, 73}, we cannot rule out false positives due to haematoma early after birth\textsuperscript{251}. None of the other RCTs in women after delivery\textsuperscript{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\textsubscript{2}O) in favour of the training group\textsuperscript{209}. From the results of Paper IV this is well below the minimal detectable change of 9.0 cmH\textsubscript{2}O for PFM strength. The same training program has been utilized previously demonstrating a change above the minimal detectable change for PFM strength\textsuperscript{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\textsuperscript{195}. This may also explain the lack of findings from the same trial on urinary incontinence\textsuperscript{196} and pelvic organ prolapse\textsuperscript{206}. 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\textsuperscript{253}. A positive effect of PFMT may also influence on psychosocial aspects such as improved self-esteem and self-acceptance, body awareness and satisfaction\textsuperscript{186}. Both Citak et al\textsuperscript{178} and Mørkved et al\textsuperscript{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.

\textbf{Paper I-III}

\textbf{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) [80]. 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: $-2.44 \pm 8.7$ cmH$_2$O, for PFM strength $-0.22 \pm 7.6$ cmH$_2$O and for muscular endurance $0.75 \pm 59.49$ cmH$_2$Osec. Interrater agreement for vaginal resting pressure was found to be: $1.36 \pm 9.0$ cmH$_2$O, for PFM strength $2.24 \pm 9.0$ cmH$_2$O and for muscular endurance $15.89 \pm 69.7$ cmH$_2$Osec. 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.
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Paper I-IV
Paper I
Dyspareunia and pelvic floor muscle function before and during pregnancy and after childbirth

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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

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 under-active [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 post-partum 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 cmH2O. PFM strength was reported as the mean of three maximum voluntary contractions, and registered as cmH2O. 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 cmH2Osec [22]. The atmospheric pressure on the balloon was calibrated to 0 cmH2O 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 (cesarean 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,” “some-what,” 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 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...
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).

**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 1 Background variables of the study population

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

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

BMI body mass index, n.a not applicable

<sup>a</sup>Three missing

### Table 2 Presence and severity of dyspareunia

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

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

Results presented as frequency with percentages (%)

<sup>a</sup>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>
<thead>
<tr>
<th>Table 3</th>
<th>Level of bother of women with dyspareunia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Pre-pregnancy, n=83</td>
<td>3.4 (2.5)</td>
</tr>
<tr>
<td>Gestational week 22, n=87</td>
<td>3.5 (2.3)</td>
</tr>
<tr>
<td>Gestational week 37, n=94</td>
<td>4.0 (2.5)</td>
</tr>
<tr>
<td>6 months postpartum, n=78a</td>
<td>4.5 (2.9)</td>
</tr>
<tr>
<td>12 months postpartum, n=55</td>
<td>5.1 (2.9)</td>
</tr>
</tbody>
</table>

Results presented as mean with standard deviation (SD)

---

*a Three missing

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

<table>
<thead>
<tr>
<th>Total</th>
<th>Gestational week 22</th>
<th>6 months postpartum</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=285</td>
<td>N=175</td>
<td>N=110</td>
</tr>
<tr>
<td>N</td>
<td>VRP (cmH2O)</td>
<td>PFM strength (cmH2O)</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>4.1 (1.13)</td>
<td>33.0 (18.4)</td>
</tr>
<tr>
<td>No-dyspareunia</td>
<td>35.0 (20.9)</td>
<td>36.0 (17.7)</td>
</tr>
<tr>
<td>Mean difference with 95 % CI</td>
<td>3.0 (−1.3, 7.3)</td>
<td>3.0 (−1.5, 7.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total</th>
<th>Gestational week 22</th>
<th>6 months postpartum</th>
</tr>
</thead>
<tbody>
<tr>
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<td>N=175</td>
<td>N=110</td>
</tr>
<tr>
<td>N</td>
<td>VRP (cmH2O)</td>
<td>PFM strength (cmH2O)</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>4.1 (1.13)</td>
<td>33.0 (18.4)</td>
</tr>
<tr>
<td>No-dyspareunia</td>
<td>35.0 (20.9)</td>
<td>36.0 (17.7)</td>
</tr>
<tr>
<td>Mean difference with 95 % CI</td>
<td>3.0 (−1.3, 7.3)</td>
<td>3.0 (−1.5, 7.9)</td>
</tr>
</tbody>
</table>

---

*a Three missing
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

### Table 5

<table>
<thead>
<tr>
<th></th>
<th>Dyspareunia (%)</th>
<th>No dyspareunia (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months postpartum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbers with elective cesarean section</td>
<td>3/78 (3.8)</td>
<td>49/7 (4.1)</td>
<td>1.0</td>
</tr>
<tr>
<td>Numbers with acute cesarean section</td>
<td>16/78 (20.5)</td>
<td>12/78 (12.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>Numbers with operative vaginal delivery (vacuum and forceps)</td>
<td>11/78 (14.1)</td>
<td>13/78 (13.4)</td>
<td>1.0</td>
</tr>
<tr>
<td>Numbers with episiotomy</td>
<td>17/78 (21.8)</td>
<td>29/78 (29.9)</td>
<td>0.4</td>
</tr>
<tr>
<td>Numbers with prolonged second stage (&gt; 120 min)</td>
<td>7/63 (11.1)*</td>
<td>16/80 (20.0)*</td>
<td>0.23</td>
</tr>
<tr>
<td>Numbers with 3rd and 4th degree perineal tears</td>
<td>4/78 (5.1)</td>
<td>1/97 (1.0)</td>
<td>0.25</td>
</tr>
<tr>
<td>Weight of infant</td>
<td>3,526.5 kg</td>
<td>3,476.3 kg</td>
<td>0.54 (95%CI: −209.6, 109.1)</td>
</tr>
<tr>
<td>12 months postpartum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbers with elective cesarean section</td>
<td>2/55 (3.6)</td>
<td>6/111 (5.4)</td>
<td>0.9</td>
</tr>
<tr>
<td>Numbers with acute cesarean section</td>
<td>11/55 (20.0)</td>
<td>13/111 (11.7)</td>
<td>0.23</td>
</tr>
<tr>
<td>Numbers with operative vaginal delivery (vacuum and forceps)</td>
<td>9/55 (16.4)</td>
<td>15/111 (13.5)</td>
<td>0.8</td>
</tr>
<tr>
<td>Numbers with episiotomy</td>
<td>12/55 (21.8)</td>
<td>32/111 (28.8)</td>
<td>0.35</td>
</tr>
<tr>
<td>Numbers with prolonged second stage (&gt; 120 min)</td>
<td>6/44 (13.6)*</td>
<td>14/91 (15.4)*</td>
<td>1.0</td>
</tr>
<tr>
<td>Numbers with 3rd and 4th degree perineal tears</td>
<td>2/55 (3.6)</td>
<td>5/111 (4.5)</td>
<td>1.0</td>
</tr>
<tr>
<td>Weight of infant</td>
<td>3,563.5 kg</td>
<td>3,474.4 kg</td>
<td>0.3 (95%CI: −258.1, 80.0)</td>
</tr>
</tbody>
</table>

*Incomplete information for 32 women at 6 months postpartum, incomplete information for 31 women at 12 months postpartum

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

* Nine missing for gestational week 37, 3 missing for 6 months postpartum.

Pre-preg = pre-pregnancy; GW = gestational week; PP = postpartum

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PFM overactivity has been shown to be unreliable [15]. It was not confirmed by vaginal surface EMG. Palpation of the PFM in women with dyspareunia, but these findings of PFM training on symptoms of dyspareunia [28]. 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 cmH2O 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 cmH2O. 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 examination.
Conflicts of interest

None.

References


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1234

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


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

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*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

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.

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 symptoms.
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 was used because the number in each categori- cal 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. VRP was measured as vaginal pressure, with no voluntary PFM activity, and was registered as cmH2O. PFM strength was reported as the mean of three maximum voluntary contractions, and registered as cmH2O. 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 cmH2Osec [21]. The atmospheric pressure on the balloon was calibrated to 0 cmH2O 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 [pre-labour 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. 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].
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, and with 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
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 cmH2O (95% confidence interval [CI] 0.7, 6.6) for VRP, 9.0 cmH2O (95% CI 2.6, 15.4) for PFM strength, and 80.0 cmH2Osec (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 women with and without symptoms, respectively. $P = 0.02$ reflects the difference between symptomatic and asymptomatic women on caesarean section.

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

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

<table>
<thead>
<tr>
<th></th>
<th>Total study population n = 177</th>
<th>No vaginal symptoms N = 47</th>
<th>Vaginal symptoms N = 130</th>
<th>Vaginal symptoms interfering with sexual life n = 61</th>
<th>No vaginal symptoms vs. vaginal symptoms</th>
<th>No vaginal symptoms vs. vaginal symptoms interfering with sexual life</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>28.7 (SD 4.3)</td>
<td>28.7 (SD 4.7)</td>
<td>28.7 (SD 4.0)</td>
<td>28.8 (SD 3.7)</td>
<td>0.97</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>24.7 (SD 4.3)</td>
<td>25.7 (SD 4.8)</td>
<td>24.4 (SD 4.0)</td>
<td>24.4 (SD 4.2)</td>
<td>0.1</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Civil status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitant</td>
<td>287 (95.7%)</td>
<td>46 (97.9%)</td>
<td>127 (97.7%)</td>
<td>61 (100%)</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Living alone</td>
<td>13 (4.3%)</td>
<td>1 (2.1%)</td>
<td>3 (2.3%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College/university</td>
<td>226 (75.3%)</td>
<td>30 (68.1%)</td>
<td>105 (80.8%)</td>
<td>47 (77.0%)</td>
<td>0.11</td>
<td>0.41</td>
</tr>
<tr>
<td>Primary/high school/other</td>
<td>74 (24.7%)</td>
<td>15 (31.9%)</td>
<td>25 (19.2%)</td>
<td>14 (23.0%)</td>
<td>0.89</td>
<td>0.89</td>
</tr>
<tr>
<td>Smoking</td>
<td>21 (11.9%)</td>
<td>6 (12.8%)</td>
<td>15 (11.3%)</td>
<td>6 (9.8%)</td>
<td>0.89</td>
<td>0.89</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 to ≥ 3 times daily</td>
<td>61 (34.5%)</td>
<td>20 (42.6%)</td>
<td>41 (31.5%)</td>
<td>23 (37.7%)</td>
<td>0.24</td>
<td>0.76</td>
</tr>
<tr>
<td>&lt; once daily</td>
<td>116 (65.5%)</td>
<td>27 (57.4%)</td>
<td>89 (68.5%)</td>
<td>38 (62.3%)</td>
<td>0.99</td>
<td>0.99</td>
</tr>
<tr>
<td><strong>Sexually active</strong></td>
<td>166 (93.8%)</td>
<td>44 (93.6%)</td>
<td>122 (93.8%)</td>
<td>59 (96.7%)</td>
<td>1.0</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>PFM function</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VRP (cmH₂O)</td>
<td>35.2 (SD 8.8)</td>
<td>36.9 (SD 9.2)</td>
<td>34.6 (SD 8.6)</td>
<td>35.2 (SD 9.1)</td>
<td>0.11</td>
<td>0.33</td>
</tr>
<tr>
<td>PFM strength (cmH₂O)</td>
<td>34.6 (SD 19.3)</td>
<td>36.6 (SD 19.2)</td>
<td>33.9 (SD 19.4)</td>
<td>34.3 (SD 19.1)</td>
<td>0.41</td>
<td>0.52</td>
</tr>
<tr>
<td>Endurance (cmH₂O/sec)</td>
<td>276.5 (SD 166.5)</td>
<td>290.1 (SD 158.4)</td>
<td>269.4 (SD 169.4)</td>
<td>268.0 (SD 160.7)</td>
<td>0.41</td>
<td>0.37</td>
</tr>
<tr>
<td>Delivery mode</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NVD</td>
<td>117 (66.1%)</td>
<td>24 (51.1%)</td>
<td>93 (71.5%)</td>
<td>42 (68.9%)</td>
<td>0.07</td>
<td>0.3</td>
</tr>
<tr>
<td>Vacuum/forceps</td>
<td>26 (14.7%)</td>
<td>10 (21.2%)</td>
<td>16 (12.3%)</td>
<td>8 (13.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-labor caesareae section</td>
<td>16 (9%)</td>
<td>7 (14.9%)</td>
<td>9 (6.9%)</td>
<td>9 (14.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesareae section during labour</td>
<td>18 (10.2%)</td>
<td>6 (13.1%)</td>
<td>12 (9.2%)</td>
<td>6 (9.8%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
**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 cmH2O and for PFM endurance it was 80 cmH2O/sec, which is thought to be clinically relevant. Search on PubMed found no other studies that are directly comparable with ours.

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

<table>
<thead>
<tr>
<th>Symptoms/Bother</th>
<th>Symptoms</th>
<th>No symptoms</th>
<th>Severe symptoms</th>
<th>Bother (0–10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coital incontinence*</td>
<td>2 (1.2%)</td>
<td>164 (98.8%)</td>
<td>0</td>
<td>4.5 (SD0.7)</td>
</tr>
<tr>
<td>Dragging pain in lower abdomen</td>
<td>45 (25.4%)</td>
<td>132 (74.6%)</td>
<td>0</td>
<td>3.3 (SD1.8)</td>
</tr>
<tr>
<td>Vagina feels sore</td>
<td>46 (26.0%)</td>
<td>131 (74.0%)</td>
<td>8 (4.5%)</td>
<td>5.0 (SD2.8)</td>
</tr>
<tr>
<td>Reduced sensation in vagina</td>
<td>20 (11.3%)</td>
<td>157 (88.7%)</td>
<td>0</td>
<td>4.1 (SD2.3)</td>
</tr>
<tr>
<td>Vagina feels loose or lax</td>
<td>46 (26.0%)</td>
<td>131 (74.0%)</td>
<td>2 (4.3%)</td>
<td>4.3 (SD2.4)</td>
</tr>
<tr>
<td>Bulge coming down in the vagina</td>
<td>32 (18.1%)</td>
<td>145 (81.9%)</td>
<td>11 (6.2%)</td>
<td>3.3 (SD2.0)</td>
</tr>
<tr>
<td>Bulge coming out of the vagina</td>
<td>5 (2.8%)</td>
<td>172 (97.2%)</td>
<td>1 (0.6%)</td>
<td>2.8 (SD0.8)</td>
</tr>
<tr>
<td>Vagina feels dry</td>
<td>73 (41.2%)</td>
<td>104 (58.8%)</td>
<td>12 (6.7%)</td>
<td>4.4 (SD2.6)</td>
</tr>
<tr>
<td>Support of finger in vagina when emptying bowel</td>
<td>13 (7.3%)</td>
<td>164 (92.7%)</td>
<td>1 (0.6%)</td>
<td>4.9 (SD3.0)</td>
</tr>
<tr>
<td>Vagina feels too tight</td>
<td>31 (17.5%)</td>
<td>146 (82.5%)</td>
<td>5 (2.8%)</td>
<td>4.5 (SD3.1)</td>
</tr>
<tr>
<td>Worries about vaginal symptoms affecting sexual life†</td>
<td>50/161 (32.3%)</td>
<td>109/161 (67.7%)</td>
<td>11 (6.8%)</td>
<td>6.3 (SD2.8)</td>
</tr>
<tr>
<td>Relationship with partner affected†</td>
<td>37/160 (23.1%)</td>
<td>123/160 (76.9%)</td>
<td>4 (2.5%)</td>
<td>7.2 (SD2.6)</td>
</tr>
</tbody>
</table>

*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
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. The need for further epidemiological studies in this area and questions covering de novo symptoms of sexual dysfunction after childbirth in addition to treatment studies is evident.

**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 pelvic floor symptoms and pelvic floor muscle function.

**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)

<table>
<thead>
<tr>
<th>Vagina</th>
<th>Dragging pain in lower abdomen</th>
<th>Vagina feels sore</th>
<th>Reduced sensation in vagina</th>
<th>Vagina feels loose/lax</th>
<th>Bulge coming down in the vagina</th>
<th>Bulge coming out of the vagina</th>
<th>Vagina feels dry</th>
<th>Support of finger in vagina when emptying bowel</th>
<th>Vagina feels too tight</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRP</td>
<td>Correlation coefficient</td>
<td>0.060</td>
<td>0.089</td>
<td>0.068</td>
<td>0.016</td>
<td>0.006</td>
<td>0.013</td>
<td>0.013</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>Significance (two-tailed)</td>
<td>0.630</td>
<td>0.369</td>
<td>0.400</td>
<td>0.560</td>
<td>0.260</td>
<td>0.270</td>
<td>0.270</td>
<td>0.270</td>
</tr>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>PFM strength</td>
<td>Correlation coefficient</td>
<td>0.045</td>
<td>0.063</td>
<td>0.065</td>
<td>0.024</td>
<td>0.007</td>
<td>0.013</td>
<td>0.013</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>Significance (two-tailed)</td>
<td>0.630</td>
<td>0.630</td>
<td>0.150</td>
<td>0.150</td>
<td>0.210</td>
<td>0.210</td>
<td>0.210</td>
<td>0.210</td>
</tr>
<tr>
<td>PFM endurance</td>
<td>Correlation coefficient</td>
<td>0.001</td>
<td>0.046</td>
<td>0.066</td>
<td>0.012</td>
<td>0.000</td>
<td>0.005</td>
<td>0.005</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Significance (two-tailed)</td>
<td>0.710</td>
<td>0.150</td>
<td>0.160</td>
<td>0.760</td>
<td>0.760</td>
<td>0.760</td>
<td>0.760</td>
<td>0.760</td>
</tr>
</tbody>
</table>

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

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

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(b) Revising It for Intellectual Content
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References
Paper III
Effect of postpartum pelvic floor muscle training on vaginal symptoms and sexual dysfunction—secondary analysis of a randomised trial

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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 (58%) 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’.

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’ and has been classified as sexual interest/arousal disorder, orgasmic disorder and genito-pelvic pain/penetration disorder.

Between 10 and 30% in the general female population experience FSD. 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.

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. Some studies have shown that strong PFM may be associated with better orgasmic and arousal potentials, desire, excitement and vaginal lubrication, in addition to improved vaginal sensation and...
tightness. However, contradictory results have also been found.

To date, there is international consensus that pelvic floor muscle training (PFMT) should be the first-line treatment for stress urinary incontinence (SUI) and pelvic organ prolapse (POP). 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, women with POP, and gynecological cancer patients. 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
tightness. However, contradictory results have also been found. To date, there is international consensus that pelvic floor muscle training (PFMT) should be the first-line treatment for stress urinary incontinence (SUI) and pelvic organ prolapse (POP). 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, women with POP, and gynecological cancer patients. 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. The present study assessed 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 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 Office (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.

Power calculation was done for the primary analyses on urinary incontinence and was based on the results from a former study. 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, 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 and 36 women were recruited at 6 weeks postpartum from the maternity ward at Akershus University Hospital, Norway, or from the community primary care clinics within the geographical area of the hospital.

Inclusion criteria were: vaginal delivery to a singleton infant after more than 32 weeks of gestation including normal or instrumental deliveries, women with vacuum and two with forceps] and the ability to understand Scandinavian languages. Exclusion criteria were: women withPOP, 8,17–19 women with SUI, 20,21 women with orgasmic disorders 22,23 and gynecological cancer patients. Two trained gynaecologists stratified the women by major 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. and Merktved and Be. 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-YS), was used for questions on vaginal symptoms and sexual matters with answers given as an average over the last 4 weeks. 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. 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-FLUTSex). 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.

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 cmH2O and PFM endurance as cmH2O/second. The method has demonstrated good reliability and validity for measurement of PFM strength and vaginal resting pressure.

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 majority 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 the baseline value plus the added average change observed in the corresponding control group 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. 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 PFMT 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 $P < 0.05$. 

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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. 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’ (data not shown) changed significantly fewer women in the training group had symptoms of ‘vagina feels loose or lax’ than the control group. No association with this outcome measures. Limitations were some loss to follow up and a small sample size in some of the symptom groups.

### 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 between training and control groups.

#### Strengths and limitations

Strengths of the present study were the RCT design, blinded 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.
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 interest2 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
endurance from 6 weeks to 6 months postpartum in favour of the training group has been found, 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. 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, there may be a potential psychosocial effect of PFMT, for example improved self-acceptance, body awareness and satisfaction.

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. studied 75 women starting in the 16th postpartum week and found a positive effect on arousal, lubrication and orgasm. Mørkved et al. followed 188 women during pregnancy and found improved satisfaction with sexual life 6 years after PFMT. Wilson and Herbst found no 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 ICQ-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. Due to the nature and complexity of this symptom, PFMT alone may not be appropriate.

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

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’

| Major levator ani defects (n = 29) | Without major levator ani defects (n = 31) |
|-----------------------------------|
| Training (n = 25)                  | Control (n = 35)                        |
| Mean difference (95% CI)          | Mean difference (95% CI)                |
| P-value                           | P-value                                 |
| Change VRP                        | Change PFM strength                    | Change PFM endurance                     |
| 2.4 (7.3)                        | 14.8 (8.5)                              | 128 (91.3)                               |
| (0.2, 4.4)                       | (9.6, 10.5)                             | (7.6, 96.5)                              |
| 0.01                             | 0.02                                    | 0.02                                    |
| Training (n = 10)                | Training (n = 10)                       | Training (n = 10)                        |
| Mean difference (95% CI)          | Mean difference (95% CI)                | Mean difference (95% CI)                |
| P-value                           | P-value                                 | P-value                                 |
| Change VRP                        | Change PFM strength                    | Change PFM endurance                     |
| 3.4 (5.3)                        | 9.6 (8.3)                               | 138 (91.3)                               |
| (0.2, 6.3)                       | (6.3, 9.6)                              | (7.6, 96.5)                              |
| 0.01                             | 0.02                                    | 0.02                                    |
| Control (n = 19)                 | Control (n = 16)                        | Control (n = 16)                         |
| Mean difference (95% CI)          | Mean difference (95% CI)                | Mean difference (95% CI)                |
| P-value                           | P-value                                 | P-value                                 |
| Change VRP                        | Change PFM strength                    | Change PFM endurance                     |
| 3.4 (5.3)                        | 9.6 (8.3)                               | 138 (91.3)                               |
| (0.2, 6.3)                       | (6.3, 9.6)                              | (7.6, 96.5)                              |
| 0.01                             | 0.02                                    | 0.02                                    |
| CI, 95% confidence interval; PFM, pelvic floor muscle; VRP, vaginal resting pressure. Values given as % with mean difference between groups at post intervention analyzed using independent sample t-test. 7ª 2015 Royal College of Obstetricians and Gynaecologists
of PFMT combined with either biofeedback or electro stimulation. 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).

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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
Pelvic floor muscle training and sexual function


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

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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 cmH2O, for PFM strength −0.22 ± 7.6 cmH2O, and for muscular endurance 0.75 ± 59.5 cmH2O/s. The interrater agreement for vaginal resting pressure was: 1.36 ± 9.0 cmH2O, for PFM strength 2.24 ± 9.0 cmH2O, and for muscular endurance 15.89 ± 69.7 cmH2O/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
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 intrarater reliability and agreement for PFM strength been assessed.

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

Materials and methods

Subjects and design

This study on intrarater 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 intrarater 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 time-point 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

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0 cmH₂O 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 cmH₂O. 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 cmH₂O.

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 cmH₂O/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].
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 intervaration 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. 

<table>
<thead>
<tr>
<th>Test 1 (SD)</th>
<th>Test 2 (SD)</th>
<th>ICC (95% CI)</th>
<th>Bias (95% CI)</th>
<th>SD</th>
<th>Limits of agreement</th>
<th>Minimal detectable change (cmH2O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRP (cmH2O)</td>
<td>24.36 (9.50)</td>
<td>21.93 (6.96)</td>
<td>0.91 (0.72, 0.97)</td>
<td>−2.44 (−4.51, −0.36)</td>
<td>4.44 (−11.13, 6.26)</td>
<td>8.7</td>
</tr>
<tr>
<td>PFM strength (cmH2O)</td>
<td>21.42 (13.19)</td>
<td>21.20 (13.80)</td>
<td>0.98 (0.95, 0.99)</td>
<td>−0.22 (−2.05, 1.60)</td>
<td>3.89 (−7.86, 7.41)</td>
<td>7.6</td>
</tr>
<tr>
<td>Muscular endurance (cmH2O/s)</td>
<td>144.30 (88.47)</td>
<td>145.05 (99.99)</td>
<td>0.98 (0.94, 0.99)</td>
<td>0.75 (−13.46, 14.96)</td>
<td>30.35 (−58.74, 60.24)</td>
<td>59.5</td>
</tr>
</tbody>
</table>

Bias = test 2 − test 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 improvements 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\textsubscript{2}O (p<0.03) and 15.5 cmH\textsubscript{2}O (p<0.01) respectively [10, 11], and 13.1 cmH\textsubscript{2}O, and for muscular endurance 107 cmH\textsubscript{2}O (p<0.001) [9]. Two recent observational studies also found statistically significant differences for vaginal resting pressure of 3.6 cmH\textsubscript{2}O (95% CI 0.7, 6.6) and 3.3 cmH\textsubscript{2}O (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\textsubscript{2}O 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

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Interater reliability analysis for VRP, PFM strength, and muscular endurance. N=20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessor 1 (SD)</td>
</tr>
<tr>
<td>VRP (cmH\textsubscript{2}O)\textsuperscript{a}</td>
<td>24.13 (9.70)</td>
</tr>
<tr>
<td>PFM strength (cmH\textsubscript{2}O)\textsuperscript{b}</td>
<td>21.56 (13.54)</td>
</tr>
<tr>
<td>Muscular endurance (cmH\textsubscript{2}O)\textsuperscript{c}</td>
<td>145.74 (90.65)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} p = one value missing for assessor 2. Assessor 1 being the first author (MKT)

Bias = assessor 2 – assessor 1

Int Urogynecol J
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.

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References


Appendix 1

Paper I and II

Letters of approval

Regional Committees for Medical Research Ethics

Data Protect Officer
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
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.


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 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. Uttrykt skjema lagres på disk og sendes til elfef.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 PROSJEKTELEDER (SØKEREN)

| A. PROSJEKTANSVARLIG (div direktør/klinikksjef): |
| Navn og stilling: | Pal Wiik |
| Klinikk/avdeling: | Kirurgisk Divisjon |
| Telefonnummer: | 67669099 |
| E-postadresse: | Pal.Wiik@ahus.no |

| B. PROSJEKTELEDER |
| Navn og stilling: | Marie Ellstrøm Engh, første amenuens, overlege |
| Klinikk/avdeling hvor prosjektet gjennomføres: | Kvinneklinikken |
| Telefonnummer: | 67664541 |
| E-postadresse: | m.e.engh@medisin.uio.no |

C. MULTISENTERSTUDIE

Er prosjektet en multisenterstudie?
Ja x Nei

D. ANNEN DATABEHANDLINGSANSVARLIG ENN AKERSHUS UNIVERSITETSSYKEHUS HF

Er prosjektet organisert fra et legemiddelfirma eller annen ekstern virksomhet?
Ja x Nei

Dersom ja, angi virksomhetens navn (Kopi av konsesjon/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 x Nei

2 PROSJEKTETS NAVN/TITTEL

Bekkenbunnsskader ved graviditet og fødsel undersøkt ved 3 og 4 dimensjonal ultralyd

3 Finansiering av prosjektet

Ja x Nei
Hvis ja – hvor (NFR, HSØ etc): HSØ og NFR
Prosjektnr/kostnadsted: 2799026/ 90002

4 BESKRIV FORMÅLET MED BEHANDLINGEN/PROSJEKTET

Formålet er å beskrive de endringene som skjer med bekkenbunnen hos gravide dels i siste halvdel av graviditeten men også etter fødselen. Disse endringer 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

a) Kobling
  - Ja, det benyttes kobling mot forskriftsregulerte registre, som for eksempel fødselsregister, kreftregister eller dodsårsaksregister, eller interne konsesjonsbefagte 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: 50

6 RETTSLIG GRUNNLAG FOR BEHANDLING AV PERSONOPPLYSNINGENE

6.1 Samtykke
  - Skal det innhentes skriftlig samtykke fra den registrerte?
    - Ja
    - Nei
  - Skal det innhentes skriftlig samtykke fra andre enn den registrerte?
    - Ja
    - Nei
  - Skal det søkes Helsedirektoratet om unntak fra taushetsplikten?
    - Ja
    - Nei

ELLER

6.2 Intern kvalitetsikring av pasientbehandling.

ELLER

6.3 Annet som hjemler melding, angi årsak/hjemmel:

6.4 Andre tillatelsener
  - X Fremleggingsplikt for De regionale komiteer for medisinsk forskningsetikk
  - Seknadsplikt til Statens legemiddelverk
  - Bioteknologiloven kommer til anvendelse (det utføres genetiske undersøkelser hvor deltakeren gis tilbakemelding om resultatet)

7 PROSJEKTERIODE

<table>
<thead>
<tr>
<th>Studiestart (dd.mm.åååå)</th>
<th>Studieslutt(dd.mm.åååå)</th>
<th>Slettning/anonymisering av data (dd.mm.åååå)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01092009</td>
<td>31122015</td>
<td>01092059</td>
</tr>
</tbody>
</table>

Beskriv hvordan data vil bli slettet/anonymisert: HØKH vil stå ansvarlig for sletting av Data. Projektskriver 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 □ Nei

Dersom ja:

Opprettes forskningsbiobanken fra en eksisterende biobank? □ Ja □ Nei

Hvis ja, navn på biobank:

Opprettes forskningsbiobanken som en ny biobank? □ Ja □ Nei

Ansvarshavende person for biobanken (Biobankloven §7):

Forskningsbiobankens navn:

Forskningsbiobankens innhold (væv, blod og lignende):

Skal biologisk materiale til forskning utlevertes fra Ahus til en ekstern biobankansvarlig institusjon?

Dersom ja: Kontakt biobankkoordinator

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

□ Navn, adresse, fødselsdato
□ 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

□ rasemessig eller etnisk bakgrunn, eller politisk, filosofisk eller religiøs oppfatning
□ at en person har vært mistenkt, siktet, tiltalt eller domt for en straffbar handling
□ helseopplysninger: Sosial status, utdanning, inntekt, type yrke og grad av belastning i yrke, røykeadler, fysisk aktivitetsnivå, BMI, gynekologisk status inkludert gradering av prolaps (POPO), ultralyd data av bekkenbunnsmorfologi, styrkemåling av bekkenbunnsmuskulatur, subjektive symptomer fra ulike validerete spørreskjema på dysfunksjon i bekkenbunnen. Eksempel: 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.

Helseopplysninger vil omfatte: Sosial status, utdanning, inntekt, type yrke og grad av belastning i yrke, røykeadler, fysisk aktivitetsnivå, BMI, gynekologisk status inkludert gradering av prolaps (POPO), ultralyd data av bekkenbunnsmorfologi, styrkemåling av bekkenbunnsmuskulatur, subjektive symptomer fra ulike validerete spørreskjema på dysfunksjon i bekkenbunnen. I tillegg vil relevante journaldata fra DIPS/PARTUS bli innhentet (f.eks. lengde på fødselsforløp, barnets hodeomkrets, eventuell instrumentell fødsel, skade i bekkenbunnen). Ekseklusjonskriterier 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.

Utskrifstidspunkt: 28.09.09 09:33 Side 3 av 7
9.2 Utvalg

Behandlingen omfatter opplysninger om (beskriv også eventuell kontrollgruppe):

- Ansatte i egen virksomhet
- Elever/studenter/barnehagebarn
- Pasienter
- Tilfeldig utvalgte
- Adgangskontrollerte
- Medlemmer
- Kunden/klienter/brukere
- Fiske frivillige
- Seleksjonsutvalgte
- Friske frivillige

Inkluderer utvalget personer med begrunnet samtykkekompetanse, eks. mindreårige, demente eller annet? □ Ja □ Nei

9.3 Innsamling av opplysningene

Hvordan samlas personopplysningene inn?

- Manuelt
- Elektronisk (bilde og tekst)
- Videopptak
- Lydopptak
- Annet (beskriv hvordan):

Hvor innhentes personopplysningene fra?

- Fra den registrerte selv
- Annet (beskriv hvorfra): DIPS og PARTUS

Hvis uttrekk av forskningsdata, hvem er ansvarlig for uttrekking og anonymisering/avidentifisering av data:

- H0KH
- SEIM
- Andre - oppgi hvem: Projektkoordinator, jordmor Tone Breines Simonsen

9.4 Utlevering av opplysningene

Bilor personopplysningene gjort tilgjengelige/utlevert til andre? □ 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 rekommendert 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?

- Elektronisk:
  - Egen forskningsserver ved Ahus
  - Lokal PC
  - Annen virksomhet - oppgi hvem
  - Forskningsserver ved UiO
  - Annet 13. Angi navn på server:

- På papir. Forklar hvordan dette sikres mot uvedkommende: I låst skab på Tone Breines Simonsen sit kontor
  - På video, tape eller annet oppptak. 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 aidentifisert (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-erklæringer inkl. ark med personopplysninger oppbevares i låst skap på Tone sitt kontor.

10 DATO FOR UTFYLING

Meldeskjemaet er forelagt divisjonsdir/klinikk- forskningsansvarlig x Ja

Sted og dato
Akershus Universitetets Sykehus, 24.09.09

Utfylt av:
Jette Staer-Jensen

Utskriftstidspunkt: 28.09.09 09:33 Side 5 av 7
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: [ ]

Sted og dato: [ ]
Navn personvernombud: [ ]

12 GODKJENNING FOR OPPRETTELSE AV REGISTER/PROSJEKT (fylles ut av direktør ved Forskningsstungenteret)

Anmodning om opprettelse av forskningsregister er:
Godkjent (skjema sendes personvernombud)
Avslatt (skjema returneres avsender)

Sted og dato: [ ]
Navn forskningsdirektør: [ ]

Aktuelle rutiner og rетningslinjer for Forsknings ved Ahus er tilgjengelig via EQS – Forskning og utvikling.

Merknader

1 Tipaset fra Datatilsynets meldeskjema
2 Prosjektlider er ansvarlig for at studien formaliseres i henhold til gjeldende lovbestemmelser. Hvis prosjektlider 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 Forskningsdirektør ved Ahus. Hvis det foretas en utlevering av data til eksterne institusjoner, skal navnet på denne virksomheten skrives her.
5 Ett av de tre hovedpunkterene under må være oppfylt for at studien skal være meldingspliktig, 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 tilradd av personvernmelding. 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. Prosjekt/behandlingen har hjemmel i lov og utføres i regi av organ i stat eller kommune (eks. kvalitetssikring etter helseresponsen§ 26) – se personopplysningsloven § 33, fjerde ledd.
   3. Prosjektet er reguleret i forskrift som spesielt angir at det er unntatt fra konsesjonspunkt eller underlag meldingsplikt (f.eks. de sentrale helseregisterforskriftene)
    Frafallsanalyser (analyser av fordelinger over utdanning, inntekt og ytelser m.m. blant fremmete og ikke-fremmete 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 innenforst sluttrapport til SLV. Enkelte større tidsskifter krever 10 års opbevaring for etterprøving. Data kan ikke oppbevares etter prosjektslutt for kvalitetssikring. Dersom forskningsprosjektet er finansiert av Norges forskningsråd, skal sluttrapport og prosjektdata arkiveres på betyggende måte i minimum 10 år etter avslutning av prosjektet (se punkt 5.3 i Norges forskningsråds generelle kontraktvilkår).
7 Som hovedregel skal skriftlig informert samtykke inneholde.
8 Kvalitetssikring er intern kvalitetskontroll av diagnostiske og behandlingsmessige metoder som har som formål å forbedre diagnostiseringen og behandlingen av pasientene ved sykehuset.
10 Når det skal gi tilbakemelding om generelle resultatet skal deltageren informeres før, under og etter uferd generetisk analyser.

Utskriftstidspunkt: 28.09.09 09:33
11 Nar 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 klinikkjef 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
Dato: 29.09.09
Deres ref.: 
Vår ref.: 2009/289a

2009/289a Effekt av bekkenbunnstrening etter fødsel


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
2009/289a  Effekt av beckenbunnstrening etter fødsel


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 forskningsansvarlighets plikter etter denne loven.

Endringerne innebærer følgende:
Endret intervensionsvarighet 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 personopplysningsforskriften 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 halvår etter prosjektslutt.

Med vennlig hilsen

Gunnar Nicolaysen (sign.)
Professor
Leder REK sør-øst A
MELDESKJEMA for forskningsstudier, kvalitetssikring og annen aktivitet som medfører behandling av person opplysninger som er melde- eller konsesjonspliktig i henhold til helserегистroloven og person opplysningsloven med forskrifter. Dette gjelder også bruk av biologisk materiale i forskning.

Uflyt skjema lagres på disk og sendes til ellef.mork@ahus.no som vedlegg til e-post sammen med eventuelt informasjonskriv. Biobank: Ta kontakt med biobankkoordinator Randi Otterstad (epost: Randi.Otterstad@ahus.no).

1 INFORMASJON OM PROJEKTANSVARLIG OG PROJEKTE LEDER (SØKEREN)

A. PROJEKTANSVARLIG (for direkte/klínisk/ff.)

Namn og stilling: Pål Wiik

Telefonnummer: 67969099
E-postadresse: pal.wiik@ahus.no

Klinikk/avdeling: Kirurgisk Divisjon

B. PROJEKTE LEDE R2

Namn og stilling: Kari Bø, professor, dr. scient. fysioterapeut

Telefonnummer: 22 26 20 09
E-postadresse: kari.bo@nih.no

Klinikk/avdeling hvor prosjektet gjennomføres: Kvinneklinikken

C. MULTISENTERSTUDIE

Er prosjektet en multisenterstudie? Dersom ja, angi ulike virksomheter som deltar: □ Ja □ Nei

Kopier elektronisk dataseksjon som etableres i prosjektet? □ Ja □ Nei

D. ANNEN DATABEHANDLINGSANSVARLIG ENN AKERSHUS UNIVERSITETS SYKEHUS HF3

Er prosjektet organisert fra et legemidelfirma eller annen ekstern virksomhet? □ Ja □ Nei

Hvis ja, angi virksomhetens navn (Kopi av konseknsjon/epidemidiagram skal sendes personvernombudet, og prosjektet skal meldes til personvernombudet som meldepliktig prosjekt, dvs skjemaet fylles ut med unntak av punkt 5.4):

Skal de eksterne også ha kodelisten/navnelisten over deltakere? □ Ja □ Nei

2 PROJEKTETS NAVN/TITTTEL

Effekt av bekkenbunnstrening etter fødsel for kvinner med og uten skade i bekkenbunnsmuskulatur

3 Finansiering av prosjektet

□ Nei □ Ja Hvis ja – hvor (NFR, HSØ etc):
Prosjektnr/kostnadssted: 2799004 / 90005

4 BESKRIV FORMÅLET MED BEHANDLINGEN/PROJEKTE T4

Hensikten med denne randomiserte kontrollerte studien er å evaluere effekt av bekkenbunnstrening eller fødsel hos førstegangsfødende med og uten skade i bekkenbunn. Forekomst av inkontinens, underlivsprolaps, styrke og skadelighet av bekkenbunnsmuskulatur er viktige effektmål.
5 AVKLARING FOR KONSESJON ELLER MELDING

a) Kobling
  x Ja, det benyttes kobling mot forskriftsregulerte registre, som for eksempel fartselsregistre, kraftregistrer eller dødsfallsregister, eller interne konsesjonbelagte registre. Hvis ja, beskriv hvilke registre: PARTUS, Dips

b) Store datasett
  Angi totalt antall inkluderte: 200
  Hvis ja, studien inkluderer et stort omfang av personer og/eller data – dvs mer enn 5000 og/eller opplysninger av særlig betrøffende karakter.

c) Varighet
  Angi antall år opplysningene vil bli lagret, inkludert oppbevaring for etterretningsområde

5 RETTSLIG GRUNNLAG FOR BEHANDLING AV PERSONOPPLYSNINGENE

6.1 Samtykke
  x Skal det innhentes skriftlig samtykke fra den registrerte?
  x Skal det innhentes skriftlig samtykke fra andre enn den registrerte?
  x Skal det sakes Helsedirektoratet om unntak fra taushetsplikten?

ELLER

6.2 Intern kvalitetssikring av pasientbehandling.

ELLER

6.3 Annet som hjemler melding, angi årsak/hjemmel:

6.4 Andre tillatelses
  x Fremleggingsplikt for De regionale komiteer for medisinsk forskningsetikk
  x Saknadsplikt til Statens legemiddelverk
  x Bioteknologiloven kommer til anvendelse (dette omfatter genetiske undersøkelser hvor deltageren glas tilbakelevering av resultatet).

7 PROSJEKTPERIODE

<table>
<thead>
<tr>
<th>Studiestart (dd.mm.yyyy)</th>
<th>Studiekutt (dd.mm.yyyy)</th>
<th>Slettning/anonymisering av data (dd.mm.yyyy)</th>
</tr>
</thead>
</table>

Beskriv hvordan data vil bli slettet/anonymisert: HUSK vil bli kontaktet før slettning av data. Projektsvaktsvirig vil bli kontaktet før slettning 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 □ Nei

Dersom ja:

□ Ja □ Nei
□ Nei

Opprettes forskningsbiobanken fra en eksisterende biobank?
□ Ja □ Nei Biobankregisternr.:
□ Nei
□ Nei

Opprettes forskningsbiobanken som en ny biobank?

□ Nei

Antvanshøvende person for biobanken (Biobankloven §7):
□ Nei

Forskningsbiobankens navn:
□ Nei

Forskningsbiobankens innehald (væv, blod og lignende):

□ Nei

Skal biologisk materiale til forskning utleveres fra Ahus til en eksistent biobankoversett institusjon?

□ Nei

Dersom ja: Kontakt biobankkoordinator

□ Nei

Veiv utført prosjektet:

□ Nei

Hva sliter med biobankmaterialet?: □ Materiale detrueres □ Materialber føres tilbake til eksisterende biobank Anmerk.:

□ Nei

Hva sliter med forskningsdata utledet av biobankmaterialet?:

□ Nei

9 DETALJER OM PROSJEKTETS INFORMASJONSBEHANDLING
9.1 Type personopplysninger behandlingen skal omfatte:

9.1.1 Ikke-sensitivt personopplysninger

Identifikasjonopplysninger:

x Adresser, telefon, mobil
x E-postadresse, nettside
x Fødselsnummer (11 siffer)
□ Fødselsnr.
□ Fødselsnr.
□ Anmerk.

Opplysninger om tredjepersoner:

□ Navn, adresse, fødselsdato
□ Fødselsnummer (11 siffer)
□ Anmerk.

9.1.2 Sensitive personopplysninger (jf. personopplysningsloven § 2 nr. 8)

Praksist: Omfattende opplysninger om:

x rasemessig eller etnisk bakgrunn, eller politisk, filosofisk eller religiøs oppfatning
□ er en person har vært mistenkt, siktet, tiltalt eller dømt for en straffbar handling
□ helseforhold
□ seksuelle forhold

Anmerk. nærmere:

Rasemessig bakgrunn vil bli registrert, da dette kan ha betydning for elastisiteten i bekkenleddene og bekkenbunnen og for fremmøbilet i bekkenet.

Helseopplysninger vil omfalte: Social status, utdanning, inntekt, type yrke og grad av belastning i yrke, fysisk aktivitetstilstand, BMI, gynekologisk status inkludert gradering av prolaps (POPQ), utvalgt data av bekkenbunnsmuskulatur, subjektive symptomer fra ulike validerete spørreskjemaer på dysfunksjon i bekkenbunnen. I tillegg vil relevante journaldata fra DIPS/PARTUS bli innhentet (f.eks. længde på fødselsforløp, bæremods hodeornkrets, eventuell instrumentell fødsel, skade i bekkenbunnen). Ekstensjonsskrifter i studien er prematur fødsel (< 32 uker), keisersnitt, alvorlig sykdom hos mor eller barn. Disse opplysningene innhentes også fra DIPS/PARTUS ved Ahus.

### 9.2 Utvalg
Behandlingen omfatter opplysninger om (beskriv også eventuell kontrollgruppe):

- [ ] Ansatte i egen virksomhet
- [x] Elever/studenter/barnehagebarn
- [ ] Pasienter
- [ ] Tilfeldig utvalgte
- [ ] Adgangskontrollerte
- [ ] Medlemmer
- [ ] Kunden/klienter/brukere
- [ ] Seleksjonsutvalgte
- [ ] Fristete/frivillige

Inkluderer utvalgte 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
- [ ] Elektronisk (bilde og tekst)
- [ ] Videoopptak
- [ ] Lydopptak
- [ ] Annet (beskriv hvordan):

Hvor innhentes personopplysningene fra?

- [x] Fra den registrerte selv
- [ ] Annet (beskriv hvor fra): DIPS og PARTUS

Hvis uttrekk av forskningsdata, hvem er ansvarlig for uttrekk og anonymisering/avidentifisering av data:

- [x] Prosjektkoordinator Tone Brines Simonsen, jordmor, prosketkoordinator
- [ ] SEIM
- [ ] Andre - oppgi hvem:

### 9.4 Utlevering av opplysningene
Bli personopplysningene gjort tilgjengelig/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?

- [ ] Ja
- [x] 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 lidt som i pkt 9.6.

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. Nærere beskrivelse:

### 9.5 Lagring og behandling av opplysninger
### Hvordan lagres opplysningene?

- **Elektronisk:**
  - Egen forskningsserver ved Ahus
  - Lokal PC
  - Annon virksomhet – oppgi hvem
  - Forskningsserver ved UiO
  - Annen
  - Angi navn på server:

- På papir. Forklar hvordan dette sikres mot uvedkommende:
  - På last skap (Tone Breines Simonsen Sitt kontor?)

- På video, tape eller annet opptak. Beskriv hvordan dette er sikret og om personen kan identifieres:
  - Annen. Forklar:

### Gjenfinning av opplysningene

- **Hvordan gjenfinnes opplysningene?** (Bruk av direkte identifisering som personnummer og navn skal forårsakes umangel)
  - Opplysningene lagres med navn, personnummer eller annet som entydig angir det enkelte individ
  - Opplysningene lagres aidentifisert (ved bruk av krysslister, kodelister, løpenummer eller lignende)

- **Hvordan er krysslister/kodedister beskyttet/iagret?** Kun autorisert personell knyttet til prosjektet (Tone Breines Simonsen) har adgang til navneliste med kodenøkkelen 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: Akershus Universitetssykehus, 24.09.09

Utfylt av: Gunvor Hilde
BEHANDLING AV PERSONVERNOMBUD

Skal det sendes saknad om konsekjon til Datatilsynet?

Ja, det må sendes saknad om konsekjon til Datatilsynet. Jfr POL §33)

Nei, ikke nødvendig – oppgi begrunnelse: X

Sted og dato: 20.11.2009

Navn personvernombud: [Signatur]

GODKJENNING FOR OPPRETTELSE AV REGISTER/PROSJEKT (fulles ut av direktør ved Forskningsstyre)

Ammendring om opprettelse av forskningsregister er:

Godkjent (skjema sendes personvernombud) X

Avslatt (skjema retumeres avsender) □

Sted og dato: 23.11.09

Navn forskningsleder: [Signatur]

Aktuelle rutiner og retningslinjer for Forskning ved Ahus er tilgjengelig via EQS – Forskning og utvikling.

Merknader

1. Tilpaset fra Datatilsynets meldeskjema

2. Prosjektleder er ansett for at studien formaliseres i henhold til gittede lovstillingar. Hvis prosjektleder ikke er ansett ved Akershus universitetssykehus HF (Ahus) må det oppgis navn på den Ahus-ansatte som er ansett for at studien formaliseres korrekt. Hvis det finnes et slike ansett, skal navnet på denne virksomheten skrives her.


4. Ett av de tre hovedpunktoane under må være oppfylt for at studien skal være meldepliktig, og unntatt fra konsekjon:

1. Prosjektet er omfattet av personopplysningsforskriften §7-21. (Par. a) må være oppfylt, samt enten b eller c)

2. Prosjektet er tilrettelagt av personvernombud. For prosjektet med medisinsk eller helsefaglig forskning skal prosjektet i tillegg være godkjent av REK. (Par. b) Ikke stor omfang, men lang varighet og identifiserbart, eller (Par. c) Store datasett og tilfredsstillende avidentifisert eller pseudonymisert.

3. Prosjektet/behandlingen har hjemmel i lov og utfares i regi av organ i stat eller kommune (eks. kvalitetssikring etter helsepersonellovens § 26) – se personvernopplysningsloven § 33, øvste ledd.

5. Prosjektet er regulert i forskrift som spesielt angir at det er unntatt fra konsesjonsplikt eller underlag meldeplikt (f.eks. de sentrale helseregistreforvaltningene) fortidsanalysen (analyser av fordelinger over utdannin, inntekt og ytelser mm. blant frematte og ikke-frematte for å beregne betydningen av fratelet) frafalleiigner som er basert på samtykke.

6. Data skal lagres i en viss tid eller av prosjektet er ferdiggjort (analyse er gjennomført) for mulig etterprøving. I forskningsstudier skal data lagres 5 år (Norsk Legemiddelexamen) eller publisering, og for kliniske studier skal data lagres i minst 15 år etter innend gradig studdertrapport til SLV. Enkelte større overskudd krever 10 års oppbevaring av slike prøver. Data kan ikke oppbevares eller prosjektet slutttrapport om kvalitetssikring. Dessuten formaliseres forskningsdata av Norges forskningsråd, skal slutttrapport og prosjektdata arkiveres på behøvnende måte i minimum 10 år etter avslutning av prosjektet (se punkt 5.3 i Norges forskningsråds generelle kontraktsvilkår).

7. Som hovudregel skal skriftlig informert samtykke innhentes.

8. Kvalitetssikring er intern kvalitetssikring av diagnostiske og behandlingsmessige metoder som har som formål å forbedre diagnosltis og behandlingen av pasientene ved sykehuset.


Underskriftspunkt: 30.11.09 07:59
Appendix 3

Paper I-III

Study information and consent form
FORESPØRSEL OM DELTAKESELLE I FORSKNINGSPROSJEKTENE:  
Kartlegging av hvordan bekkenbunnen påvirkes av graviditet og fødsel  
ved hjelp av ultralyd  
&  
Effekt av bekkenbunnstrening etter fødsel

Bakgrunn og hensikt
Dette er et spørsom program 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, smerten og underlivsprolaps (framfall/ødemykning 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.


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. Undersøkselene foregår ved gynekologisk politiklinikk på Ahus og tar ca 1 t. Du blir instruert i riktig bekkenbunnssammenrekning av fysioterapeut, som undersøker om du gjør dette riktig ved å kjenne i ytre del av skjeden. Musikstyrke i bekkenbunnen måles ved vaginal trykmåling.
Deretter vil gynekologen foreta en ultralydundersøkelse av bekkenbunnen der ultralydapparatet tas utvendig mot underlivet. I tillegg foretas en gynekologisk undersøkelse.


I tillegg til data fra undersøkelsene hos gynekolog, fysioterapeut og spørreskjema vil vi innhente relevante journaldata (f.eks. lengde på fødselsforløp, eventuelt instrumentell fødsel, barnets hodeomkrets).


Friwillig 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. Ønsker du å trekke deg kontakt 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


Hovedansvarlig for kartleggingsstudien er Marie Ellstrøm Engh, dr.med., førsteamanuensis, overlege ved Kvinneklinikken Ahus. For mer informasjon, kontakt Jette Stør-Jensen, gynekolog, doktorgradsstudent ved Kvinneklinikken Ahus. Mobil 41 14 00 32, e-post: jett@ahus

Hovedansvarlig for treningssstudien er Kari Be, dr.scient, fysioterapeut, professor ved Norges idrettshøgskole, seksjon for idrettsmedisin. For mer informasjon, kontakt Gunvor Hilde, fysioterapeut, doktorgradsstudent ved Norges idrettshøgskole, seksjon for idrettsmedisinske fag. Mobil 41 36 60 45, e-post: gunvor.hilde@nih.no

Marie Ellstrøm Engh Dr. med, førsteamanuensis, overlege Kvinneklinikken

Jette Stør-Jensen Doktorgradsstudent gynekolog

Franziska Richter Doktorgradsstudent gynekolog
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
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 bekkenbunnspalter. Vi ønsker å se på overensstemmelse av vaginal trykkmåling mellom tester og ved samme tester ved at to erfarte 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 rekrutere kvinner i fertile 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 bekkenbunnfunksjon 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 utholdenhed 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 sammentrekkninger og utholdenhed som en maksimal sammentrekning over 10 sekunder.

Komiteen har ingen forskningsetiske innvendinger til at prosjektet gjennomføres.

Komiteen har imidlertid en merknad til informasjonskrivet. 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.

Ut fra 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.


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 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
Til Marie Ellström Engh
Akershus universitets sykehus

2014/1768 Måling av funksjon i bekkenbunnsmuskelen 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 rekrutering av prosjektdeltakere fra Ahus. Denne rekruteringen 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 rekrutering ved å annoncere på grupptimer og i behandlingsammenheng 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 forhånd. 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 ettergjøres Kellynes. 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 godkjener 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

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
PERSONVERNOMBUDETS UTTELELSE

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 tester og ved samme tester ved at to erfarte kvinnelige fysioterapeuter med felles opplæring gjør undersøkelsen etter hverandre på samme dag for så å gjøre en tredje undersøkelse ukent etter av samme fysioterapeut. Dette er ikke blitt gjort blant gravide eller førstegangsfrødende kvinner og det er kun vurdert styrke, ikke hvelfunksjon eller utholdenhet av muskulaturen. Vi ønsker å rekuttile kvinner i ferd alder over 16 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. Kvinnen vil få mulighet til å se resultatene etter avsluttet testing og få tilbakemelding og eventuelle råd og tips om videre oppfølgelse.

Viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Det følgende er et formelt svar på meldingen. Forutsetningene nedenfor må være oppfylt for rekrutering 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 personvernbudet.
6. Data lagres som oppgitt i meldingen. Kodeliste som kobler aidentifiserte data med personopplysninger lagres som angitt i meldingen som separat fil på tilgangsstyrte prosjektområde på forskningsserver i sikker sonic. Det høstes ikke opplysninger fra pasientjournal eller pasientadministrative systemer, men opplysninger nedtegnes i møte med prosjektdelelkerne og puneses inn på prosjektområdet. Kontakt datafangstgruppen for opprettelse av prosjektområde på forskningsserver på datafangst@ahu.no
8. Dersom formålet, utvalget av inkluderte eller databehandlingen endres må personvernbudet gis forhåndsinformasjon om dette.

Studien er registrert i sykehusets offentlig tilgjengelig database over forsknings- og kvalitetsstudier.

Lykke til med studien!

Med vennlig hilsen

for Personvernbudet

Marianne B Blair
Personvernbud
Akershus universitetssykehus HF

Epost: personvern@ahu.no
Web: www.ahu.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