# The pelvic floor puzzle in the spotlight

The association between pelvic floor muscle function and pelvic floor symptoms in men and women

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“The levator ani is one of those muscle which has been studied the most, and at the same time one about which we know the least.”

*(Sappey P.,’Traite d,Anatomie Descriptive’ (2nd ed) 1739).*

# CONTENTS

## PREFACE

**The Coevorden-study; sub-study of pelvic floor muscle function in relation to pelvic floor symptoms.**

This thesis is submitted in fulfilment of the requirements for a postgraduate doctorate qualification at the University of Groningen and was part of a large observational population-based cohort study assessing pelvic floor symptoms in a general population. This thesis will focus on the relation between male and female pelvic floor muscle (dys) function and pelvic floor symptoms.

This research was conducted under the supervision of prof. dr. M.H. Blanker, Mrs. dr. G.E. Knol-de Vries, and Mrs. dr. M.C. Ph. Slieker-ten Hove, of the Department of Primary and Long-term Care at the University Medical Center Groningen, the Netherlands.

**De Coevordenstudie; sub-studie van bekkenbodemspierfunctie in relatie tot bekkenbodemklachten.**

Dit proefschrift is ingediend om aan de vereisten te voldoen voor de graad van doctor aan de Universiteit van Groningen en maakt deel uit van een grotere observationele cohortstudie waarin bekkenbodemklachten in een algemene populatie werden onderzocht. Dit proefschrift richt zich op de relatie tussen bekkenbodemspier(dis)functies en bekkenbodemklachten bij mannen en vrouwen.

Deze studie is uitgevoerd onder supervisie van prof. dr. M.H. Blanker, mevrouw dr. G.E. Knol-de Vries en mevrouw dr. M.C. Ph. Slieker-ten Hove, afdeling Eerstelijnsgeneeskunde en Langdurige Zorg, Universitair Medisch Centrum Groningen, Nederland.

## INFORMATIE VOOR LEKEN

Bekkenbodemklachten zoals plasproblemen of urineverlies, ontlastingsproblemen, seksuele klachten en pijn in het bekken- of bekkenbodemgebied komen vaak voor bij mannen en vrouwen. Het is onduidelijk of de bekkenbodemspieren invloed hebben op bekkenbodemklachten. Gegevens van bekkenbodemvragenlijsten, en van een inwendig handmatig onderzoek van de bekkenbodemspieren bij 199 mannen en 187 vrouwen, werden gebruikt in de analyses. We vonden dat zowel bij mannen als bij vrouwen er vaak sprake is van tegelijkertijd voorkomende bekkenbodemklachten, waarbij een op de drie mannen en vrouwen, twee of meer bekkenbodemklachten hadden. Bij mannen zonder bekkenbodemklachten vonden we dat 80% een afwijking in de bekkenbodemspierwerking had. Omdat de spieren van de bekkenbodem niet altijd lijken samen te werken, adviseren we bij de beoordeling van de bekkenbodemspierwerking bij vrouwen zowel een vaginaal als een anaal onderzoek. We vonden zowel bij mannen als bij vrouwen geen duidelijke relatie tussen de functies van de bekkenbodemspieren (spierspanning, aanspanning, ontspanning, maximale aanspanning, aantal maximale aanspanningen, duurkracht) en het aantal bekkenbodemklachten. Mannen lieten vaker een hoge bekkenbodemspierspanning zien in alle bekkenbodemspieren en vrouwen vaker een vermindering van de maximale aanspankracht van de anale sluitspier en de duurkracht van alle bekkenbodemspieren. Na een speciale statistische analyse vonden we bij de groep van voornamelijk jonge mannen zonder bekkenbodemklachten de meeste afwijkingen in de bekkenbodemspierwerking voor spierspanning, ontspanning en maximale aanspankracht. De uitkomsten van deze studie kunnen beïnvloed zijn door het ingewikkelde samenspel tussen de bekkenbodemspieren en de bekkenorganen, en de manier waarop we de gegevens hebben geanalyseerd.

## LAYMEN'S INFORMATION

Pelvic floor symptoms such as lower urinary tract symptoms, defecation problems, sexual dysfunction and pelvic pain are prevalent in men en women. However, the relation between pelvic floor (dys)function and pelvic floor symptoms is unclear. Data of pelvic floor symptom questionnaires and an internal pelvic floor muscle assessment of 199 men and 187 women were used for analysis. We found in both sexes concomittant pelvic floor symptoms, and one out of three men and women, reported two or more pelvic floor symptoms. Men without pelvic floor symptoms showed in 80% some pelvic floor muscle dysfunction. Since we found a limited cooperation between the pelvic floor muscles, we advise, in female pelvic floor evaluation, both a vaginal and an anorectal pelvic floor muscle assessment. For both men and women we did not find a relation between pelvic floor muscle function (e.g. tone, contraction, relaxation, maximum voluntary contraction, number of maximum voluntary contractions, endurance) and the number of pelvic floor symptoms. Men more often showed an increased tone in all pelvic floor muscles, while women more often showed an impairment of the maximum voluntary contraction of the anal muscle and of the endurance of all pelvic floor muscles. After a specific statistical analysis, the group of mostly younger men without pelvic floor symptoms, showed the most dissimilarity for tone, relaxation and maximum voluntary contraction. The results of this study might have been influenced by the complex interplay between the pelvic floor muscles and pelvic organs, and the way we analyzed the data.

# 1

# General introduction, aim and design of the study

# GENERAL INTRODUCTION

## 1. PELVIC FLOOR SYMPTOMS

Pelvic floor symptoms (PFS) are prevailing in both males and females and comprise of lower urinary tract symptoms (LUTS; e.g., urinary incontinence (UI), voiding problems), defecation problems (e.g., fecal incontinence (FI), constipation), sexual dysfunction and pelvic pain.[1]
Next to these symptoms females may develop pelvic organ prolapse (POP) symptoms leading to a cystocele, prolapse uteri, rectocele and / or enterocele.[2] For sexual symptoms, males may suffer from erectile dysfunction or ejaculation problems, whereas females may have an arousal disorder and / or problems with intercourse.[3,4]
PFS may present as a single symptom or as concomitant symptoms. PFS are multifactorial and show relations with a dysfunction of the bladder, the bowel and/or prostate and/or uterus. PFS have a negative impact on self-image and quality of life and incidence increase with age.[5-7]
Former research suggested that the pelvic floor musculature (PFM) could contribute to PFS, but the complexity of the pelvic systems makes the exploration of this subject a challenge.[8]

## 2. DEFINITIONS, PREVALENCE AND RISK FACTORS OF PELVIC FLOOR SYMPTOMS

PFS are also indicated as pelvic floor disorders (PFD). For both, different terminologies have been used and several questionnaires and standardizations have been proposed, depending on research topics and clinical practice. In this thesis we only use the term 'pelvic floor symptoms'.
The use of different scales and of non-validated questionnaires often leads to different terminology of PFS.[9,10] The International Urogynecological Organization (IUGA) and the International Incontinence Society (ICS) in particular, have been working on validation of several questionnaires, and have updated terminology to further improve quality of PFS research.[9-11]
Prevalence rates for PFS vary due to differences in target populations (e.g., age), methodology and study design. Female studies report that

the proportion of one PFS increase by the number of deliveries and by aging.[12,13] Percentages of FI are reported to be approximately equal for both sexes and increase with age too.[14] Compared to males, females more often suffer from double incontinence.[15,16] Pelvic floor research shows ranges in adults of 13%-67% for LUTS, 7%-26% for Overactive Bladder (OAB), 4%-50% for UI and approximately of 21% for LUTS/Bladder Outlet Obstruction.[17] Prevalence of constipation is 16%, rising up to 33,5% in elderly patients aged 60-100 years.[18] Sexual dysfunctions are seen in 40%-45% and 20%-30% of females and males respectively.[19]



In females, vaginal delivery is the most important risk factor for the development of UI, FI or POP symptoms.[20,21] Additionally, studies of female PFS showed that higher number of pregnancies, higher age, high body mass index, former hysterectomy and family members with PFS, are risk factors for PFS as well.[22] Male studies reported that aging, obesity, smoking, alcohol and hormonal imbalance are risk factors for LUTS and sexual symptoms.[23] Other contributing, but less clear factors for male PFS, include anal fissures, hemorrhoids and prostate enlargement.[24]

Furthermore, frequency, urgency UI, may develop as a result of incorrect toilet behavior (taking too little time for urination and defecation, incorrect posture and no relaxation of the PFM), or heavy work. Mental, social, and environmental circumstances, might also lead to the development of specific PFS such as Chronic Pelvic Pain Syndrome.[25]

## 3. PELVIC FLOOR MUSCLE FUNCTION AND PELVIC FLOOR MUSCLE ASSESSMENT

PFM function is complex and depends on an intact neuromuscular, viscoelastic and contractile system in the pelvic region.[26,27] A digital PFM assessment is necessary to gain insight in tone, voluntary contraction, voluntary relaxation, maximum voluntary contraction (MVC), frequency of MVC's and endurance, and in females to assess gradation of POP. Changes in PFM function items often lead to PFM dysfunction. To assess PFM function, a digital PFM assessment can be performed by medical doctors and registered pelvic floor physical therapists (PFPTs).

Outcomes of a digital PFM assessment depend on the understanding of the instruction given by the assessor and the ability to perform a specific PFM contraction or relaxation.[30] A digital PFM assessment may further be influenced by several processes such as the emotion or possible stress of the participant, alterations in the pelvic anatomy and physiology, experiences of former digital PFM assessments and the intimacy of the assessment itself.[31] Additionally, a reduction in awareness and /or sensibility of the PFM, a sexual trauma and any presence of pain may hamper PFM function, while knowledge about the PFM may improve PFM function.[32]

## 4. RELATION PELVIC FLOOR MUSCULAR FUNCTION AND PELVIC FLOOR SYMPTOMS

Since the urogenital, intestinal and sexual organs have a complex interplay with the PFM, it is of great interest to explore the relationships between PFM (dys-) function and PFS.[33-35] When the PFM is a possible (additional) factor for PFS, PFS could be diminished since PFM dysfunction is treatable. In former female pelvic floor research relationships were found between PFM dysfunction and a single type of PFS such as, UI or POP symptoms, but to date the relation between PFM function and multiple PFS has been underexposed.[36] For males, few studies assessed the relation between PFM function and PFS.[37] However, there is still a lack in studies assessing the relation of PFM function and multiple PFS in both sexes. It seems therefore highly interesting to explore male and female PFM (dys-) function in relation to concomitant PFS. Furthermore, because of variances in anatomy, it is interesting to explore similarities and differences between male and female PFM (dys-) function by the number and types of PFS and to address the relation of male PFM function and LUTS.

## 5. AIM OF THIS THESIS

To date, no study explored concomitant PFS (LUTS, defecation problems, sexual dysfunction, pelvic pain (and in females POP)) in males and females and no study made an attempt to reveal the relation between male and female PFM (dys-) function and multiple PFS. Furthermore, no study explored the similarities and differences in PFM (dys-) function by the number and type of PFS between both sexes. Most female studies concerning PFM (dys-) function have focused on one or two symptoms

such as UI, FI and POP symptoms and male research has focused mainly on prostate enlargement/LUTS and sexual dysfunction,
To address these knowledge gaps, this study aimed to offer new insights in concomitant male and female PFS. Furthermore, this study will add knowledge about the complexity of both male and female PFM (dys-) function in relation to a number and multiple types of PFS. Additionally, this study assesses differences and similarities between male and female PFM function.



## 6. DESIGN OF THE STUDY

The research described in this thesis consists of a cross sectional study, which was part of a larger prospective observational population-based cohort study exploring concomitant PFS in community-dwelling males and females with and without PFS.[38] The primary cohort study comprised questionnaires completed by males and females aged 16 years and older. Questionnaires included urinary symptoms, defecation problems, sexual symptoms and pain for males and females.[39-44] For females we added a questionnaire for POP symptoms.[45]
From this cohort, a subgroup of males and females aged 21 years or older with and without PFS, was selected by purposive sampling to undergo a digital PFM assessment.
Data from PFM assessment was used a) to gain insight in the complexity of male and female PFM function in relation to the total number of PFS, b) to compare male and female PFM function by a number (0-4) and different types (LUTS, defecation problems, sexual dysfunction and pain) of PFS, c) to explore the relation between male PFM function and LUTS (UI, voiding problems) and defecation problems and pelvic pain.
In the current study, the digital PFM assessment was conducted in males and females in accordance to prevalent protocols in pelvic floor physical therapy in the Netherlands, and the most recent ICS recommendations, at the time the study started (2019).[9-11,28] Despite these protocols, no gold standard is available for male and female digital PFM assessment.[29]

To clarify the complexity of male and female PFS we excluded other contributing factors e.g., surgery and heavy work and considered the role of PFM dysfunction as one of the factors leading to PFS.

| | |
|---|---|
| Pelvic Floor Symptoms | Symptoms referring to:<br>- Lower urinary tract symptoms<br>- Defecation problems<br>- Sexual dysfunction<br>- Pain symptoms<br>- Prolapse symptoms |
| Pelvic Floor Musculature:<br>External anal Sphincter<br>Puborectal Muscle<br>Vaginal PFM | PFM function items:<br>- Tone<br>- Voluntary contraction<br>- Voluntary relaxation<br>- Maximum Voluntary Contraction (MVC)<br>- Frequency of MVC<br>- Endurance<br>- Stage POP<br>- PFM reaction on cough (without instruction) |

## 7. THIS THESIS

The first step in this research was to study the presence of concomitant PFS in the overall cohort study of males and females. Secondly, we explored possible relationships within and between the PFM in both sexes. Thirdly, we assessed relationships between male and female PFM function and the total number of PFS. Fourthly, we explored male and female PFM (dys-) function by a number and type of PFS. Fifthly, we explored relationships between male PFM function and LUTS (and concomitant PFS).
Above questions formed the guideline of this thesis. Results may increase knowledge for general practitioners, PFPTs, urological or gynecological physician assistants, urologists and gynecologists concerning male and female PFM function in relation to PFS.

## 8. THESIS OUTLINE

In **Chapter 1** the author introduces the complex relationship between pelvic floor symptoms and pelvic floor muscle function.
In **Chapter 2** we explored concomitant PFS in community-dwelling males and females.
In **Chapter 3** we explored the associations within and between the external anal sphincter (EAS) and the Puborectal Muscle (PRM) and

between PFM (dys-) function in relation to the total number of PFS in males.
In **Chapter 4** we explored the associations within and between the EAS, the PRM and the vaginal PFM and between PFM function in relation to the total number of PFS in females.
In **Chapter 5** we compared similarities and differences in male and female PFM function with respect to tone, voluntary relaxation, MVC and endurance by a number (0-4) and type (LUTS, defecation problems, sexual dysfunction and pain) of PFS.
In **Chapter 6** we explored the relationship between male PFM function and LUTS and concomitant PFS (defecation problems and pain).
In **Chapter 7** the general discussion, describes the author her vision on this topic, indicates clinical implications for the treatment of male and female PFS and the need for further studies.
In the **appendices** the author describes the scientific summaries in English and Dutch.

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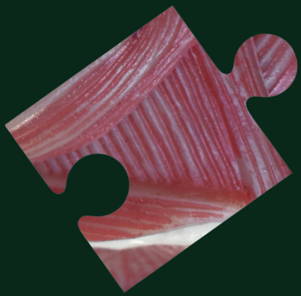

# 2

# Exploring concomitant pelvic floor symptoms in community-dwelling females and males

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## ABSTRACT

**Objectives**
Researchers and clinicians tend to focus on one pelvic floor symptom (PFS) at the time. However, the pelvic floor acts as one functional unit, increasing the likelihood of concurrent PFS in patients with pelvic floor dysfunction. There is also a paucity of literature on the prevalence of concomitant PFS, especially in males. Therefore, we explored the occurrence of concomitant PFS in community-dwelling males and females.

**Materials and Methods**
This prospective observational population-based cohort study included males and females aged ≥16 years from a single Dutch municipality. Participants completed validated questionnaires on lower urinary tract symptoms (LUTS), defecation problems, sexual dysfunction, pelvic pain, and pelvic organ prolapse. Medical general practitioner records were examined. Furthermore, a randomly selected group of non-responders aged <80 years received a short questionnaire, to study response bias.

**Results**
We invited 11,724 people, among which 839 females and 566 males completed the questionnaires. Of the female participants, 286 (34.1%) reported no PFS and 251 (29.9%) reported two or more PFS. The most prevalent PFS clusters in females were sexual dysfunction and pelvic pain, sexual dysfunction and defecation problems, LUTS and defecation problems, and LUTS, defecation problems, and pelvic pain. Of the male participants, 212 (37.5%) reported no PFS and 191 (33.7%) reported two or more PFS. The most prevalent clusters in males were sexual dysfunction and LUTS, defecation problems and LUTS, and sexual dysfunction, LUTS, and defecation problems.

**Conclusion**
A considerable overlap existed between PFS, with differences in PFS clusters between females and males. Of note, females reported pelvic pain more than males. We conclude that health care providers should address all PFS in males and females.


Keywords: concomitant conditions; general population; pelvic floor disorders; pelvic floor symptoms.

## 1. INTRODUCTION

The pelvic floor is a complex neuromyofascial unit that plays key roles in sexuality, the passage and storage of urine and feces, and the support of the pelvic organs.[1] Dysfunction of the pelvic floor musculature may lead to pelvic floor symptoms (PFS), which can be divided into five domains[2]: lower urinary tract symptoms (LUTS; e.g., urinary incontinence (UI), urgency, voiding dysfunction), defecation problems (e.g., fecal incontinence, constipation, obstructed defecation), sexual problems (e.g., dyspareunia, erectile dysfunction, ejaculation problems), pelvic pain, and in females, pelvic organ prolapse (POP). These PFS are associated with decreased well-being and quality of life,[3] and although they can occur at any point, their incidence increases with age. Given that average life expectancy is rising, the worldwide burden of PFS is expected to increase significantly.

The different pelvic floor muscles act as one functional unit, increasing the likelihood that pelvic floor dysfunction will lead to the co-occurrence of different PFS.[4] In a recent scoping review, we have shown that literature on the prevalence of concomitant PFS is scarce, especially in males.[5] Indeed, case studies have reported the prevalence of PFS in males, either using specific cohorts (e.g., post-prostatectomy[6]) or focusing on sexual problems and LUTS (either together or in isolation).[5] In females, pelvic pain and sexual dysfunction are rarely studied in combination, with most focus being on the more prevalent urinary incontinence, fecal incontinence, and POP.[5] Likewise, many physicians treating both males and females in daily practice tend to focus on one PFS domain or on the most bothersome symptom only. Gaining insight into the occurrence of concomitant PFS is important in both females and males because these patients may need different treatment approaches to those with single PFS, not least because interacting symptoms may jeopardize improvement or recovery.[7,8]

This study primarily aimed to explore the occurrence of concomitant PFS in community-dwelling males and females.

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# 2. MATERIALS AND METHODS

## 2.1 Study Design

We conducted a prospective observational population-based cohort study in a Dutch municipality, applying a mixed-methods approach that combined quantitative and qualitative elements (Figure 1). The study was performed in close collaboration with all general practitioners (GPs) in the study region to ensure knowledge of the cohort (all Dutch inhabitants are registered with a GP). Supplement A describes the procedures in detail. The local medical ethics committee approved the study, and all participants signed an informed consent form.

## 2.2 Participants

Community-dwelling males and females aged 16 years or older and living in the Dutch municipality of Coevorden were eligible to take part. We excluded anyone with a terminal illness, cognitive impairment (e.g., dementia) or current psychological condition precluding informed consent, or whom the GP considered unsuitable or too ill to participate. Eligible subjects received a personal letter from their general practice in May 2019 inviting them to take part and return a signed informed consent form to the study team (using a pre-stamped and pre-labeled envelope). We considered non-responders those who had not returned a signed consent form after one postal reminder.

## 2.3 Data Collection

*PFS Questionnaires*

Participants either received a paper version of the questionnaire or an e-mail with a link to complete the questionnaire online based on personal preference. Those who did not complete the questionnaire received several reminders (online = 3; paper = 1). Those not responding to these reminders and not answering any questions were considered dropouts. We included several validated questionnaires with additional questions (Supplement B).

In the absence of clear cutoff values for most questionnaires, we defined the five PFS domains as follows:

1. <u>LUTS</u>: the upper quartile of the International Consultation on Incontinence Modular Questionnaire (ICIQ)-male LUTS (ICIQ-

MLUTS[9], scores ≥9) and the ICIQ-female LUTS (ICIQ-FLUTS[9], score ≥11).

2. Defecation problems: the upper quartile of the combined Wexner incontinence and constipation scores, based on the Groningen Defecation and Fecal Continence (DeFeC) questionnaire, specifically category 1 (defecation pattern), categories 2 and 3 (fecal constipation), and category 4 (fecal continence).[10] We considered defecation problems to be present with scores ≥6 for males and ≥10 for females.
3. Sexual dysfunction: Assessed in sexually active participants using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR),[11] and one item on sexual problems from the Sexual Health in the Netherlands questionnaire.[12] Males also completed three items from the ICIQ-MLUTSsex on erectile problems and ejaculation.[9] We considered sexual dysfunction to be present in males with erectile and/or ejaculation problems and/or pain during intercourse or ejaculation; and, in females with orgasmic dysfunction and/or orgasmic problems and/or vaginismus and/or vaginal dryness and/or pain during intercourse.
4. POP: We considered prolapse to be present if a woman answered yes to four out of six items of the Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6).[13]
5. Pelvic pain: A questionnaire, constructed specifically for the study, included the following items: pain in specific pelvic floor areas (yes/no), severity of pain (on a numeric rating scale 0–10), presence of pain in time, and the origin/cause of pain. The presence of pain in the pelvic region (yes) was defined as having pelvic pain.



To see if this study is representative for the study population, we used two approaches: a survey among non-responders and evaluation of the GP medical record data.

*Survey Among Non-responders*

A randomly selected group of non-responders aged 16–80 years received a short survey, containing questions about age, sex, and education level, as well as LUTS, defecation problems, sexual problems, pelvic pain, POP (in females), help-seeking behavior, and impact on daily functioning (numeric rating scale, 0–10). We considered those who completed this short survey to be partial responders.

*GP Medical Record Data*

Dutch GPs keep electronic medical records, and for each registered patient, we could extract the following data: PFS consultations, diagnostic tests and diagnoses based on International Classification of Primary Care (ICPC) codes, treatment, and referrals, together with the health care provider's sex. Software developed for the Academic General Practitioner Development Network (AHON) of the University Medical Center Groningen (UMCG) enabled data dumps from the computer systems of participating practices. The medical record review covered a time scale from 4 years before to the baseline measurement to the end of the follow-up period in the cohort.

The medical record data of participants were matched by a trusted third party (ZorgTTP) and were combined with the questionnaire data. Combining the pseudonymized medical records from all registered patients in general practices (except those who refused data sharing) with the participation status allowed cohort participants to be compared with the general population of the municipality. Supplement C details the specific ICPC codes used.

## 2.4 Statistics

First, to test the representativity of participants to the general population, we compared comorbidity (e.g., cardiovascular disease, psychological disorders, asthma, chronic obstructive pulmonary disease, and diabetes mellitus) and PFS (e.g., LUTS, defecation problems, sexual dysfunction, pelvic pain, and prolapse) derived from the electronic medical records, using logistic regression analysis and correcting for age. We compared participants and partial responders by age, sex, and PFS comorbidity based on questionnaire responses.

Defecation problems and pelvic pain were compared between female and male participants because the same questionnaires were used for both groups. We compared between-group differences (participants versus the general population, participants versus partial responders, and female versus male participants) using independent Student *t*-tests or Mann–Whitney *U* tests for variables with skewed distributions, or the chi-square test, as appropriate. For males and females with PFS, we also calculated the prevalence of concomitant symptoms and presented the data for each main symptom in Sankey diagrams. Each diagram starts with the male or female subgroup with the specific PFS, and the data are ranked according to the largest overlap between symptoms.

# 3. RESULTS

## 3.1 Participants

Of the 11 724 people invited, 1691 (14.4%; 997 females and 694 males) returned the informed consent form. Among these, 839 females and 566 males completed all PFS parts of the questionnaire (full responders). Out of 973 non-responders, who received the short survey, 83 females and 50 males completed all PFS parts (i.e., partial responders). Medical record data from GPs were available for 766 of the 839 females and 528 of the 566 males who had complete PFS data (Figure 2).



## 3.2 Comparing Participants and the General Population

Table 1 presents the baseline characteristics of the participants in comparison to the general population. Participants were significantly older than the general population. Comorbid conditions did not significantly differ, except for diabetes mellitus in males (less prevalent in participants), LUTS in males and female (more prevalent in participants), and POP in females (more prevalent in participants).

## 3.3 Comparing Participants and Partial Responders

Participants and partial responders did not significantly differ by age (Table 2). The median number of PFS domains was higher in female participants (1.0, interquartile range [IQR] 0–2) than partial responders (1.0, IQR 0–1; $p = 0.02$), but did not differ between male participants (1.0, IQR 0–2) and partial responders (0.5, IQR 0–2; $p = 0.23$).

## 3.4 Comparing Female and Male Participants

Of the participants, 286 females (34.1%) and 212 males (37.5%) reported no PFS. Females had a higher combined Wexner score (median 6.0, IQR 3.0–10.0) than males (3.0, IQR 2.0–6.0; $p < 0.001$). Female participants also had more complaints of pelvic pain than male participants ($p < 0.001$).

## 3.5 Concomitant PFS

In total, 251 (29.9%) females and 191 (33.7%) males reported two or more concurrent PFS.

Of the 596 sexually active females, 283 (47.5%) reported sexual dysfunction, with almost half of these reporting no other PFS (Figure 3A). The most frequent concomitant PFS in this group was pelvic pain (31%), followed by defecation problems (29%), with or without another PFS.

Moreover, 14% had at least three concomitant PFS (sexual dysfunction, pelvic pain, and defecation problems) with or without another PFS; the largest groups comprised sexual dysfunction with pelvic pain (n = 35, 12.4%) or with defecation problems (n = 33, 11.7%) (Figure 3A, right end of the figure).

One-third (34%) of females with LUTS reported no other PFS (Figure 3B). Defecation problems (41%) were the most frequent concomitant PFS in those with LUTS, either with or without pelvic pain, sexual dysfunction, and POP. Concomitant LUTS and pelvic pain were present in 38%. The most prevalent clusters were LUTS with defecation problems (n = 29, 13.5%) or LUTS with defecation problems and pelvic pain (n = 26, 12.1%) (Figure 3B).

Defecation problems and pelvic pain symptoms frequently co-occurred, with 43% of females reporting defecation problems also experiencing pelvic pain, either with or without other PFS. Among the females with defecation problems, 42% also experienced LUTS with or without another PFS (Figure 3C).

Pelvic pain overlapped considerably with other PFS domains, with these women also experiencing defecation problems (45%), sexual dysfunction (43%), and LUTS (40%), with or without other PFS (Figure 3D). It was notable that POP was only reported in combination with other types of PFS (n = 14, 1.7%). Finally, about 9% reported PFS in four domains (i.e., LUTS, defecation problems, sexual dysfunction, and pelvic pain, Figures 3B–D) and three females reported PFS in all five domains.

Of the 436 sexually active males, 202 (46.3%) reported sexual dysfunction, of whom 37.1% reported no concomitant PFS and 41% reported concomitant LUTS, with or without defecation problems and/or pelvic pain. Many experienced both sexual dysfunction and LUTS (n = 40, 19.8%) (Figure 4A).

Among those with LUTS, 22.7% reported no concomitant PFS (Figure 4B) and approximately half reported concomitant defecation problems (47%) or sexual dysfunction (47%) (either with or without other PFS domains; Figure 4B). Likewise, 52% of all males who reported defecation problems had concomitant LUTS, with or without sexual dysfunction and/or pelvic pain. The most prevalent cluster was defecation problems with LUTS (n = 29, 18.2%) (Figure 4C).

Pelvic pain was reported by 88 males and overlapped considerably with other PFS domains (84.1%), with 33% reporting concomitant defecation problems and LUTS (Figure 4D). Around 20% of males experienced concomitant sexual dysfunction, LUTS, and defecation problems (Figures 4A–C), while 11 reported having PFS in all four domains.

## 4. DISCUSSION

In this study of concomitant PFS in females and males, considerable overlap existed between symptoms in the general population. As such, this study adds important information to the scarce number of studies on this topic.[5]

In female participants, we showed that sexual dysfunction and pelvic pain, sexual dysfunction and defecation problems, LUTS and defecation problems, and LUTS with defecation problems and pelvic pain were the most prevalent PFS clusters. To date, research into female PFS has typically focused on the co-occurrence of LUTS and defecation problems, especially double incontinence, either or not in combination with POP.[5] Our findings that LUTS and defecation problems co-occur supports the high prevalence found elsewhere.[14,15] MacLennan et al. found that at least two pelvic floor problems (stress or urgency UI, flatus or fecal incontinence, POP) were reported by 21.9% of women, with 8.7% experiencing three or more types.[16] In the National Health and Nutrition Examination Survey, Nygaard et al. also addressed those PFS, but did not report details of the prevalence of concomitant PFS.[17] Notably, other PFS were not taken into consideration in those studies. This highlights the finding that sexual dysfunction and pelvic pain are rarely studied in combination with other PFS.[5] The Boston Area Community Health Survey, also illustrated the large overlap between LUTS and pelvic pain in both females and males.[18]

In male participants, sexual dysfunction, LUTS, and defecation problems frequently co-occurred, in agreement with known prevalence data and the current focus in male PFS research.[19] In the large population-based survey of Donnelly et al., the co-occurrence of LUTS, bowel dysfunction and sexual dysfunction was 2.1% in males older than 60 years. This lower percentage could well be explained by differences in the used questionnaires and cut-off values.[19]

Most scientific attention on male PFS has focused on LUTS and sexual problems,[5,20] with scarce data available on concomitant PFS and pelvic pain.[18] We found that pelvic pain in males rarely manifests as a single

symptom, with almost 85% experiencing concomitant PFS (almost one in three with defecation problems and one in four with LUTS).
Although males and females can present with the same PFS, key anatomical, hormonal, neuromuscular, and behavioral differences exist that result in sex and gender differences in those symptoms.[21-23] We found that more females than males reported pelvic pain. This finding is well known in the literature and may be explained by differences in the neuroimmune system or how sex hormones influence nociceptive systems.[24] Despite these differences, we also found similarities between males and females, with sexual dysfunction notable for being the largest PFS group in both females and males, followed closely by LUTS and defecation problems.
This large cohort study benefited from the use of validated questionnaires to assess all pelvic floor domains, which both males and females completed at a single point, and the inclusion of a general adult population from a single Dutch city. These offer a solid basis from which we could gain accurate insights and conduct in-depth analysis in this and future research. However, the study also has limitations. First, the low response rate limits generalizability (external validity). Second, our participants were older than non-responders and the total population. Given that the incidence of PFS increases with age, participants likely experienced more PFS than the total population. Despite this, we only observed this expected difference for LUTS and POP when comparing data from medical records.
Third, an important consideration is the use of arbitrary questionnaire cutoff values in the absence of established values. Defining sexual dysfunction and pelvic pain as present when one or more symptoms occurred, together with the relatively low scores for LUTS and defecation problems (despite using the highest quartiles), could have led to higher numbers of those PFS. Together with the response bias, we are reluctant to present prevalence rates for the individual PFS in the general population. However, this liberal approach allowed us to find relations and overlap between PFS when few symptoms occurred. Choosing stricter, but similarly arbitrary, cutoff values may have failed to show these associations.
Next, although we did assess possible confounders and risk factors for developing PFS (e.g., vaginal delivery, heavy work, surgery, and comorbidities), we did not adjust for those factors in the current work because our main goal was only to explore concomitant symptoms.

Finally, the cross-sectional nature of this survey also limits our ability to draw conclusions on causal associations. Longitudinal studies are needed to clarify these potential associations.

## 5. CONCLUSION

This study in a general Dutch population revealed not only a large overlap between different PFS but also a difference in PFS clusters between females and males. Sexual dysfunction frequently co-occurred with pelvic pain and defecation problems in females, whereas sexual dysfunction, LUTS, and defecation problems frequently co-occurred in males. Females also reported pelvic pain more than males. These results indicate that clinicians and researchers should have a greater awareness of concomitant PFS and that health care providers should consider all PFS when assessing patients.

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## TABLES

**Table 1.** Comparing comorbidities at baseline among participants of the study and population based on International Classification of Primary Care (ICPC) codes described in GP medical record data

| | % yes (with 95% CI) | | |
|---|---|---|---|
| **Females n=6,034** | **Participants (all PFS) n=766** | **Population n=5,268** | **OR (95% CI) (adjusted for age in years)** |
| Age (years), mean±SD | 57.5±15.8 | 50.3±19.9 * | |
| Cardiovascular disease | 32.9 (29.6-36.2) | 25.6 (24.4-26.7) | 1.05 (0.87-1.26) |
| Psychological disorders | 4.6 (3.1-6.1) | 5.9 (5.3-6.6) | 0.80 (0.56-1.15) |
| Lung disease (asthma/COPD) | 8.5 (6.5-10.5) | 7.9 (7.2-8.6) | 0.95 (0.72-1.25) |
| Diabetes Mellitus type I and II | 9.4 (7.3-11.5) | 8.4 (7.6-9.1) | 0.93 (0.71-1.21) |
| LUTS | 11.1 (8.9-13.3) | 8.0 (7.3-8.8) | **1.29 (1.00-1.65)** |
| Defecation problems | 8.4 (6.4-10.3) | 7.4 (6.7-8.2) | 1.00 (0.76-1.32) |
| Sexual dysfunction | 1.4 (0.6-2.3) | 1.4 (1.1-1.7) | 1.66 (0.86-3.21) |
| Pelvic pain | 18.3 (15.5-21.0) | 17.8 (16.8-18.8) | 1.08 (0.89-1.32) |
| Prolapse | 4.3 (2.9-5.8) | 2.0 (1.6-2.4) | **1.91 (1.28-2.86)** |
| **Males n=6,047** | **Participants (all PFS) n=528** | **Population n=5,519** | |
| Age (years), mean±SD | 62.2±13.3 | 47.7±18.8 * | |
| Cardiovascular disease | 39.8 (35.6-44.0) | 22.6 (21.5-23.8) | 1.03 (0.84-1.26) |
| Psychological disorders | 1.7 (0.6-2.8) | 3.3 (2.8-3.8) | 0.53 (0.27-1.05) |
| Lung disease (asthma/COPD) | 7.6 (5.3-9.8) | 6.1 (5.5-6.8) | 0.85 (0.60-1.20) |
| Diabetes Mellitus type I and II | 12.5 (9.7-15.3) | 9.8 (9.0-10.6) | **0.71 (0.53-0.94)** |
| LUTS | 16.7 (13.5-19.9) | 7.2 (6.6-7.9) | **1.51 (1.17-1.96)** |
| Defecation problems | 5.1 (3.2-7.0) | 4.6 (4.0-5.1) | 0.72 (0.48-1.10) |
| Sexual dysfunction | 3.0 (1.6-4.5) | 1.4 (1.1-1.7) | 1.56 (0.90-2.73) |

**Table 1.** *Continued.*

| | % yes (with 95% CI) | | |
|---|---|---|---|
| **Males n=6,047** | **Participants (all PFS) n=528** | **Population n=5,519** | |
| Pelvic pain | 10.0 (7.5-12.6) | 8.5 (7.7-9.2) | 1.07 (0.79-1.46) |

*Note*: Comorbidities are based on ICPC codes described in HIS systems between March 1st, 2018 and May 16th, 2019.
Medical record data were available for *n* = 766 of the 839 females and *n* = 528 of the 566 males, who had complete PFS data.
OR adjusted for age (years), significant outcomes are given in bold.
Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; HIS (Dutch: Huisarts Informatie Systeem; GP, general practitioner; ICPC, International Classification of Primary Care; LUTS, lower urinary tract symptoms; OR, odds ratio; PFS, pelvic floor symptoms.
* $p < 0.001$.

**Table 2.** Baseline characteristics Participants and Partial responders based on the questionnaire

| | Females | | Males | |
|---|---|---|---|---|
| | **Participants n=839** | **Partial responders n=83** | **Participants n=566** | **Partial responders n=50** |
| Age, mean±SD | 57.0±16.0 | 53.8±16.5 | 62.1±13.7 | 60.4±14.1 |
| Age categories, % (n) | | | | |
| Age (16-35) | 11.6 (97) | 14.5 (12) | 4.2 (24) | 6.0 (3) |
| Age (35-55) | 27.4 (230) | 27.7 (23) | 20.1 (114) | 24.0 (12) |
| Age (55-75) | 47.9 (402) | 48.2 (40) | 59.2 (335) | 52.0 (26) |
| Age (>75) | 13.1 (110) | 9.6 (8) | 16.4 (93) | 18.0 (9) |
| **Pelvic floor symptoms (PFS), % yes (with 95% confidence interval) #** | | | | |
| LUTS | 25.6 (22.7-28.6) | 30.1 (20.3-40.0) | 31.1 (27.3-34.9) | 38.0 (24.6-51.5) |
| Defecation problems | 25.4 (22.4-28.3) | 15.7 (7.8-23.5) | 28.1 (24.4-31.8) | 12.0 (3.0-21.0) |
| Sexual dysfunction* | 47.5 (43.5-51.5) | 11.0 (4.2-17.7) | 46.3 (41.7-51.0) | 20.0 (8.9-31.1) |
| Pelvic pain | 24.3 (21.4-27.2) | 24.1 (14.9-33.3) | 15.5 (12.6-18.5) | 28.0 (15.6-40.5) |

**Table 2.** *Continued.*

| | Females | | Males | |
|---|---|---|---|---|
| | **Participants n=839** | **Partial responders n=83** | **Participants n=566** | **Partial responders n=50** |
| Prolapse | 1.7 (0.8-2.5) | 10.8 (4.2-17.5) | n.a. | n.a. |
| **Number of PFS domains, % (with 95% confidence interval)** | | | | |
| 0 | 34.1 (30.9-37.3) | 49.4 (38.6-60.2) | 37.5 (33.5-41.4) | 50.0 (36.1-63.9) |
| 1 | 36.0 (32.8-39.2) | 27.7 (18.1-37.3) | 28.8 (25.1-32.5) | 22.0 (10.5-33.5) |
| 2 | 18.6 (16.0-21.2) | 10.8 (4.2-17.5) | 21.6 (18.2-24.9) | 12.0 (3.0-21.0) |
| 3 | 8.1 (6.3-10.0) | 8.4 (2.5-14.4) | 10.2 (7.8-12.8) | 12.0 (3.0-21.0) |
| 4 | 2.9 (1.7-4.0) | 1.2 (0.0-3.6) | 1.9 (0.8-3.1) | 4.0 (0.0-9.4) |
| 5 | 0.4 (0.0-0.8) | 2.4 (0.0-5.7) | - | - |

Abbreviations: LUTS, lower urinary tract symptoms; na, not applicable.
[#] PFS based on questionnaire (for participants) and survey among initial non-responders (for partial responders).
[*] Sexual dysfunction was assessed in the sexually active males (*n* = 436) and females (*n* = 596), and female partial responders (*n* = 82).

2

## FIGURES

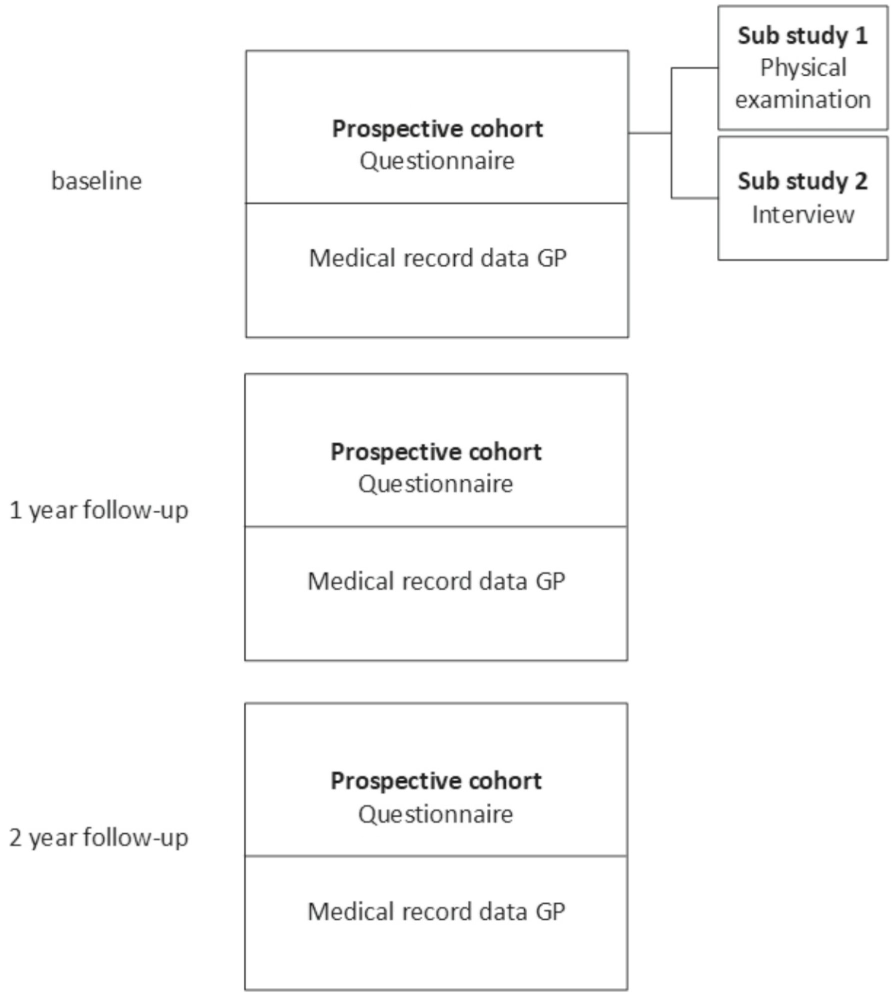



**Figure 1.** Study design. GP, general practitioners.

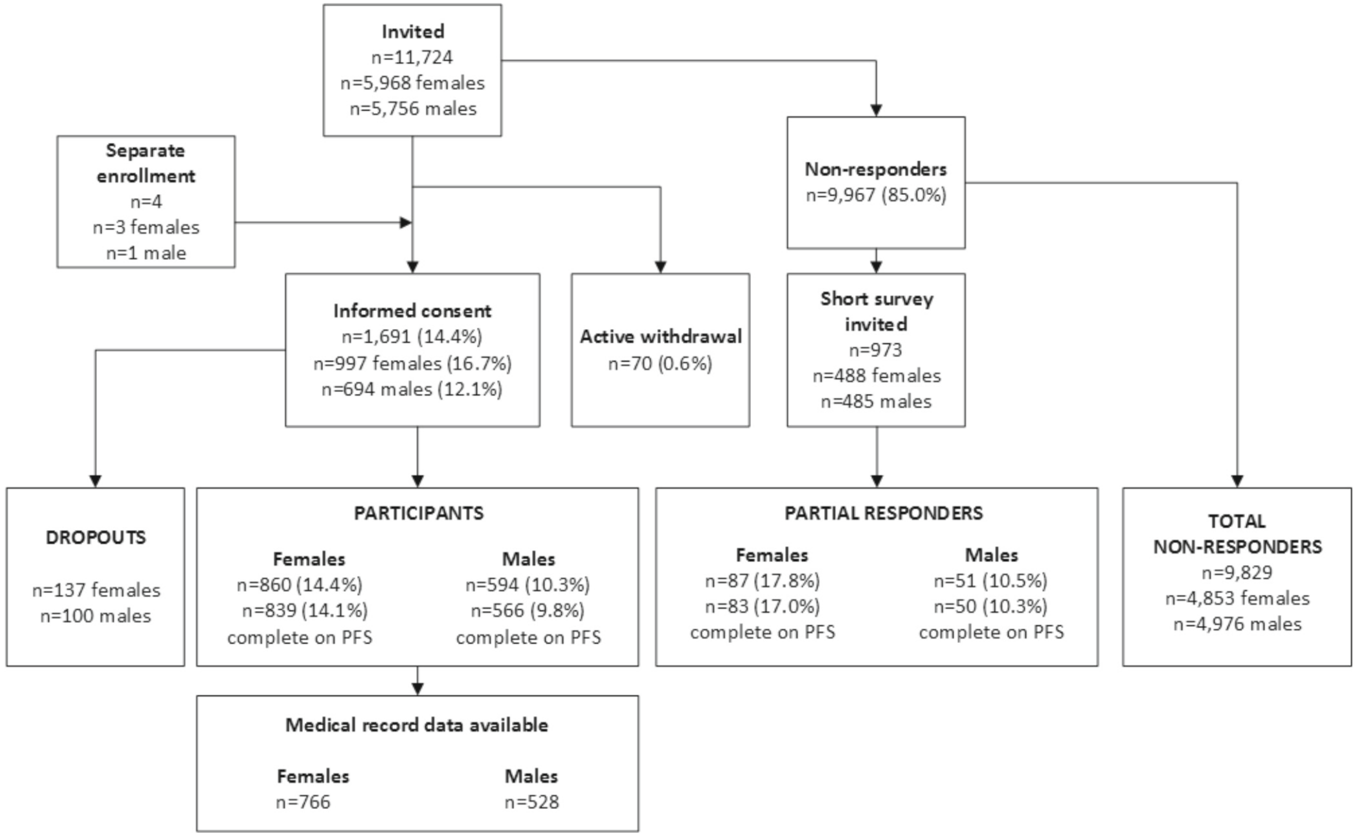



**Figure 2.** Flowchart showing the number of invitations, total number of received informed consent forms, total numbers of filled in questionnaires, and availability of medical record data (for participants). PFS, pelvic floor symptoms.

2

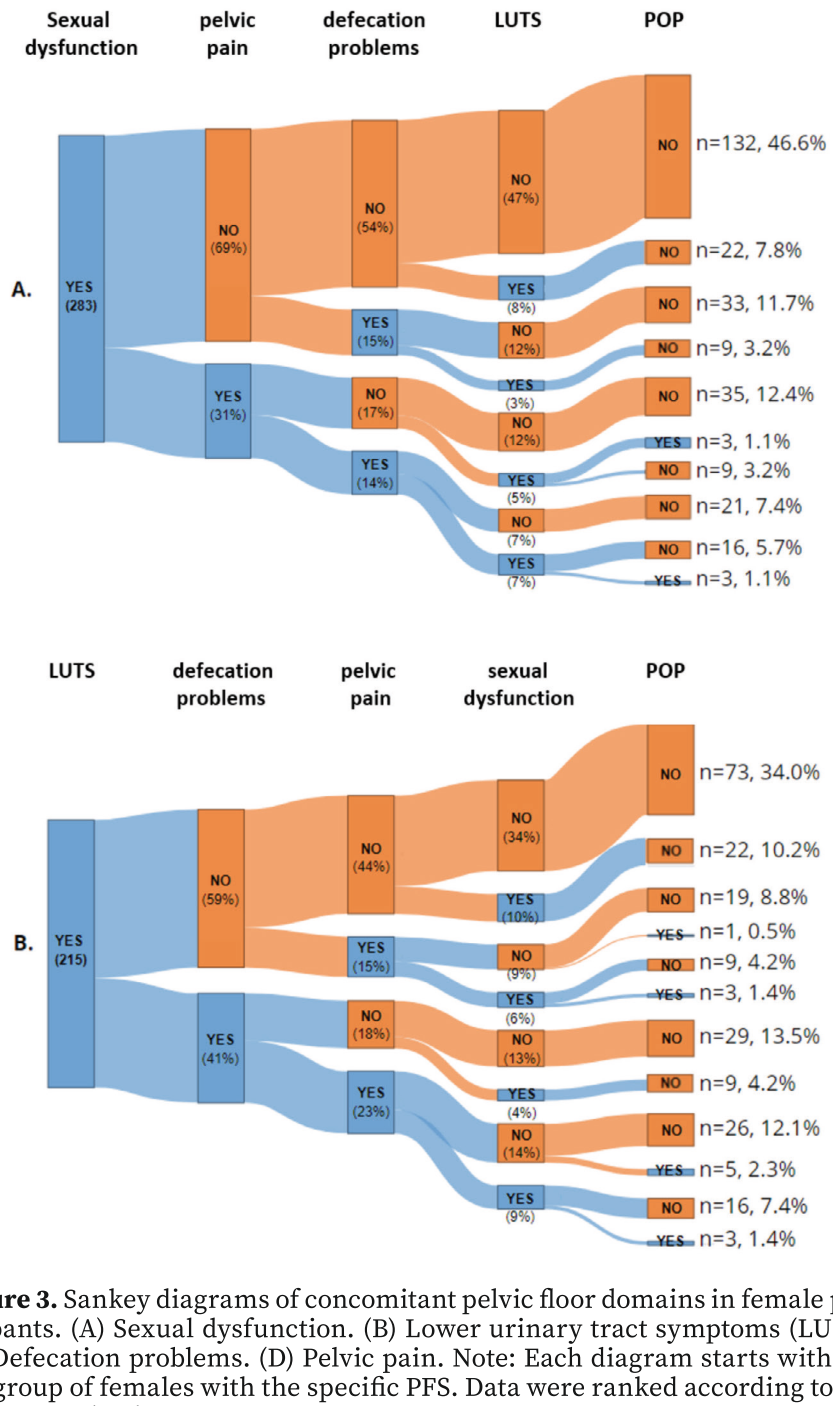
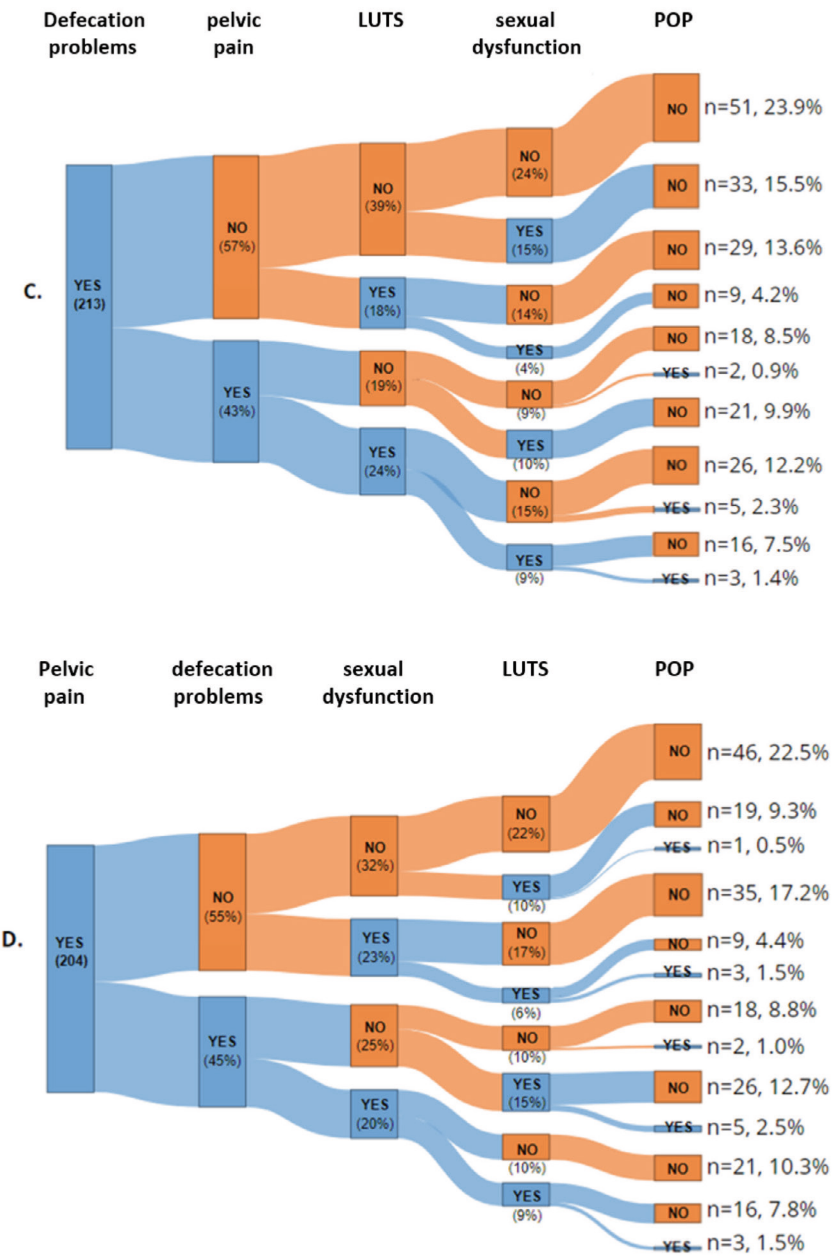



**Figure 3.** Sankey diagrams of concomitant pelvic floor domains in female participants. (A) Sexual dysfunction. (B) Lower urinary tract symptoms (LUTS). (C) Defecation problems. (D) Pelvic pain. Note: Each diagram starts with the subgroup of females with the specific PFS. Data were ranked according to the largest overlap between symptoms.




For example: (A) starts with n = 283 (of the 596 sexually active) females having sexual dysfunction, of which 69% experience no pelvic pain (in red) and 31% do experience pelvic pain (in blue), and so forth. The overlap between sexual dysfunction and pelvic pain was the largest, followed by sexual dysfunction and defecation problems, sexual dysfunction and LUTS, and sexual dysfunction and POP. POP, pelvic organ prolapse.

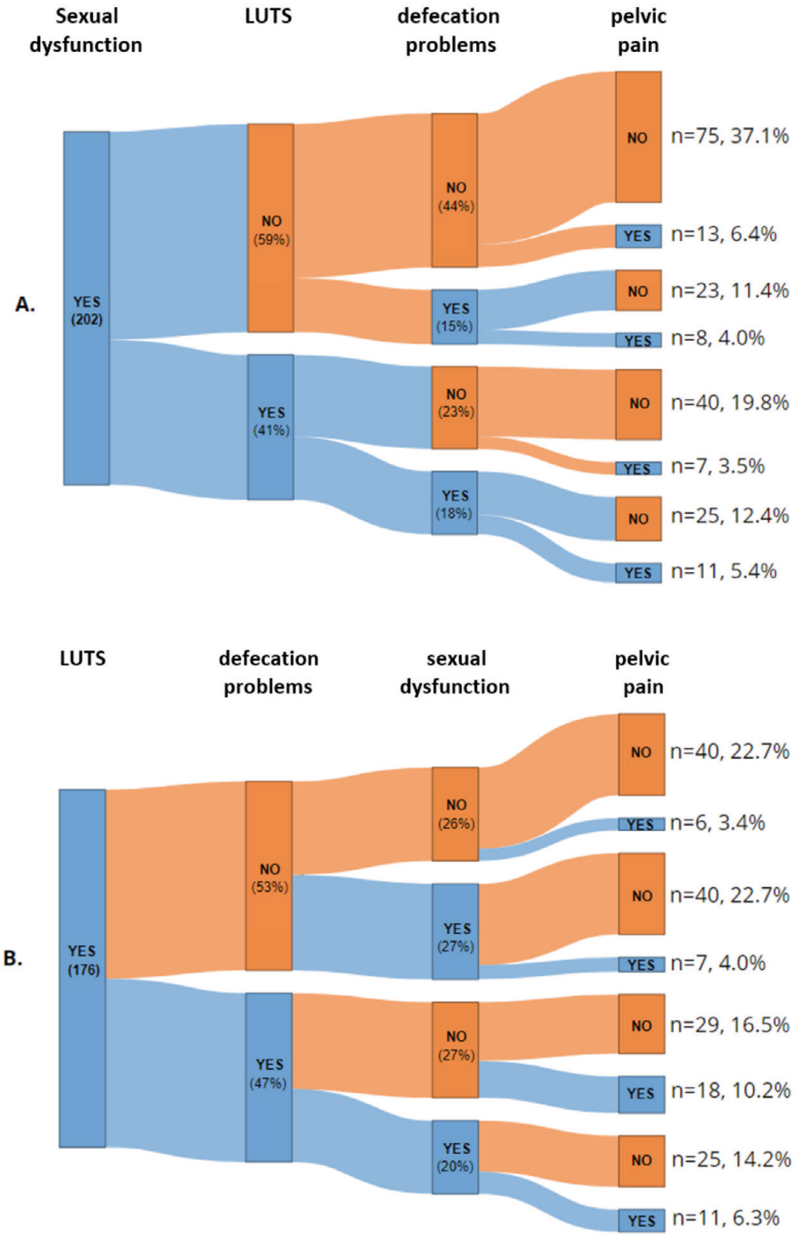
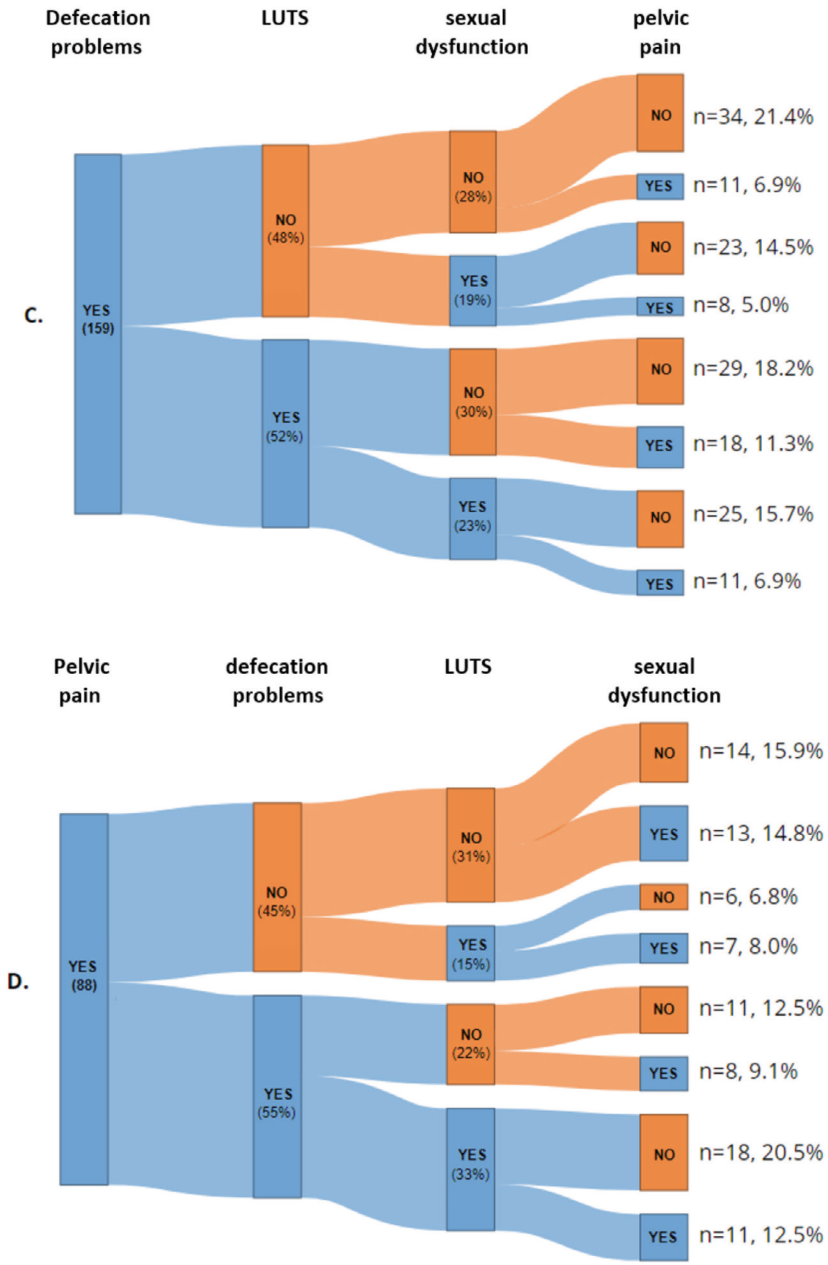



**Figure 4.** Sankey diagrams of concomitant pelvic floor domains in male participants. (A) Sexual dysfunction. (B) Lower urinary tract symptoms (LUTS). (C) Defecation problems. (D) Pelvic pain. Note: Each diagram starts with the subgroup of males with the specific PFS. Data were ranked according to the largest overlap between symptoms.

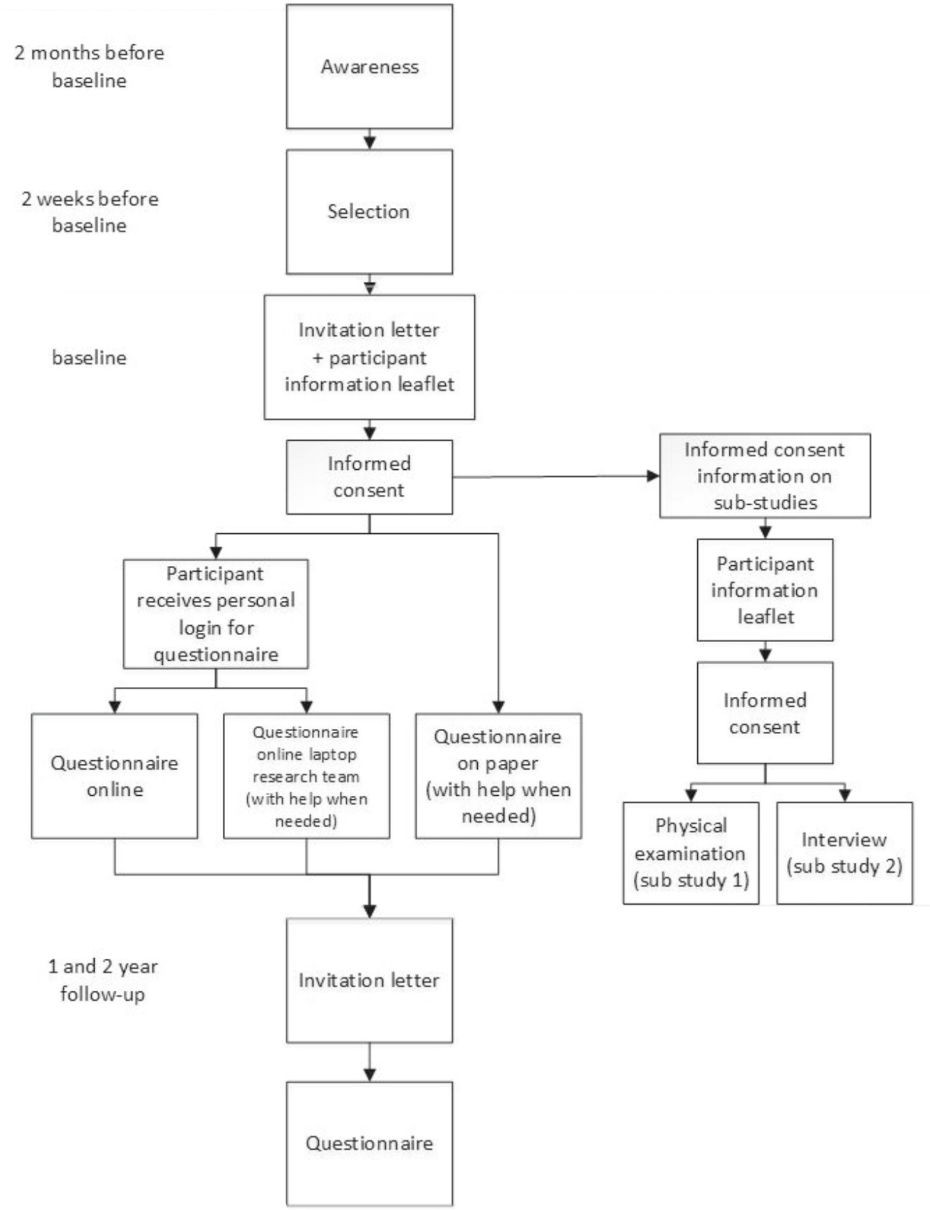



For example, (A) starts with n = 202 (of the 436 sexually active) males having sexual dysfunction, of which 59% experience no LUTS (in red) and 41% do experience LUTS (in blue), and so forth. The overlap between sexual dysfunction and LUTS was the largest, followed by sexual dysfunction and defecation problems, and sexual dysfunction and pelvic pain. PFS, pelvic floor symptoms.

2

# SUPPLEMENTARY FILES

## Supplementary file 1. Study procedures



**Supplementary file 2. Categories of data used in the questionnaire (in order of appearance in the questionnaire)**

**<u>Subject characteristics</u>**
Age, sex, gender identity, ethnicity, religion, sexual orientation, living situation and household/childcare tasks.
<u>Questionnaires used:</u>
- Healthy Life in an Urban Setting (HELIUS) questionnaire [1]
- *Seksuele Gezondheid in Nederland* (SGIN) *(Sexual Health in The Netherlands)* questionnaire [2]



**<u>Health and lifestyle</u>**
Length, weight, smoking status, physical activity, performing heavy physical work, general health perception, history of pelvic floor related surgery, characteristics of pregnancy, delivery and menopause (females only).
<u>Questionnaires used:</u>
- 'general health subscale' of the short form health survey (SF-36) [3]
- corresponding items of the Dutch Society of Obstetrics and Gynecology (NVOG) questionnaire[4]

**<u>Lower urinary tract symptoms</u>**
<u>Questionnaires used:</u>
- <u>Males:</u> The International Consultation on Incontinence Modular Questionnaire (ICIQ)-male LUTS (ICIQ-MLUTS) [5], a validated 13-item patient-completed questionnaire. Each question is scored 0–4; There are two subscales: voiding symptoms subscale (score 0-20), and the incontinence symptoms subscale (score 0-24). Higher scores indicate greater impact of individual symptoms for the participant
- <u>Females:</u> ICIQ-female LUTS (ICIQ-FLUTS) [6], a validated 12-item patient-completed questionnaire. Each question is scored 0–4; There are 3 subscales: filling symptoms subscale (score 0-16), voiding symptoms subscale (score 0-12), and the incontinence symptoms subscale (score 0-20). Higher scores indicate greater impact of individual symptoms for the participant

**Defecation problems**

Questionnaire used:

- Categories 1 (defecation pattern), 2 and 3 (fecal constipation), and 4 (fecal continence) of the Groningen Defecation and Fecal Continence (DeFeC) questionnaire [7], a patient-completed questionnaire, based on several validated constipation and fecal incontinence scores (Wexner, Vaizey) [8]

**Urogenital prolapse symptoms (females only)**

Questionnaire used:

- Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), which are items 1-6 (prolapse scale) of the Pelvic Floor Distress Inventory (PFDI)-20 [9,10], a patient-completed symptom inventory and a measure of the degree of bother and distress (quality-of-life) caused by pelvic floor symptoms. Presence of symptoms is assessed as yes versus no

**Sexual functioning**

Questionnaires used:

- The Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR) [11,12], a patient-completed measure of sexual function in females with pelvic floor disorders. Although developed for female subjects, most items are gender neutral and therefore, male subjects can answer this questionnaire as well
- One question on sexual problems (item M1 of the SGIN questionnaire)[2]
- Males: Three items from the ICIQ-MLUTSsex [13] on erection problems, and ejaculation

**Physical, emotional and sexual trauma**

Questionnaires used:

- The NEMISIS Childhood trauma questionnaire, which assesses negative events in 4 items (emotional neglect, psychological abuse, physical abuse and sexual abuse) (part 42 HELIUS) [1]. Each type of abuse is scored on a 5-point Likert scale
- One question on bullying (‘Have you been bullied in the past?’), scored on a 5-point Likert scale

<u>**Pelvic Pain**</u>
<u>Questionnaire used:</u>

- Self-constructed questionnaire including items on pain in specific (pelvic floor) areas, severity of pain (on NRS scale 0-10), presence of pain in time, origin/cause of pain

<u>**Education and economic participation**</u>
<u>Questionnaire used:</u>

- Relevant items from the iMTA Productivity Cost Questionnaire (iMTA-PCQ) [14] to assess education level, work and income. Items on informal care were added in order to generate 'gender role'

2

<u>**Wellbeing**</u>
<u>Questionnaires used:</u>

- The patient health questionnaire (PHQ-9) [15], a 9-item patient-completed diagnostic instrument for common mental disorders and to screen for the presence and severity of depression. Items are scored on a 4-point Likert scale (0-3), with higher scores indicating higher levels of depression
- Five items that assess coping style (HELIUS questionnaire part 40) [1]

<u>**Social impact of pelvic complaints**</u>
<u>Questionnaire used:</u>

- The Pelvic Floor Impact Questionnaire (PFIQ-7), which assesses life impact in females with pelvic floor disorders [9,10]. Although this questionnaire has been developed for and validated among female subjects to assess the impact of bowel dysfunction, urinary dysfunction and pelvic organ prolapse (POP) on health related quality of life, the PFIQ-7 was also used in our cohort for male subjects, without the 7 questions on POP. Each of the 7 questions is scored on a 4-point Likert-scale, with higher scores indicating higher impact

In case of overlap with another question or questionnaire, specific subscales or categories were used, to prevent that subjects had to fill in the same (type of) question more than once, thereby reducing the efforts required from participants. In case of a questionnaire, developed specifically for females, and unavailability of a specific comparable questionnaire for males, the female questionnaire was adjusted so that males could fill it in as well.

Per specific PFS, additional questions were asked about the duration of the symptom (how long ago the symptoms started), help seeking behavior (‘if you had symptoms, did you seek help?’, If yes, help from…’ If no, why not?), impact on daily life (NRS scale 0-10), and use of medication (yes/no).

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## Supplementary file 3. Comorbidities according to the International Classification of Primary Care 1st edition (ICPC-1)

| Code | Description | Type |
|---|---|---|
| K74 | Ischaemic heart disease with angina | Cardiovascular |
| K75 | Acute myocardial infarction | Cardiovascular |
| K76 | Ischaemic heart disease without angina | Cardiovascular |
| K77 | Heart failure | Cardiovascular |
| K78 | Atrial fibrillation/flutter | Cardiovascular |
| K79 | Paroxysmal tachycardia | Cardiovascular |
| K80 | Cardiac arrhythmia not otherwise specified | Cardiovascular |
| K81 | Heart/arterial murmur not otherwise specified | Cardiovascular |
| K82 | Pulmonary heart disease | Cardiovascular |
| K83 | Heart valve disease not otherwise specified | Cardiovascular |
| K84 | Heart disease other | Cardiovascular |
| K85 | Elevated blood pressure | Cardiovascular |
| K86 | Hypertension uncomplicated | Cardiovascular |
| K87 | Hypertension complicated | Cardiovascular |
| K92 | Atherosclerosis/PVD | Cardiovascular |
| K93 | Pulmonary embolism | Cardiovascular |
| K94 | Phlebitis/thrombophlebitis | Cardiovascular |
| P74 | Anxiety disorder/anxiety state | Psychological |
| P74.01 | Panic disorder | Psychological |
| P74.02 | Generalized anxiety disorder | Psychological |
| P76 | Depressive disorder | Psychological |
| R95 | Chronic obstructive pulmonary disease | Pulmonary |
| R96 | Asthma | Pulmonary |
| T83 | Overweight | Overweight |
| T90 | Diabetes non-insulin dependent | Diabetes mellitus |

| Pelvic floor symptoms | | |
|---|---|---|
| **Code** | **Description** | **Type** |
| P12 | Bedwetting/enuresis | Lower urinary tract symptoms |
| P13 | Encopresis/bowel training problem | Lower urinary tract symptoms |
| U01 | Dysuria/painful urination | Lower urinary tract symptoms |
| U02 | Urinary frequency/urgency | Lower urinary tract symptoms |
| U04 | Incontinence urine | Lower urinary tract symptoms |
| U05 | Urination problems other | Lower urinary tract symptoms |
| U07 | Urine symptom/complaint other | Lower urinary tract symptoms |
| U13 | Bladder symptom/complaint other | Lower urinary tract symptoms |
| Y06 | Prostate symptom/complaint | Lower urinary tract symptoms |
| D04 | Rectal/anal pain | Defecation problems |
| D08 | Flatulence/gas/belching | Defecation problems |
| D12 | Constipation | Defecation problems |
| D17 | Incontinence of bowel | Defecation problems |
| D18 | Change faeces/bowel movements | Defecation problems |
| P07 | Sexual desire reduced | Sexual problems |
| P08 | Sexual fulfilment reduced | Sexual problems |
| X04 | Painful intercourse female | Sexual problems |
| X13 | Postcoital bleeding | Sexual problems |
| Y07 | Impotence NOS | Sexual problems |
| Y08 | Sexual function sympt./complt. (m) | Sexual problems |
| D01 | Abdominal pain/cramps general | Pain |
| D06 | Abdominal pain localized other | Pain |
| X01 | Genital pain female | Pain |
| X03 | Intermenstrual pain | Pain |
| Y01 | Pain in penis | Pain |
| Y02 | Pain in testis/scrotum | Pain |
| X87 | Uterovaginal prolapse | Pelvic organ prolapse |
| X15 | Vaginal symptom/complaint other | Other |
| X16 | Vulval symptom/complaint | Other |

| Pelvic floor symptoms | | |
|---|---|---|
| **Code** | **Description** | **Type** |
| X17 | Pelvis symptom/complaint female | Other |
| Y04 | Penis symptom/complaint other | Other |
| Y05 | Scrotum/testis sympt./complt. other | Other |
| Y28 | Limited function/disability (y) | Other |
| Y29 | Genital sympt./complt. male other | Other |

# 3

# Exploring pelvic floor muscle function in men with and without pelvic floor symptoms: a population-based study

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## ABSTRACT

**Background**
Pelvic floor symptoms (PFS), such as lower urinary tract symptoms, defecation disorders, sexual problems, and genital-pelvic pain, are prevalent in men. Thorough physical assessments of the external anal sphincter (EAS) and the puborectal muscle (PRM) are the keys to unraveling the role of muscle dysfunction.

**Objectives**
To explore associations within and between the EAS and PRM and between muscle (dys-) function and the number of male PFS.

**Methods**
This cross-sectional study purposively enrolled men aged ≥21 years with 0–4 symptoms from a larger study. After extensive external and internal digital pelvic floor assessment, we explored (1) agreement between muscle function of the EAS versus PRM (using cross tabulation), (2) associations within and between the EAS and PRM (using heatmaps), and (3) associations between muscle function and number of PFS (using a visual presentation (heatmaps) and $\chi^2$ tests).

**Results**
Overall, 42 out of 199 men (21%) had completely normal muscle function. Sixty-six (33.2%) had no symptoms, of which 53 (80%) had some degree of muscle dysfunction. No clear dose-response relationship existed between muscle (dys-) function and the number of symptoms. The PRM showed both more dysfunction and severer dysfunction than the EAS.

**Conclusions**
No clear association exists between muscle dysfunction and the number of symptoms, and the absence of PFS does not indicate normal muscle function for all men. Dysfunction levels are highest for the PRM. Further pelvic floor muscle research is warranted in men with PFS.


Keywords: digital assessment; heatmap; male pelvic floor musculature; male pelvic floor symptoms.

## 1. INTRODUCTION

Dysfunction of the pelvic floor musculature in males has mainly been studied in isolation for pain, defecation, and sexual conditions (1). To date, no study has explored the relationship between pelvic floor muscle function and multiple pelvic floor symptoms (PFS) in males, contrasting starkly with research into female muscle function (2). Equally, no prevalence study has focused on the relationship within and between male pelvic floor muscle function. This is surprising given that the male pelvic floor musculature forms an essential component of the urogenital and bowel mechanism, having complex, coordinated, and bidirectional interplay with the prostate, bladder, and intestines for continence, urination, defecation, and sexual intercourse (3). Indeed, clear scope exists for an association between the pelvic floor musculature and PFS. We therefore started a large prospective cohort study to explore presence of concomitant PFS in a general population, applying diagnostics that are generally available in daily care for men with different PFS, especially physical examination.

In the current sub-study, we describe the outcomes of physical assessment of the external anal sphincter (EAS) and puborectal muscle (PRM). Although the EAS and PRM are anatomically close to each other, outcomes by separate assessment, may have implications for pelvic floor muscle treatment. The physical assessment involved assessing the complexity of muscle function by testing the hypothesis that (A) EAS dysfunction coincides with PRM dysfunction, and (B) male pelvic floor muscle dysfunction is associated with the number of PFS.

## 2. MATERIALS AND METHODS

### 2.1. Study design, setting, and participants

This cross-sectional study is part of a larger observational cohort study that will be detailed in a separate article. In short, through GPs, we invited people aged ≥16 years living in a Dutch municipal area and asked them to complete an initial questionnaire study and to take part in subsequent sub-studies. People with terminal illnesses, cognitive impairment (e.g., due to dementia) precluding informed consent, current psychological condition precluding informed consent, not suitable or too ill to participate based on the judgement of the GP, were excluded.

The current sub-study, conducted between July 2019 and January 2020, used purposive sampling from the total group participants to enroll men aged ≥21 years, with and without PFS, who had completed the initial questionnaire study. With this sampling method, we aimed to include a broad range of PFS (100 men with one or more PFS), allowing to compare groups with men without PFS (n = 100). As such, outcomes cannot be generalized to the overall study population.
Eligible participants received written information about the muscle function assessment, and confirmed their willingness to take part in the current sub-study. The study was approved by the medical ethical committee. All participants provided written informed consent and received a €20 gift card for participating in this sub-study.

### 2.2. Pelvic floor symptoms

We were interested in lower urinary tract symptoms (LUTS), bowel symptoms, sexual disorders, and pain defined according to the terminology of the International Continence Society (ICS) (4,5). Responses to the following questionnaires were used to determine the presence or absence of these symptoms: LUTS were identified using the International Consultation on Incontinence Questionnaire–Male LUTS Module (ICIQ-mLUTS) (6); bowel symptoms, using the Groningen Defecation and Fecal Continence (DeFeC) questionnaire (7); sexual symptoms, using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR) (8), item M1 of the Sexual Health in the Netherlands questionnaire (9), and the ICIQ-Male Sexual Matters Associated with LUTS Module for sexual dysfunction (ICIQ-MLUTS-5sex) (6); and pain, using a questionnaire constructed for the parent study that included items on pain in specific areas. Although we aimed to use the symptom scores of these questionnaires to define the presence or absence of a given symptom, most lacked established cut-off values. Therefore, we used upper quartiles when interpreting the presence of lower urinary tract and bowel symptoms. To define absence of lower urinary tract and bowel symptoms, the lowest quartile was used. Presence or absence was used when interpreting sexual dysfunction and pain. Participants were grouped by the number of affected domains, from zero to four, and age, aiming to achieve an equal age distribution in each category. Supplementary File 1 details the questionnaires and sampling procedure.

## 2.3. Pelvic floor assessment

Digital pelvic floor musculature assessment was performed by a pelvic floor physical therapist with ample experience, according to an ICS protocol for pelvic floor physical therapy, using digital, external (per perineum), and internal (per rectum) assessments (4,5,10). The assessment included external visual inspection of the anal region and internal digital palpation of the EAS and the PRM (Supplementary File 2). No data are available on the inter-tester and intra-tester reliability of this assessment in men, as previous research was limited to vaginal assessment in women. To reduce the risk of observer bias (especially confirmation bias), the pelvic floor physical therapist was blinded to the PFS status of the participant.

In the absence of clear definitions, we categorized the different assessment items according to our definitions of normal or abnormal pelvic floor muscle function, ICS standards, and established protocols (4,5,10). Table 1 summarizes the definitions of normal function, the items used in the digital assessment of the EAS and PRM, and the assessment outcome codes.

As we did not focus on LUTS as a single PFS, but on the co-occurrence of different PFS, we did not assess urethral sphincter (dys-) function, as for this, invasive techniques are needed.



## 2.4. Statistical analysis

Patient characteristics are presented as absolute numbers and percentages or as means and standard deviations, as appropriate. Analysis was then conducted as follows. First, to identify possible agreement between (dys-) function of the EAS and PRM and to detect if any disagreements showed directionality, we cross-tabulated the different elements of each pelvic floor muscle assessment. Second, we constructed two heatmaps to visualize possible relationships within and between the EAS and PRM, as well as between the function items of both muscles. Third, we constructed four heatmaps to visualize the relationship between the items of the EAS and the PRM (dys-) function and the presence of symptoms according to the number of domains affected (0–4). The heatmaps created graphical representations of the data in different colors to help identify patterns or associations (11). It helps to give an overview of patterns in a complexity of data. Finally, using our definitions of normal pelvic floor muscle function, we performed $\chi^2$ tests to assess the percentage of men with completely normal function by assessment item in relation to the number of PFS, as compared to abnormal function of the EAS and PRM. Due to the exploratory nature of this study, we refrained from further statistical testing.

## 3. RESULTS

### 3.1. Participants and descriptive statistics

Of the 400 men invited, 199 took part in the full assessment of pelvic floor muscle function (mean age, 63.0 ± 12.5 years). Among these, the mean body mass index was 27.3 ± 3.7 kg/m$^2$, 22 (11.1%) smoked, and 49 (24.6%) did heavy work. Furthermore, 7 (3.5%) had undergone bladder surgery, 19 (9.5%) bowel surgery, 11 (5.5%) anal or perineal surgery, and 21 (10.6%) prostate surgery. Sixty-six men (33.2%) reported no PFS (Figure 1).

### 3.2. Agreement of EAS and PRM items

We found that two function items, “voluntary contraction” (182 men; 91.4%) and “frequency of maximum voluntary” contractions (180 men; 90.5%), exhibited the best agreement between the EAS and PRM. We observed complete “voluntary relaxation” of both the EAS and PRM in 70 men (35.2%), partial “voluntary relaxation” in 28 (14.1%), and no “voluntary relaxation” in 8 (4.0%). In 53 men (26.6%), complete “voluntary relaxation” of the EAS coincided with partial “voluntary relaxation” of the PRM. In 52 men (26.1%), normal EAS “tone” coincided with increased PRM “tone”. For “maximum voluntary contraction”, normal function of one muscle coincided with strong and weak contraction of the other muscle in 21 (10.6%) and 43 (21.6%) men, respectively (Supplementary File 3).

### 3.3. Association within and between pelvic floor muscles

Forty-two men (21%) had a completely normal EAS and PRM function. No clear pattern of association was evident within the EAS (Figure 2A), but there appeared to be an association between decreased or increased “tone” and dysfunctional “voluntary relaxation,” “maximum voluntary contraction,” and “anorectal angle” within the PRM. However, there was no clear pattern of association between the EAS and PRM.

### 3.4. Association between the items of the pelvic floor muscles

We observed possible dysfunction at the item level for both muscle groups in the "voluntary relaxation," "tone," and "maximum voluntary contraction" domains (Figure 2B). These patterns appeared to be one-directional, with dysfunction of the EAS corresponding to dysfunction of the PRM, but not the other way around. Generally, the PRM showed both more dysfunction and more severe dysfunction compared to the EAS.

### 3.5. Association between muscle (dys-) function and the number of PFS

The PRM showed more dysfunction compared to the EAS in all groups. There was no clear dose-response relationship between the number of PFS and the presence of pelvic floor muscle dysfunction. Of the 66 men without PFS, 53 (80%) had some degree of muscle dysfunction (Figure 3). Table 2 shows an overview of the percentages of men with EAS and PRM dysfunction by assessment item. Percentages of EAS "tone" and EAS "voluntary relaxation" dysfunction were higher in asymptomatic men, while EAS "voluntary contraction" and "EAS closed" dysfunction were highest in men with two symptoms and EAS "maximum voluntary contraction" was highest in men with one symptom. Concerning the PRM, approximately half had dysfunctional "tone" (either increased or decreased) and more than half had dysfunctional "voluntary relaxation", which was highest in the group with two symptoms.

Finally, we found no significant difference between the number of symptom domains (0–4) and either normal or abnormal muscle function (EAS and PRM) ($\chi^2$ test, $P = 0.88$).

## 4. DISCUSSION

In this exploratory study of men with and without PFS, we hypothesized that EAS and PRM dysfunction would coincide, and that pelvic floor muscle dysfunction would be associated with the number of symptom domains affected. Our data add to knowledge about male pelvic floor muscle (dys-) function in relation to PFS.

Overall, no clear dose-response relationship existed between the number of PFS and pelvic floor muscle (dys-) function. Our findings suggest that associations may be present within the PRM between tone dysfunction and "voluntary relaxation," "maximum voluntary contraction," and “anorectal angle.” A possible one-sided dysfunction was seen at the item level for the EAS and the PRM in the “voluntary relaxation,” “tone,” and “maximum voluntary contraction” domains. In general, the PRM showed not only more dysfunction, but also more severe dysfunction compared with the EAS, typically in the presence of two PFS. So, despite EAS and PRM being anatomically close to each other, the separate assessment revealed notable differences, that could have implications for pelvic floor muscle treatment.

Micturition, sexual, and defecation processes may be affected by suboptimal function of the pelvic floor muscles and the pelvic organs and by factors such as higher age, prostate surgery, obesity, chronic obstipation, and stress reactions (12,13). The complexity of male pelvic floor musculature anatomy and function, and the lack of a gold-standard for the assessment and diagnosis of male pelvic floor musculature (dys-) function makes research a challenge (14). Cross-tabulation showed that in 26.1% a normal “tone” of the EAS coincided with an increased “tone” of the PRM. Although the pain, reported by 22.1% may partly explain this result, it does not fully explain the difference in tone. Hetrick et al. showed that men with chronic pelvic pain syndrome had a higher resting tone than controls, but found no difference between the different male pelvic floor muscles (15). Pelvic floor muscle tone assessment is considered difficult due to the influence of neurological and neuromuscular processes, emotion, pain, and contractile and viscoelastic tissue functionality, among which palpation alone cannot discriminate (5,16). To the best of our knowledge, no other study has described the differences in tone within and between male pelvic floor muscles by digital assessment. Cross-tabulation showed normal “voluntary relaxation” of the EAS and partial “voluntary relaxation” of the PRM in 26.6% of men. This is consistent with the more dysfunctional relaxation of the PRM what we found, compared to the EAS in men (Figures 2 and 3). Partial or absent voluntary relaxation may result from increased pelvic floor muscle tone due to pain or discomfort in the pelvic region (4,17). Cross-tabulation also showed impaired “maximum voluntary contraction” of the PRM compared to the EAS in 24.1%. This could result from prolonged overactivity of the PRM and reduced blood flow in the internal pudendal artery and venous systems causing muscle fatigue (5,18). The difference in function between muscles could be explained by the difficulty to contract the PRM due to its location within the pelvis. Indeed, some studies have shown that females were either unable or had difficulty performing a correct deep pelvic floor muscle contraction during assessment (19).

The heatmaps revealed comparable results for the EAS and the PRM at the item level for "voluntary relaxation," "tone," and "maximum voluntary contraction." The literature reveals no strict consensus about the relationship between the EAS and the PRM, though several studies have found connections between the two muscles. This supports the general approach that they act as a functional unit for holding and passing urine and feces (3,14,20). However, the PRM and EAS have also been reported to have phylogenetically different innervations, indicating some dichotomy between the muscles (21).

Contrary to our expectations, no linear relationship existed between the number of PFS and the presence of pelvic floor muscle dysfunction. Our choices of cut-off values for lower urinary tract and defecation symptoms, and the fact that we only assessed the number of PFS, could account for these results. Equally, the overrepresentation of some symptom combinations and no discrimination of symptoms within a domain might have influenced the results. Moreover, our findings suggest that pelvic floor muscle function might be influenced by a participant's sensitivity and awareness of the pelvic floor muscles, their concentration during the muscle assessment, the influence of other muscles for motor control of the pelvic ring and lower spine, the urge for bowel movement or flatus during assessment, as well as the severity and degree of PFS, the intimacy of the assessment, and the presence of bladder, prostate, or intestinal conditions (22). Pelvic floor function could also have been influenced by experiences in earlier pelvic floor musculature assessment or medical assessments, sexuality, and history of sexual abuse (23).

This exploratory study benefited from focusing on the associations within and between EAS and PRM function and their relationship to the number of pelvic floor symptom domains. Furthermore, we included men of all ages with and without PFS, and we used validated questionnaires with clear cut-off values. We identified differences in muscle function by thorough pelvic floor musculature assessment that prevented undesirable activity in other muscles, with the same well-experienced pelvic floor physical therapist performing all assessments (24). As such, inter-rater reliability issues were not present, but intra-rater reliability might limit the outcomes of our study. We are unaware of previous studies on the inter-rater and intra-rater reliability in male pelvic floor assessment, reflecting a lack of studies on the male pelvic

floor. To support health care professionals, we applied methods which are easily available, especially digital assessment. Other methods, like ultrasound or Magnetic Resonance Imaging (MRI) could reveal different outcomes, but are less feasible to apply in general care. Despite these strengths, important limitations should be considered. Most men were aged 55–75 years, skewing the age distribution and precluding extrapolation to general male populations. Furthermore, we only focused on functional aspects of the pelvic floor musculature and on the number of PFS domains. Analysis of specific male PFS within the four studied domains, coupled with analysis of symptom severity, could have affected the results and is warranted for future studies. Further evaluation of pelvic floor musculature in association with key symptoms could be valuable, as well as the analysis of electromyographic data that were collected in this study as well.
In the context of objective measurement, we could have reported timing, speed of contraction and coordination, but since these outcomes can be more precisely verified by electromyography, we decided not to perform these assessments. However, these data may give additional insight, but as such data are not readily available in general practice, and to keep an overview of all data, we kept this aside in the current study.
Despite these limitations, we think this study will help to unravel the complexity of pelvic floor musculature function in relation to PFS in men.

## 5. CONCLUSION

We found no clear dose-response relationship between the number of PFS and the presence of pelvic floor musculature dysfunction. Interestingly, one in three had no symptoms but only one in five of all men had a complete normal muscle function. Of the men without PFS, most had some degree of muscle dysfunction. This could indicate either that these men had not yet noticed the PFS or that the pelvic floor muscle dysfunction was situational and influenced by other factors than the PFS during the assessment. In general, we found no clear pattern of association between the EAS and the PRM, and PRM showed more dysfunction than the EAS. We now plan to analyze pelvic floor muscle function by the severity of specific PFS in males. Hopefully, our studies will stimulate further research into male pelvic floor muscle function, seeking to unravel the complex relationship with PFS.

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# TABLES

**Table 1.** Digital pelvic floor muscle assessment items, definitions of normal function, and pelvic floor muscle assessment outcome codes for heatmaps

| | EAS | | PRM | |
|---|---|---|---|---|
| **Item** | **Description** | **Normal function (heatmap)** | **Description** | **Normal function (heatmap)** |
| Tone | - **Normal**<br>- Decreased<br>- Increased | **0 = normal tone**<br>1 = decreased/increased tone | - **Normal**<br>- Decreased<br>- Increased | **0 = normal tone**<br>1 = decrease/increase tone |
| Voluntary contraction | - **Yes, circular closing and contraction in cephalad ventral direction**<br>- Straining<br>- No, no movement | **0 = yes**<br>0.5 = straining<br>1 = no, no movement | - **Yes, in cephalad-ventral direction**<br>- Straining<br>- No, no movement | **0 = yes**<br>0.5 = straining<br>1 = no, no movement |
| Voluntary relaxation (after contraction) | - **Yes: relaxation felt after instruction; normal finding**<br>-<br>Partial or delayed relaxation<br>-<br>No: Absent=non relaxation PFM | **0 = complete (delayed) relaxation**<br>0.5 = partial or delayed relaxation<br>1 = no relaxation | - **Yes: relaxation felt after instruction: normal finding**<br>- Partial relaxation<br>-<br>No: Absent=non relaxation PFM | **0 = complete relaxation**<br>0.5 = partial relaxation<br>1 = no relaxation |

**Table 1.** *Continued.*

| | EAS | | PRM | |
|---|---|---|---|---|
| **Item** | **Description** | **Normal function (heatmap)** | **Description** | **Normal function (heatmap)** |
| Strength: maximum voluntary contraction | - **Strong**<br>- **Normal (moderate)**<br>- Weak<br>- Absent | **0 = strong/normal (moderate)**<br>0.5 = weak<br>1 = absent | - **Strong**<br>- **Normal (moderate)**<br>- Weak<br>- Absent | **0 = strong/normal (moderate)**<br>0.5 = weak<br>1 = absent |
| Repeatability of contraction (frequency of maximum voluntary contraction (1 s) | - **10 times**<br>- **7–9 times**<br>- 4–6 times<br>- 1–3 times<br>- 0 times | **0 = 7–10 times**<br>0.33 = 4–6 times<br>0.66 = 1–3 times<br>1 = 0 times | - **10 times**<br>- **7–9 times**<br>- 4–6 times<br>- 1–3 times<br>- 0 times | **0 = 7–10 times**<br>0.33 = 4–6 times<br>0.66 = 1–3 times<br>1 = 0 times |
| Endurance | - **7–10 s**<br>- 3–7 s<br>- 1–3 s<br>- 0–1 s | **0 = 7–10 s**<br>0.33 = 3–6.99 s<br>0.66 = 1–2.99 s<br>1 = 0–0.99 s | - **7–10 s**<br>- 3–7 s<br>- 1–3 s<br>- 0–1 s | **0 = 7–10 s**<br>0.33 = 3–6.99 s<br>0.66 = 1–2.99 s<br>1 = 0-0.99 s |
| Anorectal angle | | | - **Yes, increased at contraction**<br>- No, no increase at contraction | **0 = yes**<br>1 = no |
| Sphincter closed (at rest) | - **Yes, closed**<br>- No, not closed | **0 = yes**<br>1 = no | | |

*Note*: Description is based on Frawley et al. (5)
Normal function is shown in bold and the endurance item is the mean average of three endurance contractions (10 s each).
Abbreviations: EAS, external anal sphincter; PFM, pelvic floor musculature; PRM, puborectal muscle.

3

**Table 2.** Overview of percentage with muscle dysfunction by number of pelvic floor symptoms

| | **Number of pelvic floor symptoms *** | | | |
|---|---|---|---|---|
| | **0** | **1** | **2** | **3–4** |
| Number of participants, n | 66 | 53 | 44 | 36 |
| EAS, % | | | | |
| – tone | 27.3 | 22.6 | 15.9 | 19.4 |
| – voluntary contraction | 1.5 | 1.9 | 9.1 | 2.8 |
| – voluntary relaxation | 37.9 | 24.5 | 23.3 | 33.3 |
| – maximum voluntary contraction | 18.2 | 30.2 | 20.5 | 19.4 |
| – frequency of maximum voluntary contraction | 0 | 1.9 | 4.5 | 0 |
| – endurance in categories | 10.6 | 18.9 | 18.2 | 22.2 |
| – closed | 1.5 | 0 | 9.1 | 2.8 |
| PRM, % | | | | |
| – tone | 51.5 | 45.3 | 50.0 | 44.4 |
| – voluntary contraction | 12.1 | 3.8 | 15.9 | 8.3 |
| – voluntary relaxation | 62.1 | 54.7 | 72.7 | 63.9 |
| – maximum voluntary contraction | 39.4 | 30.2 | 52.3 | 38.9 |
| – frequency of maximum voluntary contractions | 7.6 | 3.8 | 18.2 | 2.9 |
| – endurance | 19.7 | 15.1 | 31.8 | 19.4 |
| – anorectal angle during contraction | 33.3 | 26.4 | 40.9 | 22.2 |
| Normal function of EAS and PRM, % | 19.7 | 24.5 | 20.5 | 19.4 |

Abbreviations: EAS, external anal sphincter; PRM, puborectal muscle
* Lower urinary tract symptoms, defecation disorders, sexual problems, and genital-pelvic pain.

## FIGURES

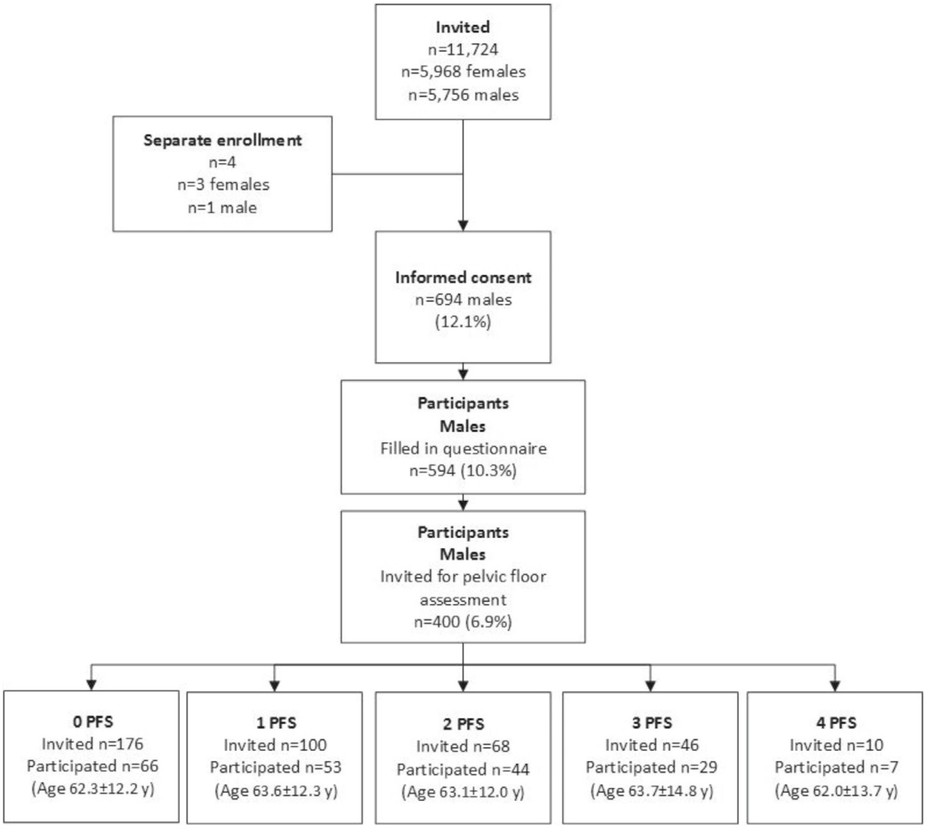



**Figure 1.** Participant flowchart. PFS, pelvic floor symptoms.

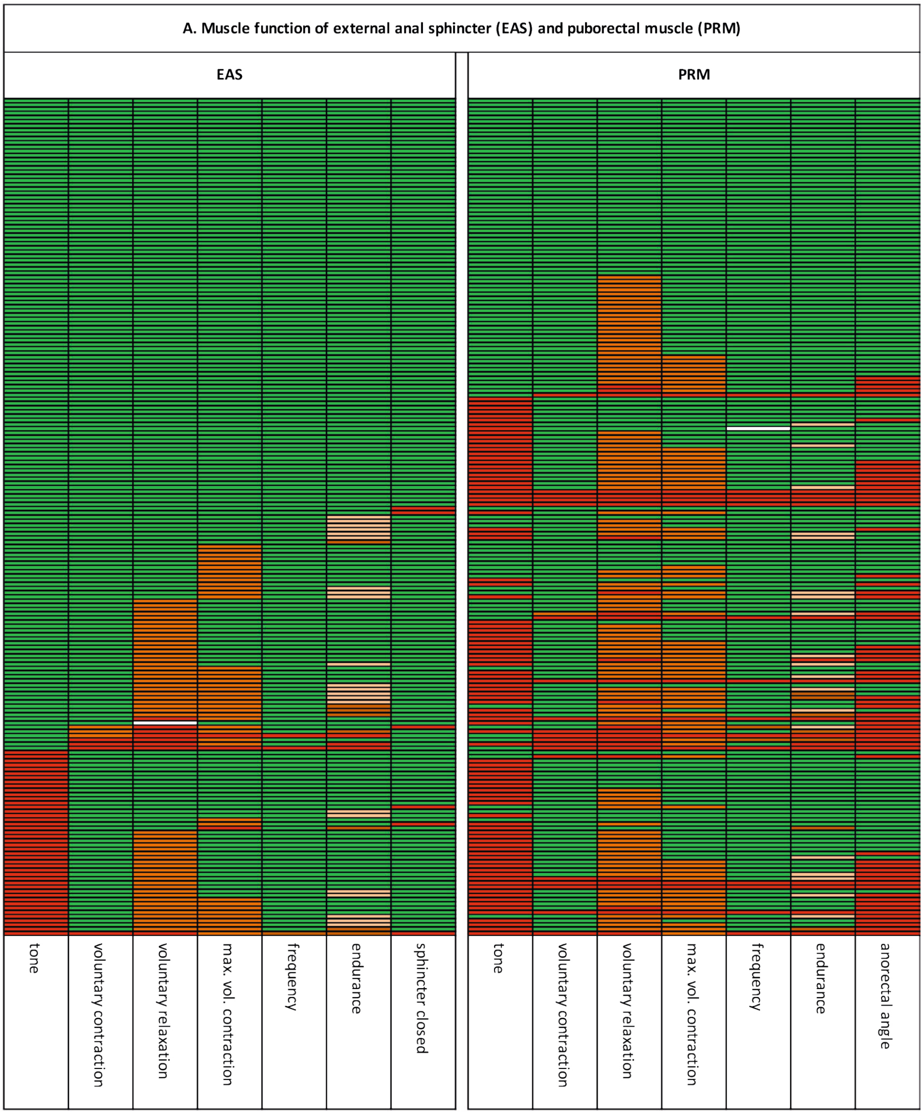



**Figure 2A.** Comparison of EAS and PRM function

Comparison of EAS and PRM function. (A) EAS and PRM function. (B) Comparison of EAS and PRM function items. Data were sorted according to EAS dysfunction in the first columns with all other items for EAS and PRM; the green cells indicate normal function and the red cells indicate dysfunction. Each line (row) includes the outcomes of an individual participant.

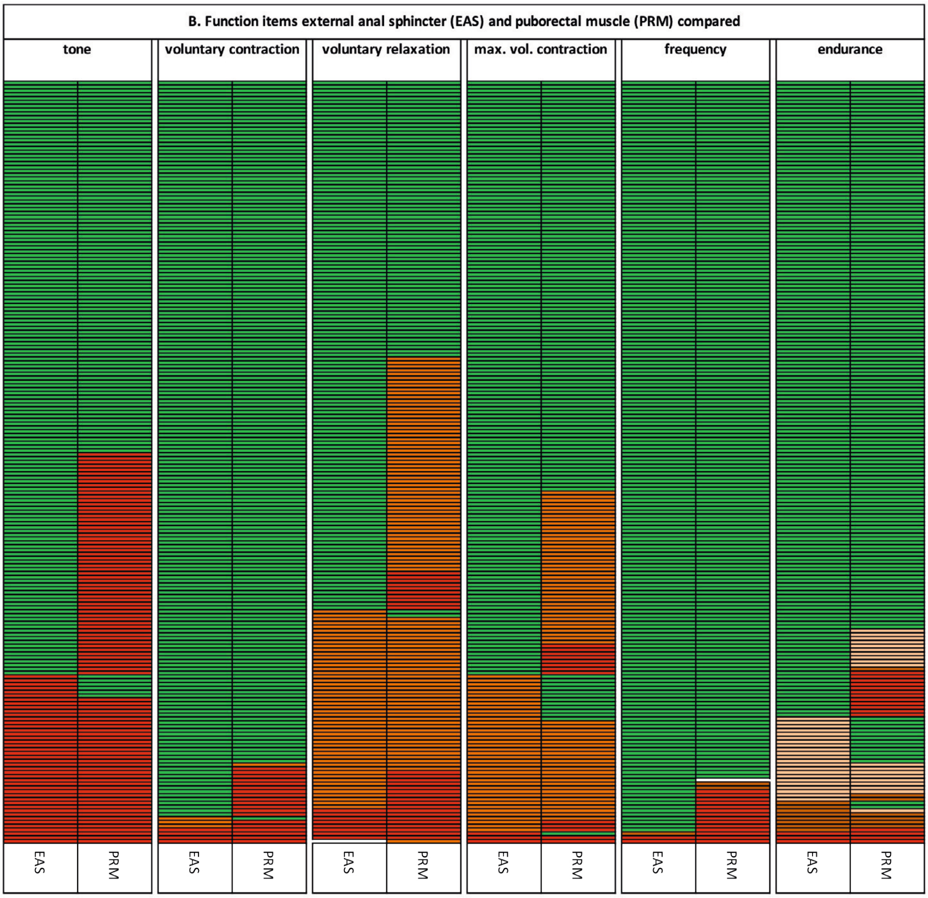



**Figure 2B.** Comparison of EAS and PRM function items.

Colors of cells: white (missing data), green (normal function), light orange (slight function decrease), orange (moderate function decrease), dark orange (strong function decrease), and red (very strong function decrease). For tone (both EAS and PRM), red represents an increase or decrease of tone; other red cells represent "no closure of EAS" and "no increase of anorectal angle," as appropriate. EAS, external anal sphincter; max. vol., maximum voluntary; PRM, puborectal muscle.

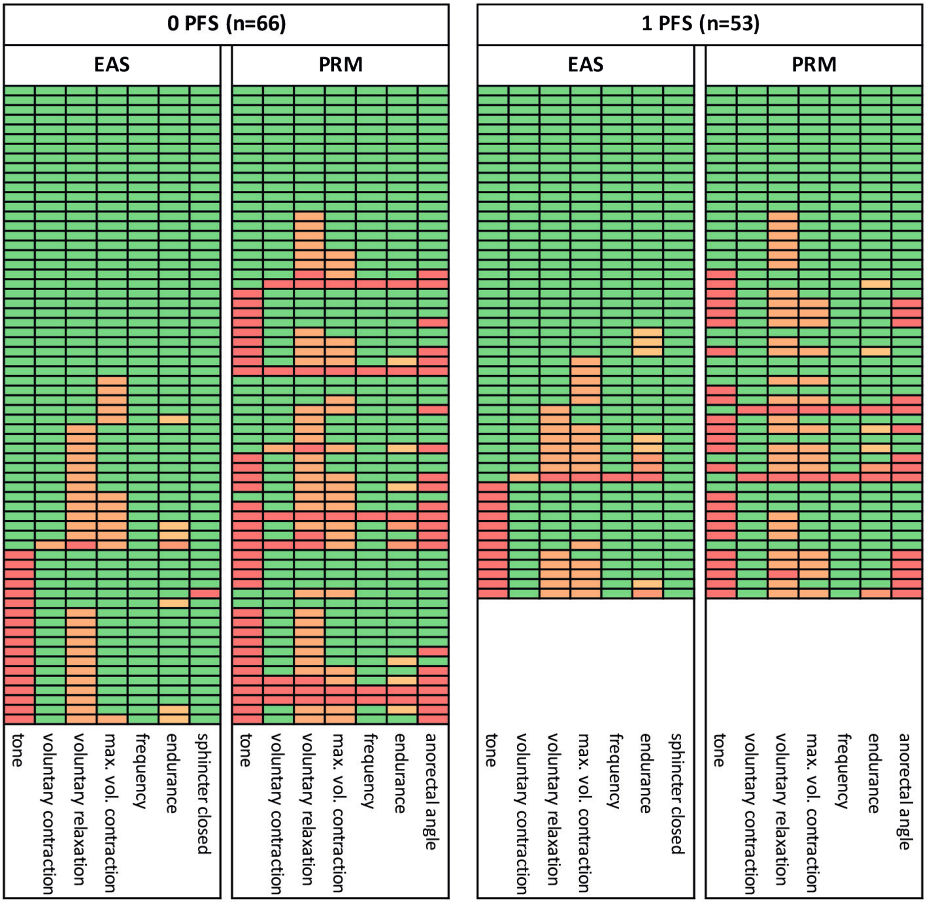
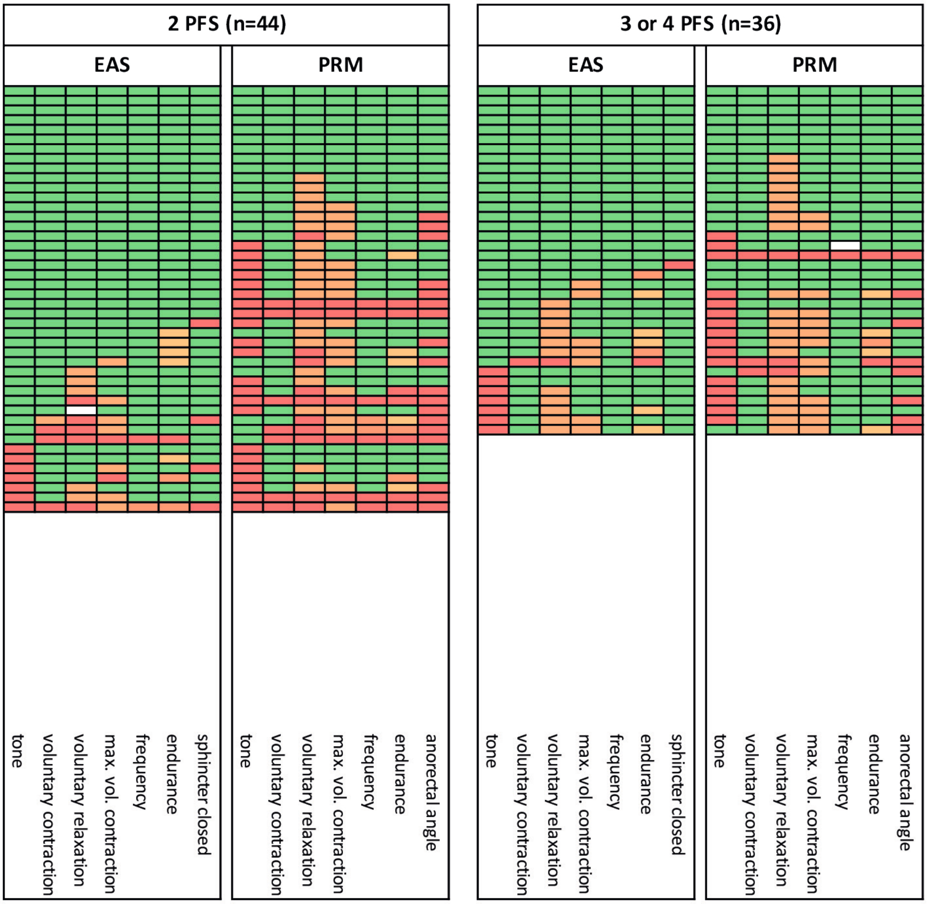



**Figure 3.** Heatmap of EAS and PRM function items by the number of pelvic floor symptoms. Data were sorted according to EAS dysfunction in the first columns with all other items for EAS and PRM; the green cells indicate normal function and the red cells indicate dysfunction. Each line (row) includes the outcomes of an individual participant.




Colors of cells: white (missing data), green (normal function), light orange (slight function decrease), orange (moderate function decrease), dark orange (strong function decrease), and red (very strong function decrease). For tone (both EAS and PRM), red represents an increase or decrease of tone; other red cells represent “no closure of EAS” and “no increase of anorectal angle,” as appropriate. EAS, external anal sphincter; max. vol., maximum voluntary; PRM, puborectal muscle.

## SUPPLEMENTARY FILES

**Supplementary file 1. Questionnaires and Sampling Procedure**
Questionnaires used for data collection

**LUTS questionnaire**
The International Consultation on Incontinence Questionnaire–male LUTS Module (ICIQ-mLUTS) is a validated 13-item patient-completed questionnaire for evaluating male LUTS in research and clinical practice. There are two subscales: voiding symptoms (score 0–20) and incontinence symptoms (0–24). Each question is scored 0–4 and higher scores indicate greater impact of individual symptoms for the participant.

**Bowel symptom questionnaire**
These were rated by items from categories 1 (defecation pattern), 2 and 3 (fecal constipation), and 4 (fecal continence) of the Groningen Defecation and Fecal Continence (DeFeC) questionnaire, which is based on several validated constipation and fecal incontinence scores (Wexner, Vaizey). Higher scores indicate greater impact.

**Sexual symptom questionnaires**
1. We used the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR), a patient-completed measure of sexual function in women and men with pelvic disorders. Higher scores indicate less impact and better sexual function;
2. Sexuality was assessed with the Sexual Health in the Netherlands questionnaire (item M1), with higher scores again indicating less impact of individual symptoms and better sexual function;
3. We also used the ICIQ-Male Sexual Matters Associated with LUTS Module for sexual dysfunction (ICIQ-MLUTS-5sex; three items on erection and ejaculation problems). Higher scores indicate more impact of individual symptoms.

**Pain symptoms questionnaire**
Pelvic pain was assessed with a self-constructed questionnaire that comprised items on pain in specific areas, severity (on a numeric rating scale), presence in time, and how it started. Higher scores indicated more pain.

**Sampling procedure**

We used the highest scores (≥9) on the ICIQ-mLUTS as cut-offs defining the presence of LUTS. We used the highest scores (≥6) on the combined constipation and incontinence Wexner score as cut-offs defining the presence of anorectal dysfunction. Having erectile and/or ejaculation problems and/or pain during intercourse or ejaculation, as mentioned in the ICIS-MLUTS-sex and the SGIN "*Sexual Health in the Netherlands*" questionnaire (item M1), defined the presence of sexual dysfunction. Finally, we defined pelvic pain as the presence of lower urinary tract and/or other pelvic pain.

**Supplementary file 2. Pelvic Floor Muscle Assessment**

The pelvic floor physical therapist showed a picture of the pelvic floor musculature and briefly explained the function of the pelvic floor muscles. Participants were asked to lie in the left-side position with their knees and hips at 90 degrees. The assessment then included the following components.

1) External assessment by visual inspection:
a) Anal region, including defects.
b) All pelvic floor muscles at rest for 10 s.
c) During a maximum voluntary contraction of all pelvic floor muscles for 3 s, followed by a maximum voluntary relaxation of all pelvic floor muscles.
d) During a cough and an abdominal strain.
2) Internal digital assessment of the external anal sphincter (EAS) and puborectal muscle (PRM) by palpation with the right gloved index finger:
a) For 1 minute rest, manual palpation to detect tone and painful areas.
b) During a maximum voluntary contraction lasting 3 s, followed by maximum voluntary relaxation.
c) During ten maximum voluntary contractions (3 s each) followed by maximum voluntary relaxations.
d) During three endurance contractions of sub-maximum power (10 s each) followed by maximum voluntary relaxations.
e) During a cough and an abdominal strain.

Subjects were allowed short rest periods of 3 s between each maximum voluntary contraction and 10 s between each sub-maximum endurance contraction of EAS and the PRM. The instruction given on how to activate the EAS was “try to squeeze your circular anal muscle as if you hold back bowel movements, flatus and for the PRM “try to lift your anal muscle inwards en forwards as if you hold back bowel movements, flatus.” The instruction for sub-maximum endurance power of the EAS and PRM was “try to contract 70% of your maximum power and hold this contraction for 10 s.” The instruction to relax the EAS and the PRM was “try to perform a maximum relaxation after each maximum contraction or after each sub-maximum endurance contraction.” The instruction for abdominal straining was “try to push as if you are pushing out bowel.” Measurements were repeated if the researcher observed co-contraction of the abdominal wall, gluteal and/or upper leg muscles, and/or the absence of an inward movement of the anal region and perineum during contraction. To avoid differences in instruction, this written protocol was followed during all assessments.

## Supplementary file 3. Comparison of separate pelvic floor muscle function items for the EAS and PRM

**3A** Muscle tone

| | | PRM (rest) | | | |
|---|---|---|---|---|---|
| | | Normal | Decreased | Increased | Total |
| EAS (rest) | Normal tone | 97 | 6 | 52 | 155 |
| | Decreased tone | 6 | 9 | 1 | 16 |
| | Increased tone | 0 | 2 | 26 | 28 |
| | Total | 103 | 17 | 79 | 199 |

**3B** Voluntary contraction

| | | PRM | | | |
|---|---|---|---|---|---|
| | | Yes* | No, descend in dorso-caudal direction | No, no movement | Total |
| EAS | Yes, circular closing and contraction in ventral-cranial direction* | 178 | 1 | 13 | 192 |
| | No, opening and descend in dorso-caudal direction | 1 | 0 | 2 | 3 |
| | No, no movement | 0 | 0 | 4 | 4 |
| | Total | 179 | 1 | 19 | 199 |

**3C** Voluntary relaxation

| | | PRM | | | |
|---|---|---|---|---|---|
| | | Complete * | Partial | No | Total |
| EAS | Complete relaxation* | 70 | 53 | 10 | 133 |
| | Complete delayed relaxation* | 2 | 3 | 0 | 5 |
| | Partial relaxation | 2 | 28 | 7 | 37 |
| | Partial relaxation, delayed | 0 | 12 | 3 | 15 |
| | No relaxation | 0 | 0 | 8 | 8 |
| | Total | 74 | 96 | 28 | 198 |



**3D** Maximum voluntary contraction

| | | PRM | | | | |
|---|---|---|---|---|---|---|
| | | Strong* | Normal* | Weak | Absent | Total |
| EAS | Strong* | 3 | 19 | 8 | 0 | 30 |
| | Normal* | 2 | 83 | 32 | 8 | 125 |
| | Weak | 1 | 11 | 26 | 3 | 41 |
| | Absent | 0 | 1 | 0 | 2 | 3 |
| | Total | 6 | 114 | 66 | 13 | 199 |

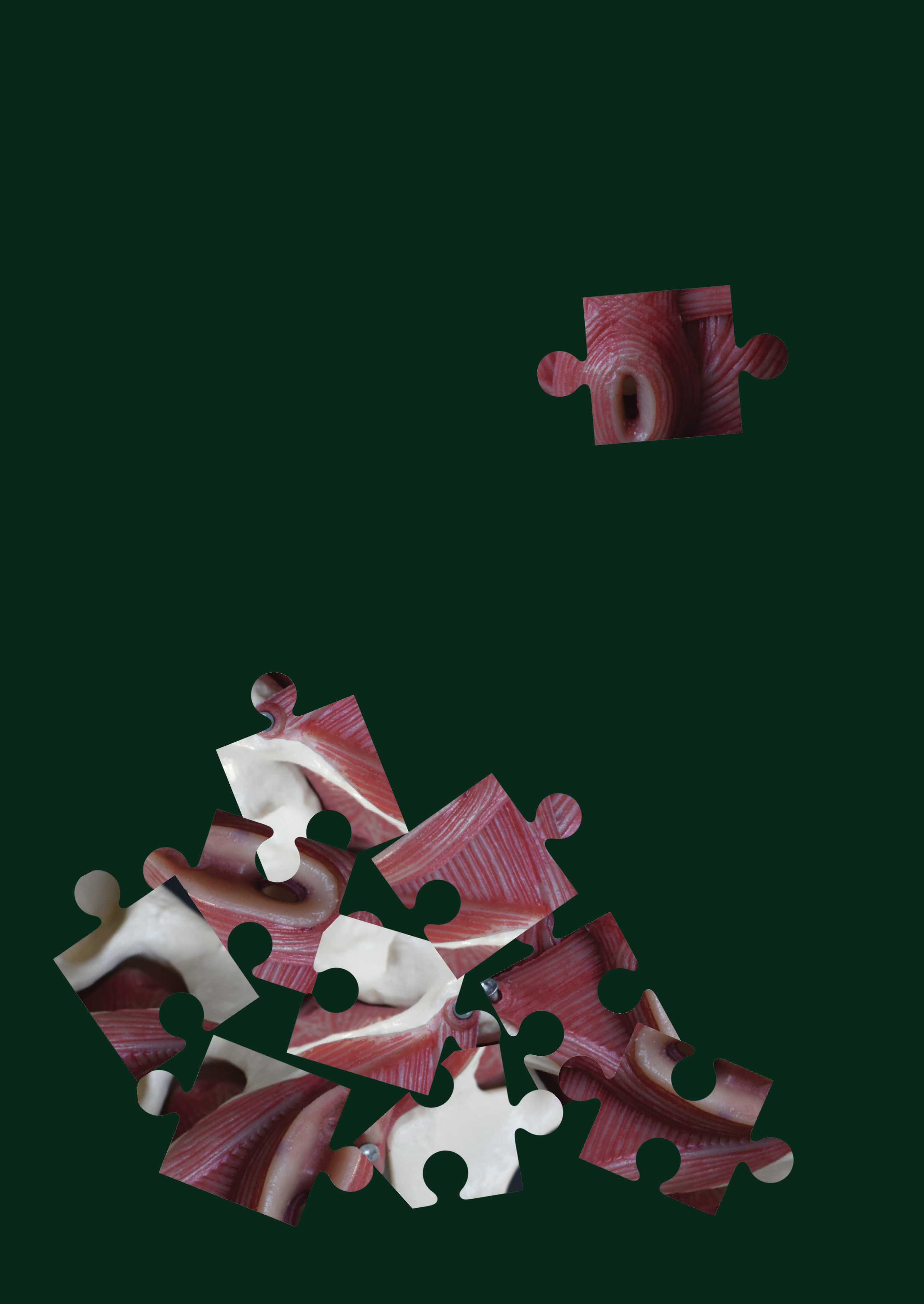
**3E** Frequency of maximum voluntary contractions

| | | PRM | | | |
|---|---|---|---|---|---|
| | | 0 times | 1, 2, 3 times | 10 times* | Total |
| EAS | 0 times | 2 | 0 | 0 | 2 |
| | 1, 2, 3 times | 1 | 0 | 0 | 1 |
| | 7, 8, 9 times* | 0 | 0 | 2 | 2 |
| | 10 times* | 11 | 2 | 180 | 193 |
| | Total | 14 | 2 | 182 | 198 |

**3F** Average of three endurance contractions in categories (maximum 10 s each)

| | | PRM | | | | |
|---|---|---|---|---|---|---|
| | | 7- 10 * | 3-7 | 1-3 | 0 | Total |
| EAS | 7-10 * | 143 | 10 | 1 | 12 | 166 |
| | 3-7 | 12 | 8 | 2 | 0 | 22 |
| | 1-3 | 2 | 1 | 4 | 1 | 8 |
| | 0 | 0 | 0 | 0 | 3 | 3 |
| | Total | 157 | 19 | 7 | 16 | 199 |

Abbreviations: EAS, external anal sphincter; PRM, puborectal muscle.
* = normal function



# 4

# Exploring pelvic floor muscle function in women with and without pelvic floor symptoms: A population-based cross-sectional study

Françoise J.M. Notenboom-Nas, Grietje E. Knol-de Vries, Iris E. de Koning, Carla S. Haijer, Marijke C. Ph. Slieker-ten Hove, Janny H. Dekker, Gommert A. van Koeveringe, Marco H. Blanker

## ABSTRACT

### Background
Pelvic floor symptoms, including genital-pelvic pain and lower urinary tract, defecation, sexual, and prolapse symptoms, are prevalent in women. Assessing the pelvic floor musculature could identify relationships between muscle function and symptoms.

### Objectives
To explore associations within and between pelvic floor muscle function and between muscle function/dysfunction and the number of pelvic floor symptoms in women.

### Methods
We selected 608 women aged ≥21 years among women who completed questionnaires about pelvic floor symptoms, using purposive sampling from a larger study. Complete digital assessment was performed to assess possible interconnections between the intravaginal and anorectal muscles (external anal sphincter and puborectal muscle). We explored agreement between different muscle function items, associations within and between all three muscle groups, associations between items of muscle function, and associations between muscle function/dysfunction and the number of symptoms.

### Results
In total, 187 women with and without pelvic floor symptoms took part. Most intravaginal muscle dysfunction appeared on prolapse staging and cough response, while most puborectal muscle dysfunction appeared on assessing tone and voluntary relaxation. The puborectal muscle showed more (and more severe) dysfunction than the intravaginal muscles or the external anal sphincter. We observed high percentages of association indicating patterns within the pelvic floor musculature, and found weak patterns between pelvic floor musculature. We found no dose-response relationship between dysfunction and the number of symptoms.

### Conclusion
We propose that consultation of female pelvic floor symptoms should include both intravaginal and anorectal muscle assessment due to their functional unity.

Keywords: Female pelvic floor symptoms; digital pelvic floor assessment; intravaginal pelvic floor musculature; External Anal Sphincter, Puborectal muscle; heatmap.

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## 1. INTRODUCTION

Female pelvic floor symptoms (PFS) are prevalent in the population and extensively described in the literature. [1] However, despite women often experiencing several concurrent PFS, most research has only given limited attention to symptom co-occurrence. [2] The same tends to apply in general, urological, genealogical practice, where both patient and caregiver tend to focus on the most bothersome symptoms. This in contrast to pelvic floor physical therapy, where in the first consultation all domains referring to PFS (urological, gynecological, protological and orthopedic) are questioned. Moreover, intravaginal and anorectal assessments are not routinely performed both with the former typically reserved for prolapse, pain, or (stress) urinary incontinence and the latter mostly for symptoms related to defecation. [3] However, according to the literature, the intravaginal and anorectal muscles, tendons, ligaments, fascia, membranes and connective tissues of the pelvic floor form one anatomical and functional system. [4] Following this, all patients should undergo a complete assessment of the pelvic floor musculature (PFM) to explore the contribution of the PFMs to their symptoms. A better understanding of the complicated interaction within and between PFM function and female PFS could support targeted care for those affected.

Therefore, we explored the relationships within and between the various female PFMs (levator ani: pubococcygeal muscle, puborectal muscle, iliococcygeal muscle; coccygeal muscle) and the association between PFM (dys-) function and absence or presence of PFS, assuming that intravaginal PFM assessment would show agreement with the anorectal component.

We studied the associations in muscle function between the intravaginal PFM, external anal sphincter, and puborectal muscle during a defined protocol including a set number of voluntary contractions, voluntary relaxations, maximum voluntary contractions (MVC), frequency of MVCs and endurance, to test a functional correlation between these muscles. [5] Next, we compared PFM (dys-) function for participants without or with one or more PFS, to test if the number of PFS coincides with more change in muscle function.

## 2. MATERIALS AND METHODS

### 2.1 Study Design, Setting, and Participants

We conducted a cross-sectional study, as part of a larger prospective observational study in a general population, between July 2019 and December 2020. [6] Our medical ethics committee approved the larger study and additional sub-studies.

All participants who provided written informed consent received a € 20 gift card after participating to the current study.

In the parent study, in which we explored the occurrence of concomitant PFS in community-dwelling males and females, all inhabitants aged ≥16 years from a single Dutch municipality were invited to complete a questionnaire at baseline (2019) and then two annual follow-up questionnaires (2020 and 2021). We excluded anyone with terminal illness, cognitive impairment (e.g., dementia), or a current psychological condition precluding informed consent, as well as those whose GP considered unsuitable or too ill to participate.

In the current exploratory sub-study, we aimed to include women with and without PFS by purposive sampling, using their responses of lower urinary tract symptoms (LUTS), defecation problems, sexual dysfunction and pelvic pain of the baseline questionnaires, while number of PFS and age were used to create equal groups. The sampling procedure matched the procedure applied in our study on male PFS. [7] The type of assessment decided us to level-up the age to ≥21 years. Considering the duration of the study, our goal was to include 100 women without PFS and 100 with ≥1 PFS, based on presence of symptoms. We conducted no sample size calculation in advance due to the explorative nature of our study. We assumed that with 200 participants, the variability in both symptoms and physical examination outcomes would allow to compare subgroups. For this purpose, PFS were defined using the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS), [8] the Groningen Defecation and Fecal Continence (DeFeC) questionnaire, [9] the Pelvic Organ Prolapse/Incontinence Sexual questionnaire, [10] the 6-item, Pelvic Organ Prolapse Distress Inventory (POPDI-6), [11] and using a self-constructed questionnaire to assess pelvic or genital-pelvic pain. The sampling procedure did not seek to reflect the general population, Unfortunately, the study had to be suspended due to COVID-19 regulations, and on restarting, purposive sampling of subsequent women was performed based on their responses to the second (first follow-up one year later (2020)) questionnaire. It was necessary to use the questionnaire closest to the date of the physical exam because we were assessing a possible link between muscle dysfunction and current symptoms. Details of the questionnaires and sampling procedure for the current study are provided in Supplementary File 1.

### 2.2 Pelvic Floor Symptoms

Most questionnaires on PFS lack established cut-off values, so we used the following definitions. For LUTS and bowel symptoms, we used the highest quartiles. Sexual problems and pelvic pain were defined as having ≥1 sexual problem and pain in ≥1 pelvic (floor) area, respectively. Prolapse symptoms were considered present if the woman responded yes on ≥4 questions of the 6-item Pelvic Organ Prolapse Distress Inventory (POPDI-6). Subsequently, participants were categorized by the number of affected domains (i.e., 0–4), seeking an equal age distribution in all groups. [6]

### 2.3 Pelvic Floor Assessment

One experienced pelvic floor physical therapist performed all digital PFM assessments according to the latest recommendations of the International Continence Society (ICS) and prevailing protocols for PFM assessment. [5,12-14] These comprised external (per perineum) inspection of the vaginal and anal region, and because of (possible) connections between the muscle groups, internal digital palpation of the vaginal PFM (per vaginam), and the external anal sphincter (EAS) and the puborectal muscle (PRM) (per rectum). In the deep anorectal PFM layer, the sling-formed PRM was chosen, since this muscle is well localizable in the anorectum. Additionally, intravaginal PFM assessment included internal assessment of pelvic organ prolapse (POP) by the Simplified Pelvic Organ Prolapse Quantification (S-POP-Q) system (Supplementary File 2).
The assessor was blinded to the PFS status of the participant to limit confirmation bias. We categorized the different items of the PFM assessment according to our own definitions, ICS standards, and established protocols used in pelvic floor physical therapy (Table 1 provides details about the items of digital PFM assessment). [5,12-14]

### 2.4. Statistical Analysis

First, we present the patient characteristics as frequencies and percentages or as means and standard deviations, as appropriate.

To examine agreement and detect trends in (dys-) function between different muscles, we then cross-tabulated the items of the PFM assessment. Second, we constructed heatmaps to visualize possible associations within and between the function items of the vaginal PFM, the EAS, and the PRM; and between the intravaginal PFM, EAS, and PRM and the presence of PFS, according to the number of affected pelvic floor domains. Since there is no clear scoring-scale for tone we followed the usual categories for tone; decreased, normal and increased. The heatmaps provided a graphical overview of the findings and facilitated the visualization of patterns or associations by using colors to indicate certain data (see Table 1 for used codes in the heatmaps). [15] Finally, $\chi^2$ tests compared, with the number of PFS, completely normal PFM function with dysfunctional PFM function. Due to the exploratory design, we refrained from further statistical testing. We were unable to predefine strong or weak associations, based on the heatmaps.



## 3. RESULTS

### 3.1 Participants

Of the 608 invited women, 187 (30.8%) with a mean age of 58.6 ± 14.1 years agreed to participate. Among the participants, 67 (35.8%) reported having no PFS. In three females a part of the PFM assessment could not be performed because of intravaginal or anorectal burning or pain. A flowchart of the participants is shown in Figure 1.

### 3.2 Agreement of the Intravaginal and Anorectal Muscle Characteristics

Normal tone of the vaginal PFM coincided with normal tone of the EAS in 55.4%, with this pattern also found in 39.7% for the intravaginal PFM and PRM and in 47.6% for the EAS and PRM. Normal tone of the intravaginal PFM or EAS coincided with increased tone of the PRM in 17.9 and 22.2%, respectively. Concerning voluntary contraction and the frequency of maximum voluntary contractions, we observed high agreement for all three muscle combinations, ranging from 90.8% to 95.1%. Agreement of complete (delayed) voluntary relaxation was seen in 66.9% between the intra vaginal PFM and the EAS. Furthermore, among women with a complete (delayed) voluntary relaxation of the intravaginal PFM and EAS, partial voluntary relaxation of the PRM was present in 31.0% and

33.9%, respectively. Normal maximum voluntary contraction (defined as strong or moderate (normal)) showed agreement of approximately 50% in all three muscle groups. In the EAS, however, this was associated with weak contraction of the intravaginal PFM and the PRM in 13.4% and 15.8%, respectively.
Table 2 shows an overview of the percentage agreement in outcome between the intravaginal PFM, the EAS and the PRM and Supplementary file 3 shows the relevant cross-tabulations.

### 3.3 Association Within and Between the Pelvic Floor Muscles

Figure 2A summarizes the results for intravaginal PFM, EAS, and PRM function.
POP and lack of involuntary PFM contraction on cough were the most common PFM dysfunctions observed during the intravaginal assessment.
The EAS typically had dysfunctions of tone, voluntary relaxation, maximum voluntary contraction, and endurance. Of the 44 women with dysfunctional voluntary relaxation, 35 (79.5%) also had dysfunctional maximum voluntary contraction.
Decreased/increased tone, voluntary relaxation, and maximum voluntary contraction items were the most present dysfunctions observed during the PRM rectal assessment.
Having dysfunctional tone, maximum voluntary contraction, endurance, and anorectal angles seemed to be associated with voluntary relaxation. Of the 82 women with dysfunctional maximum voluntary contraction, 70 (85.4%) had dysfunctional voluntary relaxation; in reverse, 65.4% with dysfunctional voluntary relaxation had dysfunctional maximum voluntary contraction. Dysfunctional tone, endurance, and anorectal angles coincided with dysfunctional voluntary relaxation in 70.7%, 74.5%, and 95% of women, respectively. Of the 60 with dysfunctional anorectal angles, 59 (98.3%) showed dysfunctional maximum voluntary contraction; in reverse, 72.0% with dysfunctional maximum voluntary contraction had dysfunctional anorectal angles. All PRM items related to dysfunctional tone in about two-thirds of women (60.7%–68.3%). Dysfunctional endurance was associated with dysfunctions of maximum voluntary contraction and of anorectal angles in 78.2% and 65.5%, respectively.

We saw no clear associations between the three PFMs, but some weak patterns regarding voluntary relaxation, maximum voluntary contraction and endurance.

### 3.4 Association Between Pelvic Floor Muscle Items

Giving more insight by looking at item level, we observed the same weak pattern between the intravaginal PFM, the EAS and the PRM for voluntary relaxation, maximum voluntary contraction, and endurance items (Figure 2B).

### 3.5 Association Between Pelvic Floor Muscle (Dys-) Function and Number of Symptoms

We found no clear dose-response relationship between PFM dysfunction and the number of PFS. Women with three or four symptoms showed the highest percentages of an increased or decreased tone in all three muscles (Figure 3 and Table 3). The difference between the number of PFS domains (0–4) and normal intravaginal PFM, EAS, and PRM function compared to abnormal function was not statistically significant ($\chi^2$ tests $P = 0.62$).



## 4. DISCUSSION

In this exploratory study, we tried to unravel the complex and multifactorial PFM function in relation to female PFS. We explored the associations within and between the intravaginal and anorectal PFM and whether PFM (dys-) function was associated with the number of affected PFS domains. Given the functional unity of the PFMs, formed by the levator ani in which the PRM plays an important role in all three female compartments, we considered it important to assess the intravaginal PFM, the EAS, and the PRM. This revealed that most intravaginal PFM dysfunction appeared when assessing the POP stage and cough response, and that for both the EAS and PRM, most women with dysfunctional voluntary relaxation also experienced problems with maximum voluntary contraction. We recorded high percentages of dysfunction within each PFM, particularly in the PRM. Furthermore, some weak patterns were found between the different muscles. Based on this study, we found no dose-response relationship between PFM function and the number of PFS.

Normal tone of the intravaginal PFM or EAS coincided with increased PRM tone for almost one in three women in our study. A clear explanation for these outcomes is difficult to give, but it is suggested that some PFS, accompanied with pain, such as provoked vestibulodynia, induce increased PFM tone more in the deeper layer of the pelvic floor since larger angles in the levator plate were found. [16,17] Dysfunctional tone might be explained by our sample of women being aged ≥55 years, which could have affected our outcomes because hormonal changes and inactivity may decrease normal PFM tone with age. We also acknowledge that PFM tone assessments are complicated by compounded neuromuscular, neurological, viscoelastic, contractile, emotional, and pain processes, and that they depend on the assessor's interpretation. [5,18]
We found more cases of dysfunctional voluntary relaxation of the PRM compared to either the EAS or the intravaginal PFM. Some research has shown that a non-relaxing pelvic floor is indicative of PFS such as problems with urinary and bowel evacuation or the presence of dyspareunia. [19] However, this does not account for the differences in outcomes observed between the muscles. Dysfunctional voluntary relaxation of the PRM (either partial or delayed) might also compensate for dysfunctional tone, strength, or endurance of the intravaginal PFM and/or the EAS, but might also be present as result of rigidity in the connective tissues of the PRM, a temporary increase of basic PRM tone during PFM assessment but might also be present because of connective tissues to other pelvic or low back muscles having an increased tone. The high percentages of increased and decreased tone and impaired voluntary relaxation of the PRM may reflect a change in the viscoelasticity of these muscle fibers that affects their ability to relax.[5]
Although only a few women reported POP symptoms in the baseline questionnaires, most had a POP stage of one or higher on assessment. This could indicate that women with a POP stage below stage two do not report major symptoms, even though many reported vaginal delivery (87.2%), leaving us to conclude that POP status probably does not predict PFM dysfunction. [20]
Furthermore, the high percentage of PFM dysfunction in response to cough may be explained by the lack of specific instruction to ensure involuntary contraction prior to coughing. [5]
The existing literature and anatomical perspectives provide relationships between the intravaginal PFM, the EAS, and the PRM, but our data supports only limited associations between these muscles. [4,21] However,

we endorse the functional unity of the PFM and, therefore, it seems essential that a broader assessment of both the intravaginal and anorectal PFM should be performed during PFM consultations. Future studies should focus on which symptoms may be related to which part of the female pelvic floor so that in time and based on additional research, recommendations might be given for specific intravaginal or anal pelvic floor assessment. We found no dose-response relationship between PFM dysfunction and the number of PFS, indicating that patient reported symptoms may not be the optimal method for identifying associations with PFM (dys-) function. Future research may instead need to consider the associations with the severity and type of PFS, factors that we did not include in our analysis, and of which little has been reported in pelvic floor research. [22,23]

Several strengths and limitations warrant consideration. First, no causal relationships could be established in this study. Second, the use of validated questionnaires and transparent cut-off values, though clear, may have influenced our outcomes for LUTS and defecation symptoms. Third, the same experienced therapist performed all PFM assessments, thereby preventing inter-observer variation, but potentially introducing systematic errors. [24] Fourth, to approximate the assessment of GPs, pelvic floor physical therapists and other specialists for PFS during initial consultations, we did not use other objective measurement devices (e.g., ultrasound or magnetic resonance imaging) and did not measure urethral sphincter function. These may be necessary before treatment and in later consultations. Fifth, half of our participants were aged 55–75 years and 14% were aged >75 years, biasing the sample toward older women. This may not only have led to a potential increase in the number of PFS but a higher age may also lead to a decline in the number of striated muscles. [25] This skewed age distribution, coupled with our use of purposive sampling, prevents extrapolation to the general female population. However, for analysis of correlations this is no issue or even desirable. Additionally, we realize that participants with PFS might have been inquisitive for a PFM dysfunction and might have been overrepresented. Finally, we only analyzed PFM function related to the number of PFS, and we did not assess specific female PFS within domains, potentially causing some PFS to be overrepresented in different groups. Further evaluation of PFM in association with specific female PFS could be valuable as well as electromyography measurement analysis, which was collected in this study as well.

## 5. CONCLUSION

We believe this study has begun the process of unraveling the possible associations between female PFM function and PFS. This might be relevant to both PFS treatment and future clinical research. We found that the PRM showed most dysfunction and that some associations existed within the PFM, again most notably in the PRM. We failed to identify an association between the number of PFS and female PFM dysfunction and observed only weak patterns between the three assessed pelvic floor muscles. Because of the functional unity of the female PFM, we propose that assessments of both the intravaginal and the anorectal musculature should be essential in the first consultation. Future research should concentrate on analyzing PFM function in relation to specific female PFS and exploring which PFS is related to which part of the female PFM.

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# TABLES

**Table 1.** Items of digital pelvic floor muscle (PFM) assessment, definitions of normal function, and codes for PFM assessment heatmaps

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Stage POP | - **Stage 0 = no prolapse**<br>- Stage 1 = most distal part of the prolapse is > 1 cm. above the level of the remaining hymen<br>- Stage 2 = most distal part of the prolapse is 1 cm. above up to 1 cm. past the level of the remaining hymen<br>- Stage 3 = most distal part of the prolapse is > 1 cm. under the level of the remaining hymen<br>- Stage 4 = complete eversion of the vagina | - **0 = 0, stage 0**<br>- 0.25 = 1, stage 1<br>- 0.5 = 2, stage 2<br>- 0.75 = 3, stage 3<br>- 1 = 4, stage 4 | n.a. | n.a. | n.a. | n.a. |

**Table 1.** *Continued.*

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Cough | - **Yes, contraction in cephalad ventral direction**<br>- No, descend in dorso-caudal direction | - **0 = yes**<br>- 1 = no | n.a. | n.a. | n.a. | n.a. |
| Tone at rest | - **Normal**<br>- Decreased<br>- Increased | - **0 = normal tone**<br>- 1 = decreased/ increased tone | - **Normal**<br>- Decreased<br>- Increased | - **0 = normal tone**<br>- 1 = decreased/ increased tone | - **Normal**<br>- Decreased<br>- Increased | - **0 = normal tone**<br>- 1 = decreased/ increased tone |

**Table 1.** *Continued.*

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Voluntary contraction (direction of pelvic floor muscle movement) | - **Yes, circular closing and contraction in cephalad ventral direction (correct contraction, cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorso-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>- No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | - **0 = yes**<br>- 0.5 = no, opening and descent (straining)<br>- 1 = no, no movement | - **Yes, circular closing and contraction in cephalad ventral direction (correct contraction, cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorsal-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>- No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | - **0 = yes**<br>- 0.5 = no, opening and descent (straining)<br>- 1 = no, no movement | - **Yes, contraction in cephalad ventral direction (correct contraction, cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorsal-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>- No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | - **0 = yes**<br>- 0.5 = no, descent (straining)<br>- 1 = no, no movement |

**Table 1.** *Continued.*

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Voluntary relaxation (Relaxation post contraction) | - **Complete relaxation to original rest tone, not delayed (Yes: relaxation felt directly after instruction; normal finding)**<br>- **Complete relaxation to original rest tone, delayed**<br>- Partial relaxation, not delayed<br>- Partial relaxation, delayed<br>- No relaxation (no: absent = non-relaxation PFM) | - **0 = complete (delayed) relaxation**<br>- 0.5 = partial (delayed) relaxation<br>- 1 = no relaxation | - **Complete relaxation to original rest tone, not delayed (Yes: relaxation felt directly after instruction; normal finding)**<br>- **Complete relaxation to original rest tone, delayed**<br>- Partial relaxation, not delayed<br>- Partial relaxation, delayed<br>- No relaxation (no: absent = non-relaxation PFM) | - **0 = complete (delayed) relaxation**<br>- 0.5 = partial (delayed) relaxation<br>- 1 = no relaxation | - **Complete relaxation to original rest tone (Yes: relaxation felt directly after instruction; normal finding)**<br>- Partial relaxation<br>- No relaxation (no: absent = non-relaxation PFM) | - **0 = complete relaxation**<br>- 0.5 = partial relaxation<br>- 1 = no relaxation |

**Table 1.** *Continued.*

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Strength: Maximum voluntary contraction measurement (digital muscle test) | - **Strong**<br>- **Moderate**<br>- Weak<br>- Absent | - **0 = strong/ moderate**<br>- 0.5 = weak<br>- 1 = absent | - **Strong**<br>- **Moderate**<br>- Weak<br>- Absent | - **0 = strong/ moderate**<br>- 0.5 = weak<br>- 1 = absent | - **Strong**<br>- **Moderate**<br>- Weak<br>- Absent | - **0 = strong/ moderate**<br>- 0.5 = weak<br>- 1 = absent |
| Frequency of maximum voluntary contraction (1 s) (Repeatability of contraction/ Number of rapid contractions performed) | - **10 times**<br>- **7–9 times**<br>- 4–6 times<br>- 1–3 times<br>- 0 times | - **0 = 7–10 times**<br>- 0.33 = 4–6 times<br>- 0.66 = 1–3 times<br>- 1 = 0 times | - **10 times**<br>- **7–9 times**<br>- 4–6 times<br>- 1–3 times<br>- 0 times | - **0 = 7–10 times**<br>- 0.33 = 4–6 times<br>- 0.66 = 1–3 times<br>- 1 = 0 times | - **10 times**<br>- **7–9 times**<br>- 4–6 times<br>- 1–3 times<br>- 0 times | - **0 = 7–10 times**<br>- 0.33 = 4–6 times<br>- 0.66 = 1–3 times<br>- 1 = 0 times |

**Table 1.** *Continued.*

| Items of digital pelvic floor assessment | Vaginal muscles | | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Endurance (Average of three endurance contractions each with a maximum of 10 seconds) | - **7–10 s**<br>- 3–7 s<br>- 1–3 s<br>- 0–1 s | - **0 = 7–10 s**<br>- 0.33 = 3–6.99 s<br>- 0.66 = 1–2.99 s<br>- 1 = 0–0.99 s | - **7–10 s**<br>- 3–7 s<br>- 1–3 s<br>- 0–1 s | - **0 = 7–10 s**<br>- 0.33 = 3–6.99 s<br>- 0.66 = 1–2.99 s<br>- 1 = 0–0.99 s | - **7–10 s**<br>- 3–7 s<br>- 1–3 s<br>- 0–1 s | - **0 = 7–10 s**<br>- 0.33 = 3–6.99 s<br>- 0.66 = 1–2.99 s<br>- 1 = 0–0.99 s |
| Palpation | - **Yes, 1 or 2 fingers**<br>- No, 0 fingers | - **0 = 1 or 2 fingers**<br>- 1 = 0 fingers | n.a. | n.a. | n.a. | n.a. |
| Symmetry | - **Yes**<br>- No: left>right; right>left | - **0 = yes symmetry**<br>- 1 = no symmetry | | | | |
| Sphincter closed (at rest) | n.a. | n.a. | - **Yes, closed**<br>- No, not closed | - **0 = yes**<br>- 1 = no | n.a. | n.a. |

**Table 1.** *Continued.*

| **Items of digital pelvic floor assessment** | **Vaginal muscles** | | **External Anal Sphincter** | | **Puborectal muscle** | |
|---|---|---|---|---|---|---|
| | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Anorectal angle | n.a. | n.a. | n.a. | n.a. | - **Yes, increase of anorectal angle at contraction**<br>- No, no increase of anorectal angle at contraction | - **0 = yes**<br>- 1 = no |

Abbreviations: n.a., not applicable; PFM, pelvic floor musculature.
Note: normal function is highlighted in bold. *Anorectal angle* indicates the increase in the anorectal angle during contraction.

**Table 2.** Percentage agreement in outcomes between the vaginal PFM, the EAS, and the PRM

| Function item | Pelvic floor muscles | | |
| --- | --- | --- | --- |
| | **Vaginal PFM and EAS % (n)** | **Vaginal PFM and PRM % (n)** | **EAS and PRM % (n)** |
| Tone at rest | 65.6% (122) | 59.2% (109) | 63.8% (118) |
| Voluntary contraction | 93.0% (173) | 90.8% (167) | 95.1% (176) |
| Voluntary relaxation | 70.1% (129) | 57.6% (106) | 57.9% (106) |
| Maximum voluntary contraction | 61.8% (115) | 63.9% (117) | 71.2% (131) |
| Frequency of maximum voluntary contractions | 93.0% (172) | 92.4% (169) | 95.1% (176) |
| Endurance | 69.2% (128) | 73.8% (135) | 72.4% (134) |

Abbreviations: EAS, external anal sphincter; PFM, pelvic floor musculature; PRM, puborectal muscle.
Notes: all items contained missing values, and percentages were calculated according to the included cases.



**Table 3.** Overview of percentages of dysfunction of vaginal PFM, the EAS, and the PRM in the presence of 0–4 pelvic floor symptoms

| | Number of pelvic floor symptoms | | | |
| --- | --- | --- | --- | --- |
| | **0** | **1** | **2** | **3–4** |
| | **N = 67** | **N = 49** | **N = 39** | **N = 32** |
| **Vaginal muscles** | | | | |
| - stage POP | 80.3 | 81.6 | 92.1 | 78.1 |
| - cough | 61.2 | 67.4 | 65.8 | 62.5 |
| - tone at rest | 31.3 | 24.5 | 36.8 | 46.9 |
| - voluntary contraction | 9.0 | 8.2 | 10.5 | 12.5 |
| - voluntary relaxation | 23.9 | 26.5 | 34.2 | 25.0 |
| - maximum voluntary contraction | 38.8 | 38.8 | 44.7 | 40.6 |
| - frequency of maximum voluntary contractions | 7.6 | 4.1 | 7.9 | 12.5 |

**Table 3.** *Continued.*

| | Number of pelvic floor symptoms | | | |
|---|---|---|---|---|
| | **0** | **1** | **2** | **3–4** |
| | **N = 67** | **N = 49** | **N = 39** | **N = 32** |
| - endurance (in categories) | 27.3 | 28.6 | 42.1 | 25.0 |
| - palpation (of none to 2 fingers) | 3.0 | 0.0 | 12.8 | 3.1 |
| - symmetry | 31.3 | 38.8 | 29.0 | 40.6 |
| **External anal sphincter** | | | | |
| - tone at rest | 17.9 | 22.5 | 18.0 | 34.4 |
| - voluntary contraction | 4.5 | 2.0 | 5.1 | 3.1 |
| - voluntary relaxation | 23.9 | 20.4 | 29.0 | 22.6 |
| - maximum voluntary contraction | 26.9 | 36.7 | 38.5 | 34.4 |
| - frequency of maximum voluntary contractions | 4.5 | 2.0 | 5.1 | 3.1 |
| - endurance (in categories) | 38.8 | 28.6 | 41.0 | 34.4 |
| - sphincter closed | 1.5 | 2.0 | 5.1 | 0.0 |
| **Puborectal muscle** | | | | |
| - tone at rest | 49.3 | 41.7 | 52.6 | 59.4 |
| - voluntary contraction | 10.5 | 4.2 | 13.2 | 3.1 |
| - voluntary relaxation | 50.8 | 64.6 | 63.2 | 56.3 |
| - maximum voluntary contraction | 47.8 | 44.7 | 47.4 | 34.4 |
| - frequency of maximum voluntary contractions | 9.0 | 2.1 | 10.5 | 3.1 |
| - endurance (in categories) | 35.8 | 22.9 | 34.2 | 21.9 |
| - anorectal angle | 29.9 | 37.5 | 36.8 | 25.0 |

Abbreviations: EAS, external anal sphincter; POP, pelvic organ prolapse; PFM, pelvic floor musculature; PRM, puborectal muscle.

## FIGURES

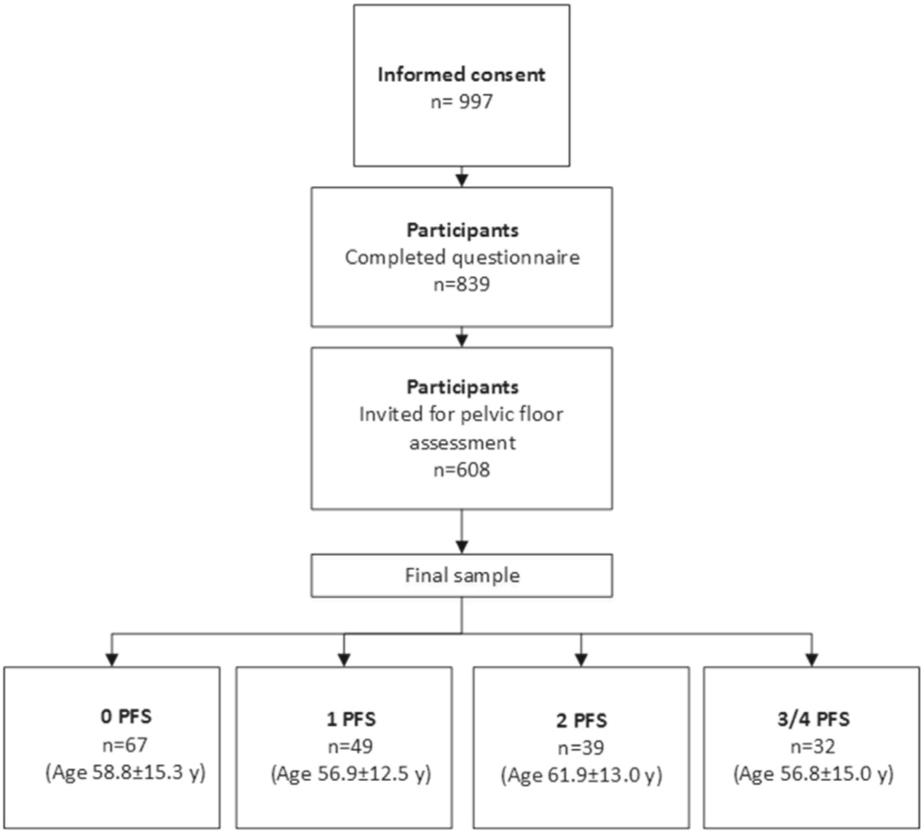



**Figure 1.** Flowchart of females participating in the pelvic floor muscle assessment study


**Figure 2:** A. vaginal PFM, EAS, and PRM function.

Data were sorted according to vaginal PFM dysfunction in the first columns with all other items for vaginal PFM, EAS, and PRM; the green cells indicate normal function, and the red cells indicate dysfunction. Each line (row) includes the outcomes of an individual participant.

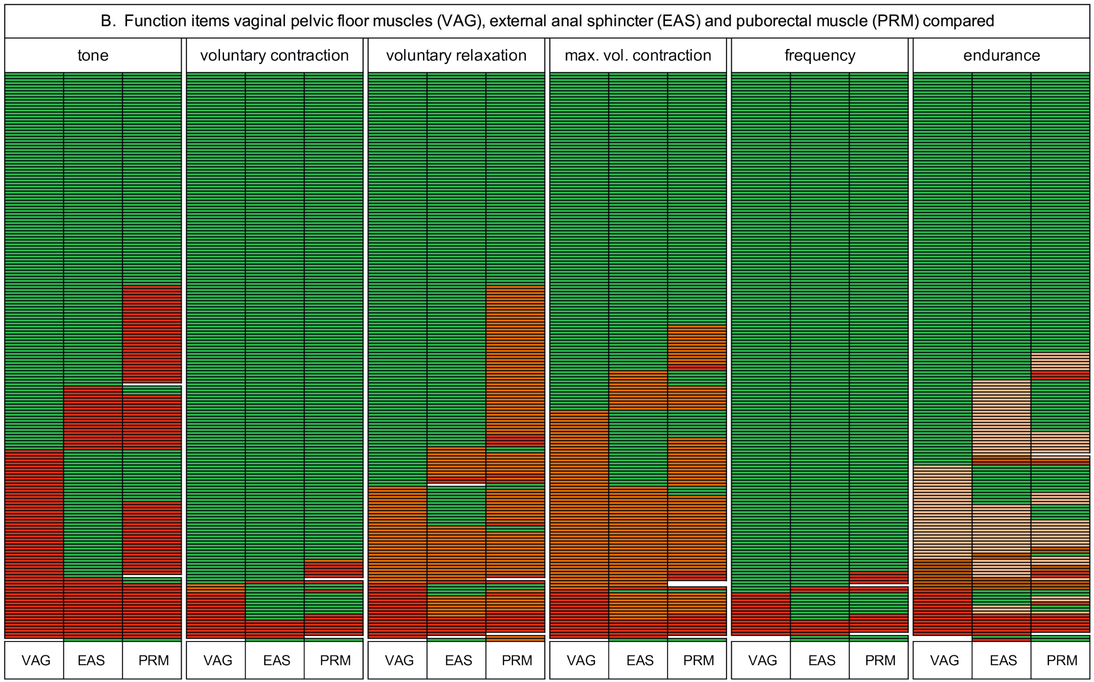



**Figure 2:** B. Comparison of vaginal PFM, EAS, and PRM function items.

Colors of cells: white (missing data), green (normal function), light orange (slight function decrease), orange (moderate function decrease), dark orange (strong function decrease), and red (very strong function decrease). For tone (vaginal PFM, EAS, and PRM), red represents an increase or decrease of tone; other red cells represent “no closure of EAS” and “no increase of anorectal angle,” as appropriate. Abbreviations: vaginal PFM, vaginal pelvic floor musculature, EAS, external anal sphincter; max. vol., maximum voluntary; PRM, puborectal muscle.

4

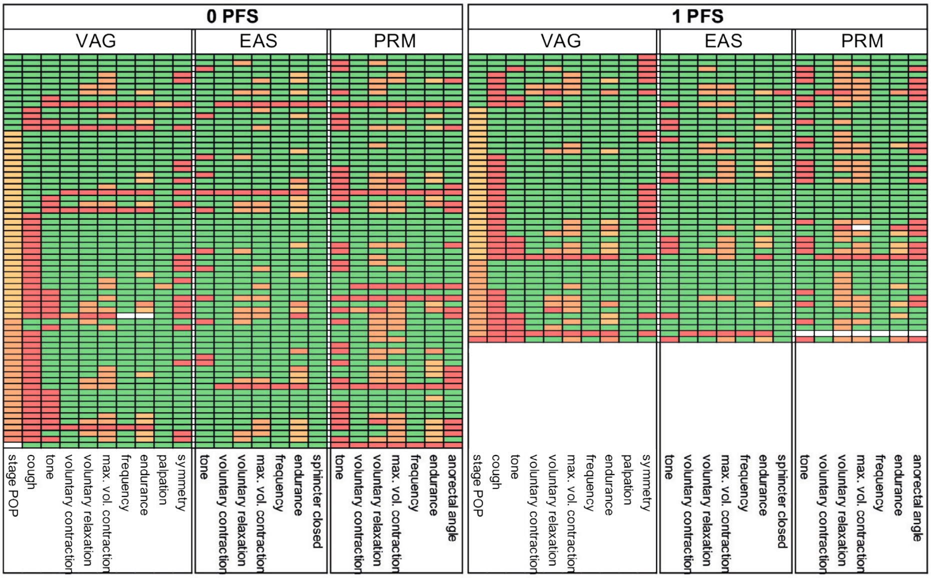
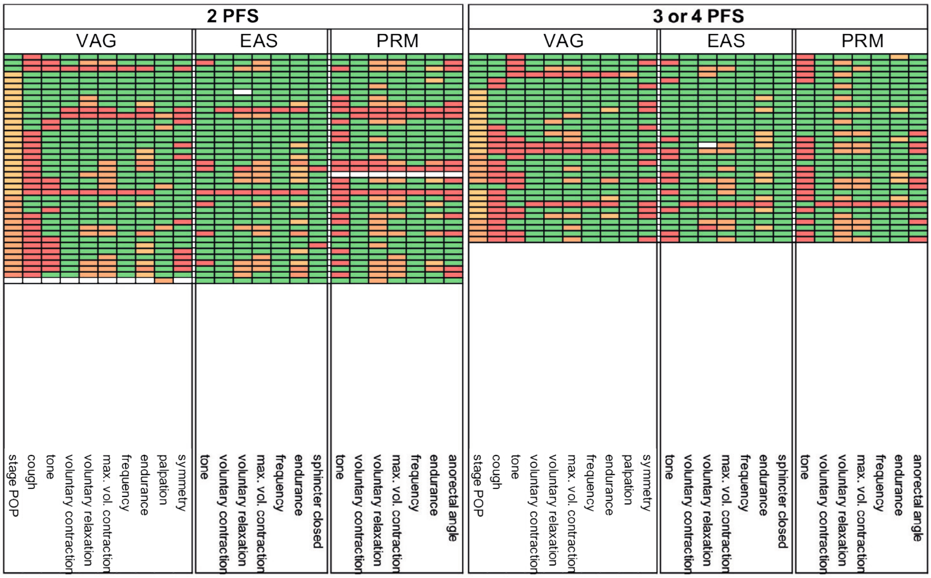



**Figure 3:** Heatmap of function items of vaginal pelvic floor musculature (PFM), external anal sphincter (EAS) and puborectal muscle (PRM), and number of PFS (0–4 PFS).

Data were sorted according to vaginal PFM dysfunction in the first columns with all other items for vaginal PFM, EAS, and PRM; the green cells indicate normal function, and the red cells indicate dysfunction. Each line (row) includes the outcomes of an individual participant

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Colors of cells: white (missing data), green (normal function), light orange (slight function decrease), orange (moderate function decrease), dark orange (strong function decrease), and red (very strong function decrease). For tone (vaginal PFM, EAS, and PRM), red represents an increase or decrease of tone; other red cells represent "no closure of EAS" and "no increase of anorectal angle," as appropriate. Abbreviations: vaginal PFM, vaginal pelvic floor musculature; EAS, external anal sphincter; max. vol., maximum voluntary; PRM, puborectal muscle.

4

## SUPPLEMENTARY FILES

### Supplementary file 1. Questionnaires and sampling procedure

#### Lower urinary tract symptoms

The International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) a validated 12-item patient-completed questionnaire for evaluating female lower urinary tract symptoms in research and clinical practice. Each question is scored 0–4. There are three subscales for filling (scores 0–16), voiding (scores 0–12), and incontinence (score 0–20) symptoms. Higher scores indicate a greater impact of individual symptoms for the participant.

#### Bowel symptoms

We used items from category 1 (defecation pattern), categories 2 and 3 (fecal constipation), and category 4 (fecal continence) of the Groningen Defecation and Fecal Continence (DeFeC) questionnaire. This is based on several validated constipation and fecal incontinence scores (Wexner, Vaizey), and higher scores indicate higher impact of individual symptoms.

#### Sexual symptoms

For sexual symptoms we used The Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR) a patient-completed measure of sexual function in people with pelvic disorders in which a higher score indicates less impact and better sexual function.

#### Pelvic pain

We constructed a questionnaire to assess pelvic pain. This comprised items on lower urinary tract pain and/or other pelvic pain, pain severity (on a numerical rating scale), the presence of pain in time, and how the pain started. Higher scores on the numeric rating scale indicate more pain.

#### Pelvic organ prolaps

The validated 6-item Pelvic Organ Prolapse Distress Inventory (POPDI-6) was used.

**Sampling procedure**

We defined the presence of lower urinary tract symptoms using the highest scores (≥11) in the ICIQ-FLUTS, the presence of anorectal dysfunction using the highest scores (≥10) on the combined constipation and incontinence Wexner score. Sexual dysfunction was considered present when the woman reported having orgasmic dysfunction and/or orgasmic problems and/or vaginismus and/or vaginal dryness and/or pain during intercourse. Pelvic pain was considered present when pelvic pain symptoms were reported. Finally, urogenital prolapse symptoms were considered present if the woman responded positively on ≥4 questions of the POPDI-6.

**Supplementary file 2. Pelvic floor muscle assessment**

The pelvic floor physical therapist (PFPT) gave a brief explanation of the function of the pelvic floor musculature (PFM) and showed a picture of the pelvic floor. For the digital vaginal PFM assessment, participants were asked to lie in the supine position with their knees in leg rests. For the anorectal muscle assessment, they were asked to lie in a left-lateral position with their knees and hips flexed to 90 degrees.

1) External PFM assessment by visual inspection:
   (a) Of the vaginal region, including defects, during a 10 s rest,
   (b) For the duration of a 3 s maximum voluntary contraction of all vaginal muscles followed by a maximum voluntary relaxation of all vaginal muscles,
   (c) For the duration of a cough and an abdominal straining movement.
2) Internal digital PFM assessment of the vaginal and internal obturator muscles by palpation with the right gloved index finger:
   (a) During a 1-minute rest, with digital palpation by the PFPT to detect tone and painful areas (vaginal PFM or the attachment of the internal obturator).
3) Internal digital PFM assessment of the vaginal PFM with the right gloved index and middle finger of the PFPT:
   (a) During maximum voluntary contraction lasting 3 s followed by maximum voluntary relaxation,
   (b) During ten maximum voluntary contractions, each lasting 3 s and followed by maximum voluntary relaxations,
   (c) During three endurance contractions of sub-maximum power, each lasting 10 s and followed by maximum voluntary relaxations,
   (d) During a cough and an abdominal straining movement.
4) Internal digital prolapse assessment, using the Simplified Pelvic Organ Prolapse Quantification method, with the right gloved index finger of the PFPT to detect bladder, uterine, or rectal prolapse during Valsalva straining movements.
5) External PFM examination by visual inspection:
   (a) Of the anal region, including defects,
   (b) Of all pelvic floor muscles during a 10 s rest,
   (c) During a 3 s maximum voluntary contraction of all pelvic floor muscles, followed by a maximum voluntary relaxation of all pelvic floor muscles,
   (d) For the duration of a cough and an abdominal straining movement.

6) Internal digital PFM assessment of the external anal sphincter (EAS) and the puborectal muscle (PRM) by palpation with the right gloved index finger of the PFPT:
   (a) Manual palpation to detect tone and painful areas during a 1 minute rest period,
   (b) During a 3 s maximum voluntary contraction followed by maximum voluntary relaxation,
   (c) During ten maximum voluntary contractions, each lasting 3 s and followed by maximum voluntary relaxations,
   (d) During three endurance contractions of sub-maximum power, each lasting 10 s and followed by a maximum voluntary relaxation,
   (e) During a cough and abdominal straining movement.

Subjects were allowed short rest periods of 3 s between each maximum voluntary contraction and 10 s between each sub-maximum endurance contraction of the vaginal PFM, the EAS, and the PRM. The instruction given on how to activate the vaginal PFM was “try to lift your vagina inwards”; for the EAS, “try to squeeze your circular anal muscle as if holding back bowel movements or flatus; and for the PRM, “try to lift your anal muscle inwards and forwards as if holding back bowel movements or flatus.” The instruction for sub-maximum power during endurance assessments of the vaginal PFM, the EAS, and PRM was “try to contract to 70% of your maximum power and hold this contraction for ten seconds.” Instruction for relaxation of the vaginal PFM, the EAS, and the PRM was “try to perform a maximum relaxation after each maximum voluntary contraction or after each sub-maximum endurance contraction.” The instruction for pushing the vagina was “try to push your vagina,” while that for the EAS and the PRM was “try to push as if you are pushing out bowel.” Measurements were repeated if the researcher observed co-contraction of the muscles of the abdominal wall and/or the gluteal muscles and/or the muscles of the upper legs and/or the absence of an inward movement of the vaginal or anal region and perineum during contraction.
A written protocol was followed during all PFM assessments to avoid differences in instruction.

## Supplementary file 3. Comparison of the separate items of pelvic floor muscle function of the vaginal pelvic floor muscles, the external anal sphincter, and the puborectal muscle.

**1.1.** Tone in rest vaginal muscles and external anal sphincter

| | | External anal sphincter | | | |
|---|---|---|---|---|---|
| | | Decreased | Normal tone | Increased tone | Total |
| Vaginal | Decreased tone | 15 | 23 | 1 | 39 |
| | Normal tone | 13 | 103 | 8 | 124 |
| | Increased tone | 0 | 19 | 4 | 23 |
| | Total | 28 | 145 | 13 | 186* |

*: one missing

**1.2.** Tone in rest vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Decreased tone | Normal tone | Increased tone | Total |
| Vaginal | Decreased tone | 19 | 14 | 6 | 39 |
| | Normal tone | 17 | 73 | 33 | 123 |
| | Increased tone | 0 | 5 | 17 | 22 |
| | Total | 36 | 92 | 56 | 184* |

*: three missing

**1.3.** Tone in rest external anal sphincter and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Decreased tone | Normal tone | Increased tone | Total |
| External anal sphincter | Decreased tone | 20 | 3 | 5 | 28 |
| | Normal tone | 15 | 88 | 41 | 144 |
| | Increased tone | 1 | 2 | 10 | 13 |
| | Total | 36 | 93 | 56 | 185* |

*: two missing

4

**2.1.** Voluntary contraction vaginal muscles and external anal sphincter

| | | External anal sphincter | | | |
|---|---|---|---|---|---|
| | | Yes, circular closing and contraction in cephalad ventral direction | No, opening and descend in dorso-caudal direction (straining; pelvic floor descent) | No, no movement (no contraction; no change; absent: non-contracting pelvic floor muscles) | Total |
| Vaginal muscles | Yes, closing and inward contraction in cephalad ventral direction | 167 | 0 | 1 | 168 |
| | No, opening and descend in dorso-caudal direction (straining; pelvic floor descent) | 3 | 0 | 0 | 3 |
| | No, no movement (no contraction; no change; absent: non-contracting pelvic floor muscles) | 9 | 0 | 6 | 15 |
| | Total | 179 | 0 | 7 | 186* |

*: one missing

**2.2.** Voluntary contraction vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Yes, contraction in cephalad- ventral direction | No, descend in dorso-caudal direction (straining; pelvic floor descent) | No, no movement (no contraction; no change; absent: non-contracting pelvic floor muscles) | Total |
| Vaginal muscles | Yes, closing and inward contraction in cephalad-ventral direction | 160 | 1 | 6 | 167 |
| | No, opening and descend in dorso-caudal direction (straining; pelvic floor descent) | 2 | 0 | 1 | 3 |
| | No, no movement; (no contraction; no change; absent: non-contracting pelvic floor muscles) | 7 | 0 | 7 | 14 |
| | Total | 169 | 1 | 14 | 184* |

*: three missing

4

**2.3.** Voluntary contraction external anal sphincter and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Yes, contraction in cephalad- ventral direction | No, descend in dorso-caudal direction (straining; pelvic floor descent) | No, no movement (no contraction; no change absent: non-contracting pelvic floor muscles) | Total |
| External anal sphincter | Yes, circular closing and contraction in cephalad-ventral direction | 170 | 1 | 8 | 179 |
| | No, opening and descend in dorso-caudal direction (straining; pelvic floor descent) | 0 | 0 | 0 | |
| | No, no movement (no contraction; no change absent: non-contracting pelvic floor muscles) | 0 | 0 | 6 | 6 |
| | Total | 170 | 1 | 14 | 185* |

*: two missing

**3.1.** Voluntary relaxation (relaxation post-contraction) vaginal muscles and external anal sphincter

| | | External anal sphincter | | | | | |
|---|---|---|---|---|---|---|---|
| | | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | Complete relaxation, to original rest tone (yes: relaxation felt directly after instruction; normal finding), delayed | Partial relaxation | Partial relaxation, delayed | No relaxation; (no: absent = non-relaxing pelvic floor muscles) | Total |
| Vaginal muscles | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | 103 | 3 | 2 | 5 | 1 | 114 |
| | Complete relaxation to original rest tone (yes: relaxation felt directly after instruction; normal finding), delayed | 12 | 5 | 0 | 3 | 1 | 21 |
| | Partial relaxation | 5 | 0 | 2 | 2 | 0 | 9 |
| | Partial relaxation, delayed | 5 | 3 | 1 | 13 | 1 | 23 |
| | No relaxation (no: absent = non-relaxing pelvic floor muscles) | 2 | 2 | 3 | 4 | 6 | 17 |
| | Total | 127 | 13 | 8 | 27 | 9 | 184* |

*: three missing

**3.2.** Voluntary relaxation vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | Partial relaxation | No relaxation; (no: absent = non-relaxing pelvic floor muscles) | Total |
| Vaginal muscles | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | 67 | 44 | 4 | 115 |
| | Complete relaxation to original rest tone (yes: relaxation felt directly after instruction; normal finding), delayed | 6 | 13 | 2 | 21 |
| | Partial relaxation | 0 | 9 | 0 | 9 |
| | Partial relaxation, delayed | 3 | 16 | 3 | 22 |
| | No relaxation; (no: absent = non-relaxing pelvic floor muscles) | 2 | 7 | 8 | 17 |
| | Total | 78 | 89 | 17 | 184* |

*: three missing

**3.3.** Voluntary relaxation external anal sphincter and puborectal muscle

| | | Puborectal muscle | | | |
|---|---|---|---|---|---|
| | | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | Partial relaxation | No relaxation; (no: absent = non-relaxing pelvic floor muscles) | Total |
| External anal sphincter | Complete relaxation to original rest tone, not delayed (yes: relaxation felt directly after instruction; normal finding) | 70 | 54 | 4 | 128 |
| | Complete relaxation (yes: relaxation felt directly after instruction; normal finding), delayed | 3 | 8 | 2 | 13 |
| | Partial relaxation | 2 | 5 | 1 | 8 |
| | Partial relaxation, delayed. | 2 | 21 | 3 | 26 |
| | No relaxation; (no: absent = non-relaxing pelvic floor muscles) | 0 | 1 | 7 | 8 |
| | Total | 77 | 89 | 17 | 183* |

*: four missing

**4.1.** Maximum voluntary contraction vaginal muscles and external anal sphincter

| | | External anal sphincter | | | | |
|---|---|---|---|---|---|---|
| | | Strong | Moderate | Weak | Absent | Total |
| Vaginal muscles | Strong | 5 | 20 | 0 | 0 | 25 |
| | Moderate | 2 | 71 | 13 | 0 | 86 |
| | Weak | 1 | 24 | 33 | 1 | 59 |
| | Absent | 0 | 1 | 9 | 6 | 16 |
| | Total | 8 | 116 | 55 | 7 | 186* |

*: one missing

**4.2.** Maximum voluntary contraction vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | Strong | Moderate | Weak | Absent | Total |
| Vaginal muscles | Strong | 5 | 19 | 1 | 0 | 25 |
| | Moderate | 0 | 64 | 20 | 2 | 86 |
| | Weak | 0 | 12 | 41 | 4 | 57 |
| | Absent | 0 | 1 | 7 | 7 | 15 |
| | Total | 5 | 96 | 69 | 13 | 183* |

*: four missing

**4.3.** Maximum voluntary contraction external anal sphincter and puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | Strong | Moderate | Weak | Absent | Total |
| External anal sphincter | Strong | 2 | 6 | 0 | 0 | 8 |
| | Moderate | 3 | 83 | 29 | 2 | 117 |
| | Weak | 0 | 8 | 40 | 5 | 53 |
| | Absent | 0 | 0 | 0 | 6 | 6 |
| | Total | 5 | 97 | 69 | 13 | 184* |

*: three missing

**5.1.** Frequency of maximum voluntary contractions vaginal muscles and external anal sphincter

| | | External anal sphincter | | | | |
|---|---|---|---|---|---|---|
| | | 10 times | 7–9 times | 1–3 times | 0 times | Total |
| Vaginal muscles | 10 times | 167 | 2 | 0 | 2 | 171 |
| | 7–9 times | 0 | 0 | 0 | 0 | 0 |
| | 1–3 times | 0 | 0 | 0 | 0 | 0 |
| | 0 times | 9 | 0 | 0 | 5 | 14 |
| | Total | 176 | 2 | 0 | 7 | 185* |

*: two missing

**5.2.** Frequency of maximum voluntary contractions vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | 10 times | 7–9 times | 1–3 times | 0 times | Total |
| Vaginal muscles | 10 times | 163 | 1 | 0 | 6 | 170 |
| | 7–9 times | 0 | 0 | 0 | 0 | 0 |
| | 1–3 times | 0 | 0 | 0 | 0 | 0 |
| | 0 times | 7 | 0 | 0 | 6 | 13 |
| | Total | 170 | 1 | 0 | 12 | 183* |

*: four missing

**5.3.** Frequency of maximum voluntary contractions external anal sphincter and puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | 10 times | 7–9 times | 1–3 times | 0 times | Total |
| External anal sphincter | 10 times | 170 | 1 | 0 | 6 | 177 |
| | 7–9 times | 2 | 0 | 0 | 0 | 2 |
| | 1–3 times | 0 | 0 | 0 | 0 | 0 |
| | 0 times | 0 | 0 | 0 | 6 | 6 |
| | Total | 172 | 1 | 0 | 12 | 185* |

*: two missing

**6.1.** Average of three endurance contractions in categories (each with a maximum of 10 s) of vaginal muscles and external anal sphincter

| | | External anal sphincter | | | | |
|---|---|---|---|---|---|---|
| | | 7–10 s | 3–6.99 s | 1–2.99 s | 0–0.99 s | Total |
| Vaginal muscles | 7–10 s | 101 | 25 | 2 | 1 | 129 |
| | 3–6.99 s | 13 | 16 | 2 | 0 | 31 |
| | 1–2.99 s | 0 | 6 | 4 | 0 | 10 |
| | 0–0.99 s | 5 | 3 | 0 | 7 | 15 |
| | Total | 119 | 50 | 8 | 8 | 185* |

*: two missing

**6.2.** Average of three endurance contractions in categories (each with a maximum of 10 s) of vaginal muscles and puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | 7–10 s | 3–6.99 s | 1–2.99 s | 0–0.99 s | Total |
| Vaginal muscles | 7–10 s | 109 | 14 | 1 | 4 | 128 |
| | 3–6.99 s | 15 | 14 | 2 | 0 | 31 |
| | 1–2.99 s | 0 | 3 | 5 | 2 | 10 |
| | 0–0.99s | 4 | 3 | 0 | 7 | 14 |
| | Total | 128 | 34 | 8 | 13 | 183* |

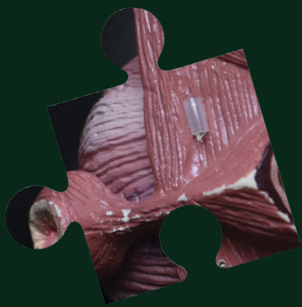
*: four missing

**6.3.** Average of three endurance contractions in categories (each with a maximum of 10 s) of the external anal sphincter and the puborectal muscle

| | | Puborectal muscle | | | | |
|---|---|---|---|---|---|---|
| | | 7–10 s | 3–6.99 s | 1–2.99 s | 0–0.99 s | Total |
| External anal sphincter | 7–10 s | 104 | 12 | 0 | 4 | 120 |
| | 3–6.99 s | 24 | 19 | 4 | 2 | 49 |
| | 1–2.99 s | 1 | 3 | 4 | 0 | 8 |
| | 0–0.99 s | 1 | 0 | 0 | 7 | 8 |
| | Total | 130 | 34 | 8 | 13 | 185* |

*: two missing

4



# 5

# Comparing male and female pelvic floor muscle function by the number and type of pelvic floor symptoms

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## ABSTRACT

**Aims**
Pelvic floor symptoms (PFS), including lower urinary tract symptoms, defecation problems, sexual dysfunction, and pelvic pain, are common in males and females. Comparing pelvic floor musculature (PFM) function between sexes may reveal important differences relevant to clinical care. This study aimed to compare male and female PFM function and to assess the function of both sexes with the number and type of PFS.

**Methods**
We purposively enrolled males and females aged ≥21 years with 0–4 PFS based on questionnaire responses in an observational cohort study. Participants then underwent PFM assessment, and muscle function in the external anal sphincter (EAS) and puborectal muscle (PRM) were compared between sexes. The relationships between muscle function and the number and type of PFS were explored.

**Results**
Of the invited 400 males and 608 females, 199 and 187 underwent PFM assessment, respectively. Compared with females, males more often showed increased EAS and PRM tone during assessments. Compared with males, females more often showed weaker maximum voluntary contraction (MVC) of the EAS and dysfunctional endurance of both muscles; additionally, those with zero or one PFS, sexual dysfunction, and pelvic pain more often showed a weak MVC of the PRM.

**Conclusions**
Despite a few similarities between males and, females we found differences in muscle tone, MVC, and endurance between male and female PFM function. These findings provide useful insights into the differences in PFM function between males and females.


Keywords: Males, Females, Pelvic floor Musculature assessment, Pelvic Floor Symptoms.

# 1. INTRODUCTION

Males and females both frequently report pelvic floor symptoms (PFS) that reduce quality of life. These include lower urinary tract symptoms (LUTS), defecation problems, sexual dysfunctions, and pelvic pain [1,2]. Although both sexes may experience similar PFS, sex-specific symptoms can occur, sometimes presenting in dominant combinations, due to differences in the complex anatomy of the urinary tract, genitals and pelvic floor musculature (PFM) [3,4]. For example, sexual symptoms and pelvic pain often co-occur in females, while defecation problems, sexual symptoms, and LUTS co-occur in males [5].
PFS may be related to PFM dysfunction in either sex [6]. However, a recent scoping review found less research about concomitant PFS in male populations compared with female populations [7]. Few studies have described the differences in PFS between males and females, and those that have, have mainly focused on double incontinence [7]. We have previously described the relationships between PFM function in males with and without PFS [8]. This research showed that neither sex had a clear dose-response relationship between PFM function and the number of PFS. Nevertheless, given the clear anatomical differences in the urogenital tract and PFM between sexes, we may also expect differences in PFM function. This information could open new avenues to improve the treatment of PFS in both sexes. In this study, we compare data on male and female PFM function, exploring the differences and similarities in muscle function between sexes and assessing the relationship of PFM function to the number and type of PFS.

# 2. MATERIALS AND METHODS

## 2.1 Study design, setting and participants

This exploratory work was part of a larger observational cohort study among inhabitants from a municipal area in the Netherlands who had consented to participate in a sub-study concerning PFM assessment [5]. General practitioners performed the initial selection in the parent study [5]. The current sub-study took place from July 2019 to December 2020. Participants aged ≥21 years with and without PFS were included by purposive sampling from among those with complete baseline questionnaires. Details of the questionnaires and sampling procedures

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for the previous studies are provided in Supplementary File 1. We aimed to include two groups comprising 200 males and 200 females with or without PFS based on responses to the baseline questionnaire. The local medical ethics committee approved the study. All participants provided written informed consent, and for their contribution to the sub-study, received a €20 gift card after participation.

### 2.2 Pelvic floor symptoms

We compared females and males based on four types of PFS (called domains), defined as follows:

- **LUTS:** upper quartile of International Consultation on Incontinence Questionnaire (ICIQ)-MLUTS (sum score of the two subscales) and ICIQ-FLUTS (sum score of the three subscales) for males and females, respectively [9].
- **Defecation problems:** upper quartile of the combined Wexner score (constipation and incontinence), based on the Groningen Defecation and Fecal Continence questionnaire [10].
- **Sexual symptoms:** only assessed in sexually active participants, using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR), [11] the Sexual Health in the Netherlands questionnaire (one item), [12] and additionally the ICIQ-MLUTSsex for assessing erectile, ejaculation, and orgasm problems in males [9].
- **Pelvic pain:** assessed by report of pain in the pelvic region.

We applied a two-step approach. First, for each PFS (LUTS, defecation problems, sexual symptoms and pelvic pain), the presence or absence was defined, based on the mentioned questionnaires. Secondly, the total number of PFS domains was assessed to categorize participants into groups (i.e. 0, 1, 2, and 3 or 4), and invite them for this additional study. Participants were categorized by their age and the number of affected domains, from zero to three or four, aiming to achieve an equal age distribution in each group.

### 2.3 Pelvic floor musculature assessment

A digital assessment was performed for measurement of PFM function in both sexes. This assessment, based on the P(ower) E(ndurance) R(epetitions) F(ast) E(very) C(contraction) T(imed) scheme is, despite of its subjective character, a valuable tool for PFM function measurement [13] An experienced pelvic floor physical therapist, blinded to the PFS status, performed all digital PFM assessments. She created a safe and agreeable environment for the participants, so outcomes specifically of tone, would be as little as possible influenced by any stress reactions. PFM function was compared based on complete assessment of the anal sphincter (EAS) and the puborectal muscle (PRM) by internal digital palpation (per rectum) in both males and females. Participants received a description of the PFMs in a short presentation with instruction to facilitate proprioception, contraction, and relaxation. The muscle function aspects of tone, voluntary contraction, voluntary relaxation, maximum voluntary contraction (MVC), frequency, and endurance were assessed for both muscles. In the absence of well-defined standards, we used International Continence Society standards and prevailing pelvic floor physical therapy protocols specifically developed for PFM assessment in the Netherlands, when assessing male and female PFM function [14-17]. Concerning relaxation, a 'delayed relaxation' was defined as a slow relaxation, 'a partial relaxation' as an incomplete relaxation, a 'delayed partial relaxation' as a slow and incomplete relaxation and 'endurance' as the ability to maintain a contraction within a certain time span on the same level'. Full details of the PFM assessment have been published elsewhere [8]and can be found in supplementary file 2.



### 2.4 Statistical analysis

Patient characteristics are reported as absolute numbers and percentages. Differences and similarities in EAS and PRM function between sexes are displayed in figures that show the percentages for different muscle function aspects. Finally, EAS and PRM function aspects with >10% dysfunction are compared with the total number of PFS (i.e., 0, 1, 2, and 3 or 4), and the type of PFS (i.e., LUTS, defecation problems, sexual symptoms, and pelvic pain) between males and females. Muscle function aspects with <10% dysfunction were excluded, since the numbers of the participants in those groups would be too small and would have limited meaning. The cut-off value of 10% was chosen arbitrarily. We refrained from further statistical testing because of the exploratory study design.

# 3 RESULTS

## 3.1 Participants and descriptive statistics

Of the 400 males and 608 females invited, 199 (age 63.0 ± 12.5 years) and 187 (age 58.6 ± 14.1 years) took part in the PFM assessment, respectively. Figure 1 summarizes participant flow.

## 3.2 Comparison of male and female muscle function

### *3.2.1 External anal sphincter (Figure 2A)*

Overall, the prevalence of normal tone did not differ between males and females (78% for both), but more males had increased tone (14.1% vs. 7.0%) and more females had decreased tone (15.0% vs. 8.0%). In addition males more often exhibited partial relaxation compared to females (18.7% vs. 4.3%), whereas females more often exhibited weak or absent MVC (33.1% vs. 22.1%) and less often exhibited strong MVC (4.3% vs. 15.1%). Males more often had normal muscle function on the endurance test than females (83.4% vs. 64.2%).

### *3.2.2 Puborectal muscle (Figure 2B)*

Overall, the prevalence of normal tone did not differ between males and females (51.8% vs. 50.3%), but more men had increased tone (39.7% vs. 30.3%) and more females had decreased tone (19.5% vs. 8.5%). Males more often showed no relaxation compared to females (14.1% vs. 9.2%) and females more often showed weak or absent MVC (44.6% vs. 39.7%). Functional patterns for voluntary contraction, frequency and sphincter closure (EAS) were comparable between males and females, showing high percentages of normal function.

## 3.3 Muscle function and the number of PFS

### *3.3.1 External Anal Sphincter (Table 1)*

Females with 3 or 4 PFS more often showed decreased tone compared to males (28.1% vs. 5.6%). Compared to females, males with 0 or 1 PFS more often showed increased tone and males with 0 and 3 or 4 PFS more often showed partial (delayed) relaxation. Differences in strong MVCs between males and females were highest for those with 0 (27.3% vs. 7.5%) or 1 (13.2% vs. 2.0%) PFS. Females with 2–4 PFS more often had weak MVC compared to males. Of the males with 0 PFS, 89.4% had normal endurance compared to 61.2% for females. However, females with 0 PFS and 3 or 4 PFS more often showed dysfunctional endurance (3–7 s/10 s) compared with males, whereas these differences were less for females and males with 1 or 2 PFS.

#### *3.3.2 Puborectal Muscle (Table 1)*

In the presence of 3 or 4 PFS, females more often (28.1%) showed decreased tone compared to males (5.6%), while in the presence of 0 PFS, males more often showed increased tone and partial (delayed) relaxation than females (less often for males and females with 1 PFS). Males with 2 PFS more often showed no relaxation compared to females (27.3% vs. 13.2%), and females with 1 PFS more often showed weak MVC compared to males (42.6% vs. 26.4%). Of those with 0 PFS, more males than females showed normal endurance (80.3% vs. 64.2%), while more females showed dysfunctional endurance (3–7 s/10 s).

### 3.4 Muscle function and type of PFS

#### *3.4.1 External Anal Sphincter (Table 2)*

Females in all domains had decreased tone more often than males. Compared to females, males with defecation problems (12.1% vs. 3.6%) and sexual symptoms (14.5% vs. 4.7%) more often had increased tone and males with both defecation problems and pelvic pain more often showed partial (delayed) relaxation. Males with LUTS and defecation problems more often showed strong MVC (8.6% vs. 1.8% and 9.1% vs. 1.8%, respectively), whereas females more often showed weak MVC (36.4% vs. 14.3% and 30.9% vs. 18.2%, respectively). Males with LUTS also showed normal endurance (80.0% vs. 60.0%) compared with females, while females who had defecation problems and sexual symptoms more often showed dysfunctional endurance compared with males (3–7 s/10 s).

#### *3.4.2 Puborectal Muscle (Table 2)*

Again, females in all domains had decreased tone more often than males. Compared to females, males with defecation problems and sexual symptoms more often had increased tone. Females with pelvic pain more often showed partial (delayed) relaxation compared to males who more often (18.2%) showed no relaxation compared to females (1.8%). Males with LUTS and defecation problems more often had weak MVCs compared to females, whereas females with sexual symptoms and pelvic pain more often had weak MVCs. In addition, males with LUTS showed normal endurance compared to females (80.0% vs. 67.3%), whereas females with sexual symptoms more often showed dysfunctional endurance compared to males (3–7 s/10 s). Finally, females with LUTS and males with sexual symptoms and pelvic pain more often showed dysfunctional endurance compared to the other sex (0–3 s/10 s). Females with LUTS more often showed no increase in the anorectal angle at contraction.

## 4. DISCUSSION

This study of the anorectal PFM found relevant differences between the sexes. Overall, females more often had decreased tone, males more often showed partial relaxation, a stronger MVC, and a normal endurance in the EAS, whereas males more often had increased tone, no relaxation, and normal endurance in the PRM. For a better understanding of this complex topic, we discuss the differences and similarities in PFM function between males and females both in the total group and by the number and type of PFS. We premise that a digital PFM assessment is not an objective measurement and several factors, concerning both the assessor and the participant could influence outcomes. Nevertheless, we chose digital PFM assessment and think this a valuable tool best reflecting first-line PFM assessments in daily general practice and for PFM assessment in pelvic floor physical therapy.
Overall, we found more cases of dysfunctional tone in the PRM, with females more often showing decreased tone and males more often showing increased tone. It may be that an increase in PRM tone compensates for the decrease in EAS tone, which was more common in females than males; however, it does not explain why even more males showed increased PRM tone compared to increased EAS tone. Assessing tone is difficult because no rating scale exists to define “normal,” which is a variable that fluctuates in response to different participant and assessor characteristics between males and females. In the participant, factors include neuromuscular conditions, non-contractile viscoelasticity of the biomechanical component, sensibility, reaction to digital palpation, and reaction to the assessor. In the assessor, factors include differences in finger size, palpation technique, experience, interpretation, and gender [18]. To prevent increase of tone by stress reactions, the pelvic

floor physical therapist provided an agreeable and safe environment for the participant. Besides, the assessor works for 14 years as a pelvic floor physical therapist, is aware of the factors of influence during PFM assessment and has experience in detecting a decreased, normal or increased tone of the EAS and the PRM. Add to this research findings that emotion and LUTS symptoms may affect pelvic floor function [19] and the issues with tone assessment are abundantly clear. We want to emphasize that the assessment of the muscle property of tone, via digital palpation, is less well understood than that of strength or endurance [17]. By omitting the severity of PFS from our analysis, confounding could have been introduced since the severity of PFS could differ between both sexes [6]. Based on the higher percentage of males with partial EAS relaxation, men seemed to have more trouble with complete EAS relaxation than females. No comparable difference for partial relaxation was shown for the PRM. According to the number of PFS and partial (delayed) EAS relaxation, the groups with 0 PFS and 3 or 4 PFS showed the greatest differences between males and females. Again, this contrasted with the PRM, in which irrespective of sex, these differences were less for all PFS groups. These differences by sex and muscle grouping are difficult to explain solely by muscle function and the number of PFS, indicating that we must find other explanations.



Partial (delayed) relaxation might result not only from pelvic pain and discomfort but also from the PFM assessment itself [20]. Of note, more females reported pain in the EAS and the PRM during the PFM assessment compared to males, possibly due to higher levels of pain in the vaginal pelvic floor. Factors other than pain or PFS that we did not report, such as the awareness of the PFM and the feeling of anorectal flatus, may also have influenced the findings of partial (delayed) relaxation [20]. Given that males need a less profound PFM relaxation during voiding than females the capacity for PFM relaxation in males could be more compromised. Partial (delayed) relaxation could also be related to defecation problems that females reported more often, indicating a relationship between constipation and insufficient relaxation of both the EAS and PRM [21].

Concerning the number and type of PFS, females more often showed weak MVC of the EAS compared to males, but this pattern only appeared for the PRM among females in two groups and two domains, namely those with 0 or 1 PFS, sexual symptoms, and pelvic pain. This indicates that a PRM with a weak MVC is more related to the type than the number of PFS. Overall, we found a large difference for normal endurance of the

EAS in males compared to females, whereas this was less pronounced for the PRM. For both the EAS and the PRM, females more often had dysfunctional endurance (3–7 s/10 s) compared with males, irrespective of the level of analysis. Other differences in EAS function were found between the sexes, mostly for strong and weak MVC with 0–1 and 2–4 PFS, respectively. An impact of PFS type on EAS most often occurred for strong and weak MVC with LUTS and defecation problems. Differences between sexes in a weak MVC of the PRM also appeared with 1 PFS and sexual dysfunction. The differences in EAS function between sexes may be explained by the female hormonal status or a history of vaginal (instrumental) delivery [22]. Although the anorectal angle in females might be larger than in males, 30% of both sexes had a dysfunctional anorectal angle during contraction. It seems logical that an association between the MVC and anorectal angle of the PRM exists, given that PRM dysfunction leads to no or little change in the anorectal angle [3].

Some limitations need to be considered. First, despite setting out to recruit participants of all ages, the final cohort mainly included older age groups, as is often the case with such studies. Second, male participants were significantly older than female participants, which might have influenced our results because aging causes a decline in striated muscle function [23]. Third, the unequal distribution of PFS between sexes might have influenced our results by the over- representation of certain groups. Fourth, although the same experienced female pelvic floor physical therapist performed all assessments in this study to prevent inter-observer variation, we acknowledge the lack of previous studies on inter-rater and intra-rater reliability in male PFM assessment [24]. While our reliance on one assessor for PFM assessments might have introduced systematic errors, it will also have prevented differences in outcomes of PFM function due to different assessors. Fifth, bias may have resulted from enquiring about PFM function and by virtue of participants having complaints. Sixth, patient characteristics such as the association of different PFS with sex, symptom severity, and education level about PFM function might have affected PFM function differently [25]. Finally, despite the relevance of vaginal PFM function to the assessment of female LUTS and sexual dysfunction, we focused solely on the EAS and the PRM because these muscles are comparable in both sexes.

## 5. CONCLUSION

This study improves knowledge and understanding of the differences between male and female PFM function and can initiate efforts to improve consultations about PFS in both sexes.
Overall, females more often have decreased tone, a weak MVC, and dysfunctional endurance of the EAS, whereas males more often have increased tone, no relaxation, and normal endurance of the PRM. In addition, the EAS and PRM both show distinct patterns of decreased tone for females and increased tone for males, while the EAS shows a pattern of strong MVC for males and weak MVC for females. For the PRM females with either 0 or 1 PFS, sexual dysfunction, or pelvic pain more often show a weak MVC. Dysfunctional endurance (3-7 s.) of the EAS and the PRM for females appeared both in the total group and by the number and type of PFS.

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## TABLES

**Table 1.** External anal sphincter and puborectal muscle functional assessment compared to the number of pelvic floor symptoms, in males and females.

| | | 0 PFS | | 1 PFS | | 2 PFS | | 3 or 4 PFS | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| **External Anal Sphincter** | | | | | | | | | |
| Tone | **(n)** | (66) | (67) | (53) | (49) | (44) | (39) | (36) | (32) |
| | Decreased (%) | 9 | 9 | 6 | 14 | 11 | 15 | 6 | 28 |
| | Normal (%) | 73 | 82 | 77 | 78 | 84 | 82 | 81 | 66 |
| | Increased (%) | 18 | 9 | 17 | 8 | 5 | 3 | 14 | 6 |
| Voluntary relaxation | (n) | (66) | (67) | (53) | (49) | (44) | (38) | (36) | (31) |
| | Complete (delayed) (%) | 62 | 76 | 76 | 80 | 77 | 71 | 67 | 77 |
| | Partial (delayed) (%) | 36 | 19 | 23 | 18 | 12 | 21 | 31 | 16 |
| | No (%) | 2 | 5 | 2 | 2 | 12 | 8 | 3 | 7 |
| Maximum voluntary contraction | (n) | (66) | (67) | (53) | (49) | (44) | (39) | (36) | (32) |
| | Strong (%) | 27 | 8 | 13 | 2 | 7 | 3 | 6 | 3 |
| | Normal (%) | 55 | 66 | 57 | 61 | 73 | 59 | 75 | 63 |
| | Weak (%) | 18 | 22 | 28 | 35 | 16 | 33 | 19 | 31 |
| | Absent (%) | 0 | 5 | 2 | 2 | 5 | 5 | 0 | 3 |

**Table 1.** *Continued.*

| | | 0 PFS | | 1 PFS | | 2 PFS | | 3 or 4 PFS | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| Endurance | (n) | (66) | (67) | (53) | (49) | (44) | (39) | (36) | (32) |
| | 7–10s (%) | 89 | 61 | 81 | 71 | 82 | 59 | 78 | 66 |
| | 3–7s (%) | 9 | 27 | 11 | 25 | 11 | 26 | 14 | 31 |
| | 0–3s (%) | 2 | 12 | 8 | 4 | 7 | 15 | 8 | 3 |
| **Puborectal Muscle** | | | | | | | | | |
| Tone | (n) | (66) | (67) | (53) | (48) | (44) | (38) | (36) | (32) |
| | Decreased (%) | 12 | 24 | 6 | 10 | 9 | 16 | 6 | 28 |
| | Normal (%) | 49 | 51 | 55 | 58 | 50 | 47 | 56 | 41 |
| | Increased (%) | 39 | 25 | 40 | 31 | 41 | 37 | 39 | 31 |
| Voluntary relaxation | (n) | (66) | (67) | (53) | (48) | (44) | (38) | (36) | (32) |
| | Complete (delayed) (%) | 38 | 49 | 45 | 35 | 27 | 37 | 36 | 44 |
| | Partial (delayed) (%) | 47 | 39 | 49 | 58 | 46 | 50 | 56 | 53 |
| | No (%) | 15 | 12 | 6 | 6 | 27 | 13 | 8 | 3 |

**Table 1.** *Continued.*

| | | 0 PFS | | 1 PFS | | 2 PFS | | 3 or 4 PFS | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| Maximum voluntary contraction | (n) | (66) | (67) | (53) | (47) | (44) | (38) | (36) | (32) |
| | Strong (%) | 8 | 6 | 2 | 0 | 0 | 0 | 0 | 3 |
| | Normal (%) | 53 | 46 | 68 | 55 | 48 | 53 | 61 | 63 |
| | Weak (%) | 32 | 37 | 26 | 43 | 41 | 37 | 36 | 31 |
| | Absent (%) | 8 | 10 | 4 | 2 | 11 | 11 | 3 | 3 |
| Endurance | (n) | (66) | (67) | (53) | (48) | (44) | (38) | (36) | (32) |
| | 7–10s (%) | 80 | 64 | 85 | 77 | 68 | 66 | 81 | 78 |
| | 3–7s (%) | 9 | 22 | 8 | 15 | 11 | 16 | 11 | 19 |
| | 0–3s (%) | 11 | 13 | 8 | 8 | 21 | 18 | 8 | 3 |
| Anorectal angle (Increase at contraction) | (n) | (66) | (67) | (53) | (48) | (44) | (38) | (36) | (32) |
| | Yes (%) | 67 | 70 | 74 | 63 | 59 | 62 | 78 | 75 |
| | No (%) | 33 | 30 | 26 | 38 | 41 | 37 | 22 | 25 |

Data are shown as percentages unless in the number (n) row. Participants in the PFS groups are not mutually exclusive (i.e., may be present in all groups).
Abbreviations: PFS, pelvic floor symptoms.

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**Table 2.** External anal sphincter and puborectal muscle functional assessment compared to the type of pelvic floor symptoms, in males and females.

| | | LUTS | | Defecation problems | | Sexual dysfunction | | Pelvic pain | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| **External Anal Sphincter** | | | | | | | | | |
| Tone | (n) | (70) | (55) | (66) | (55) | (76) | (64) | (44) | (56) |
| | Decreased (%) | 9 | 26 | 6 | 22 | 4 | 16 | 14 | 21 |
| | Normal (%) | 83 | 69 | 82 | 75 | 82 | 80 | 75 | 71 |
| | Increased (%) | 9 | 6 | 12 | 4 | 15 | 5 | 11 | 7 |
| Voluntary relaxation | (n) | (70) | (54) | (65) | (53) | (75) | (64) | (44) | (54) |
| | Complete (delayed) (%) | 74 | 76 | 68 | 76 | 73 | 73 | 73 | 78 |
| | Partial (delayed) (%) | 19 | 15 | 25 | 15 | 24 | 23 | 23 | 17 |
| | No | 7 | 9 | 8 | 9 | 3 | 3 | 5 | 6 |
| Maximum voluntary contraction | (n) | (70) | (55) | (66) | (55) | (76) | (64) | (44) | (56) |
| | Strong (%) | 9 | 2 | 9 | 2 | 7 | 3 | 5 | 4 |
| | Normal (%) | 76 | 56 | 68 | 62 | 66 | 59 | 75 | 64 |
| | Weak (%) | 14 | 36 | 18 | 31 | 28 | 36 | 18 | 29 |
| | Absent (%) | 1 | 6 | 5 | 6 | 0.0 | 2 | 2 | 4 |

**Table 2.** *Continued.*

| | | LUTS | | Defecation problems | | Sexual dysfunction | | Pelvic pain | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| Endurance | (n) | (70) | (55) | (66) | (55) | (76) | (64) | (44) | (56) |
| | 7–10s (%) | 80 | 60 | 77 | 60 | 84 | 67 | 77 | 68 |
| | 3–7s (%) | 14 | 29 | 14 | 31 | 11 | 28 | 11 | 25 |
| | 0–3s (%) | 6 | 11 | 9 | 9 | 5 | 5 | 11 | 7 |
| **Puborectal Muscle** | | | | | | | | | |
| Tone | (n) | (70) | (55) | (66) | (54) | (76) | (63) | (44) | (55) |
| | Decreased (%) | 9 | 26 | 9 | 22 | 3 | 14 | 9 | 20 |
| | Normal (%) | 60 | 47 | 47 | 44 | 55 | 52 | 50 | 42 |
| | Increased (%) | 31 | 27 | 44 | 33 | 42 | 33 | 41 | 38 |
| Voluntary relaxation | (n) | (70) | (55) | (66) | (54) | (76) | (63) | (44) | (55) |
| | Complete (delayed) (%) | 37 | 38 | 30 | 43 | 36 | 35 | 34 | 42 |
| | Partial (delayed) (%) | 49 | 49 | 53 | 48 | 55 | 59 | 48 | 56 |
| | No (%) | 14 | 13 | 17 | 9 | 9 | 6 | 18 | 2 |

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**Table 2.** *Continued.*

| | | LUTS | | Defecation problems | | Sexual dysfunction | | Pelvic pain | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** | **Males** | **Females** |
| Maximum voluntary contraction | (n) | (70) | (55) | (66) | (54) | (76) | (62) | (44) | (55) |
| | Strong (%) | 0 | 0 | 0 | 2 | 1 | 2 | 0 | 2 |
| | Normal (%) | 57 | 56 | 53 | 59 | 62 | 55 | 59 | 60 |
| | Weak (%) | 41 | 33 | 39 | 30 | 30 | 42 | 32 | 36 |
| | Absent (%) | 1 | 11 | 8 | 9 | 7 | 2 | 9 | 2 |
| Endurance | (n) | (70) | (55) | (66) | (54) | (76) | (63) | (44) | (55) |
| | 7–10s (%) | 80 | 67 | 76 | 70 | 80 | 78 | 71 | 78 |
| | 3–7s (%) | 11 | 16 | 12 | 19 | 7 | 14 | 14 | 18 |
| | 0–3s (%) | 9 | 16 | 12 | 11 | 13 | 8 | 16 | 4 |
| Anorectal angle (Increase at contraction) | (n) | (70) | (55) | (66) | (54) | (76) | (63) | (44) | (55) |
| | Yes (%) | 71 | 64 | 67 | 69 | 72 | 70 | 71 | 71 |
| | No (%) | 29 | 36 | 33 | 32 | 28 | 30 | 30 | 29 |

Data are shown as percentages unless in the number (n) row. Participants in the PFS groups are not mutually exclusive (i.e., may be present in all groups).
Abbreviations: PFS, pelvic floor symptoms.

## FIGURES

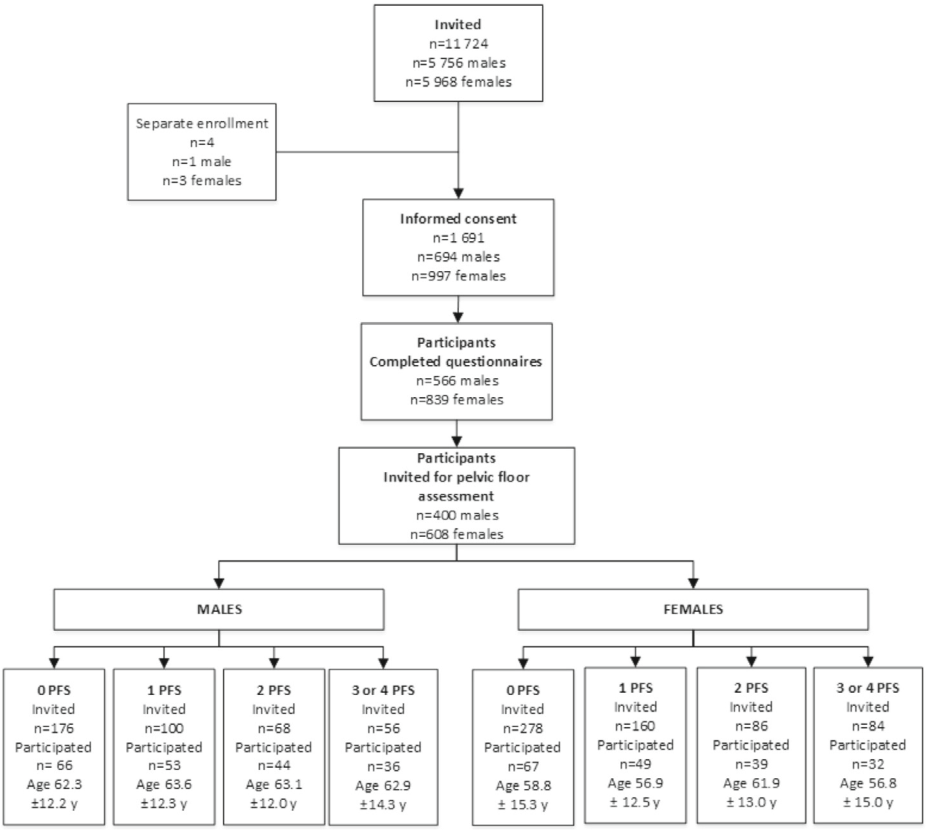


**Figure 1.** Participant flow chart. PFS, Pelvic Floor Symptoms

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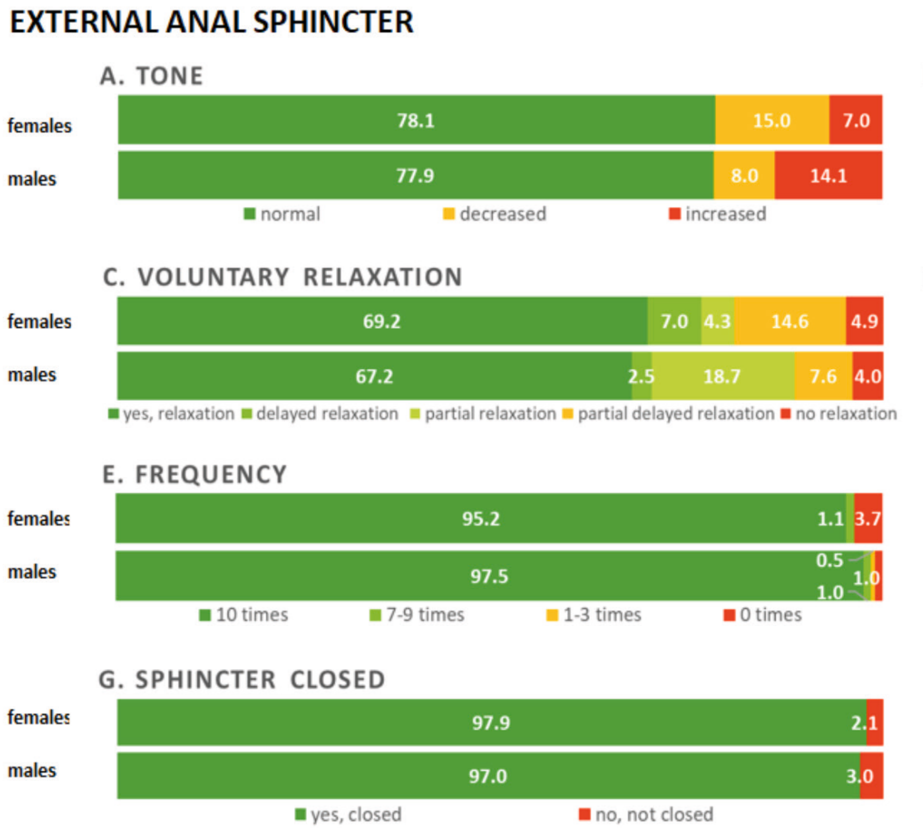
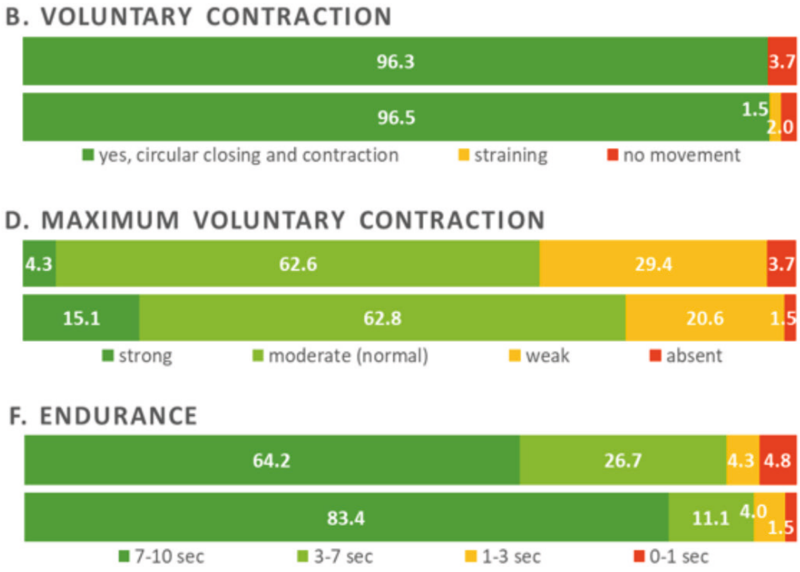



**Figure 2A.** Comparison between female and male pelvic floor muscle function (External Anal Sphincter).

Data show the percentages with each function item for the external anal sphincter and puborectal muscle.


B. VOLUNTARY CONTRACTION
96.3
3.7
96.5
1.5
2.0
yes, circular closing and contraction
straining
no movement
D. MAXIMUM VOLUNTARY CONTRACTION
4.3
62.6
29.4
3.7
15.1
62.8
20.6
1.5
strong
moderate (normal)
weak
absent
F. ENDURANCE
64.2
26.7
4.3
4.8
83.4
11.1
4.0
1.5
7-10 sec
3-7 sec
1-3 sec
0-1 sec

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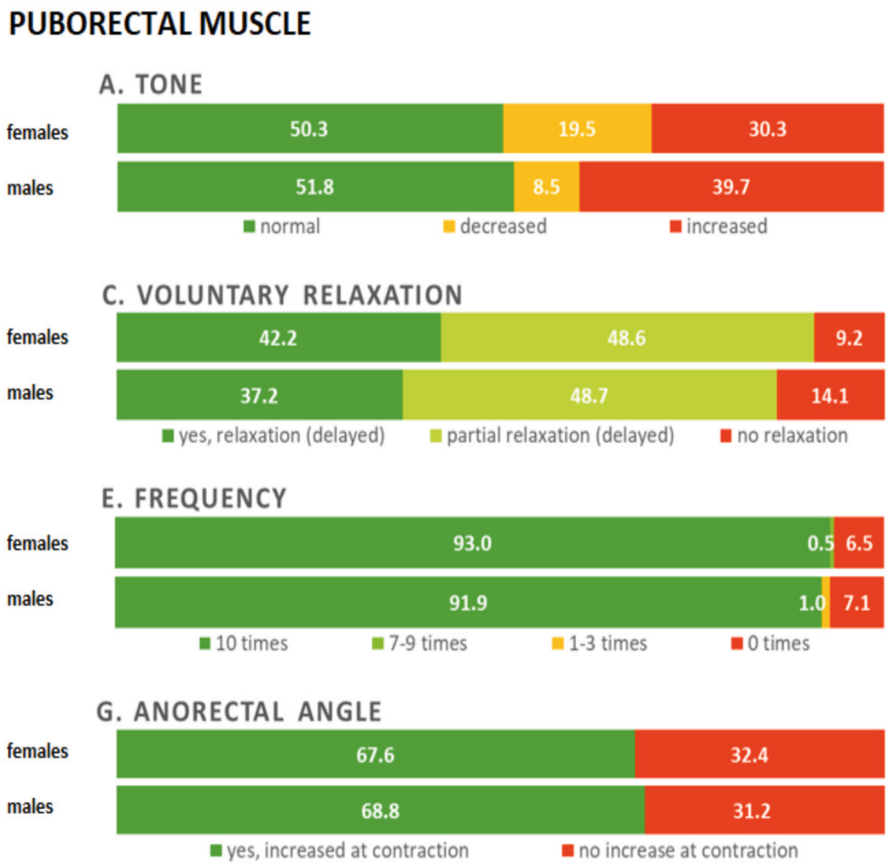
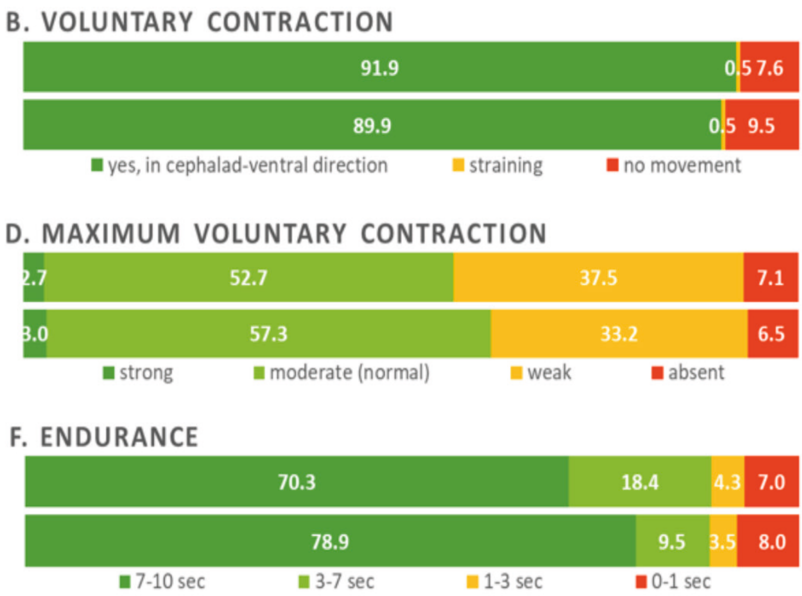



**Figure 2B.** Comparison between female and male pelvic floor muscle function (Puborectal Muscle).


B. VOLUNTARY CONTRACTION
91.9
0.5
7.6
89.9
0.5
9.5
yes, in cephalad-ventral direction
straining
no movement
D. MAXIMUM VOLUNTARY CONTRACTION
2.7
52.7
37.5
7.1
3.0
57.3
33.2
6.5
strong
moderate (normal)
weak
absent
F. ENDURANCE
70.3
18.4
4.3
7.0
78.9
9.5
3.5
8.0
7-10 sec
3-7 sec
1-3 sec
0-1 sec

5

## SUPPLEMENTARY FILES

### Supplementary file 1. Questionnaires and sampling procedure

**Data collection questionnaires**

Details of the questionnaire elements used for participant selection in this sub-study are summarized here for reference [1-4] .

*Lower urinary tract symptoms*

For males, we used the International Consultation on Incontinence Questionnaire–male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS). This is a validated 13-item patient-completed questionnaire for evaluating male LUTS in research and clinical practice. It contains two subscales: voiding symptoms (score, 0–20) and incontinence symptoms (0–24). For females, we used the female module (the ICIQ-FLUTS). This is a validated 12-item patient-completed questionnaire for evaluating female LUTS in research and clinical practice, including subscales for filling (scores 0–16), voiding (scores 0–12), and incontinence (score 0–20). In both questionnaires, each question is scored 0−4, with higher scores indicating greater impact of individual symptoms for the participant.

Bowel symptoms

We used the Groningen Defecation and Fecal Continence (DeFeC) questionnaire for both males and females. The DeFeC is based on several validated constipation and fecal incontinence scores (Wexner, Vaizey) and rates items from categories 1 (defecation pattern), 2 and 3 (fecal constipation), and 4 (fecal continence). Higher scores indicate greater impact.

*Sexual symptoms*

We used the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR), for both males and females. This is a patient-completed score of sexual function in women and men with pelvic disorders, with higher scores indicating less impact and better function. Additionally, we assessed sexuality in both sexes with the Sexual Health in the Netherlands questionnaire (item M1). For males, we added the ICIQ-Male Sexual Matters Associated with LUTS Module for sexual dysfunction (ICIQ-MLUTSsex) that contains three items on erection and ejaculation problems. Higher scores indicated a greater impact of individual symptoms.

*Pelvic pain*
We constructed a questionnaire to assess pelvic pain. This included items on lower urinary tract pain and/or other pelvic pain, pain severity (on a numerical rating scale), the presence of pain and how the pain started.

**Sampling procedure**

*Males*
We used the highest scores (≥9) on the ICIQ-MLUTS as cut-offs defining the presence of LUTS. For the combined constipation and incontinence Wexner score, we used the highest scores (≥6) as cut-offs defining the presence of anorectal dysfunction. Sexual dysfunction was defined by the presence of erectile and/or ejaculation problems and/or pain during intercourse or ejaculation, as mentioned in the ICIQ-MLUTSsex and the Sexual Health in the Netherlands questionnaire (item M1). Pelvic pain was defined as the presence of lower urinary tract and/or other pelvic pain.

*Females*
We defined the presence of lower urinary tract symptoms using the highest scores (≥11) in the ICIQ-FLUTS and defined anorectal dysfunction using the highest scores (≥10) on the combined constipation and incontinence Wexner score. Sexual dysfunction was considered present when the woman reported having orgasmic dysfunction, orgasmic problems, vaginismus, vaginal dryness, and/or pain during intercourse. Pelvic pain was considered present when lower urinary tract and/or pelvic pain symptoms were reported.

## REFERENCES


1. Bristol Urological Institute, 2014 - 2022. The International Consultation on Incontinence Questionnaire - ICIQ Modules. https://iciq.net/iciq-modules. Accessed February 2, 2022.
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3. van Dongen H, van der Vaart H, Kluivers KB, Elzevier H, Roovers JP, Milani AL. Dutch translation and validation of the pelvic organ prolapse/incontinence sexual questionnaire-IUGA revised (PISQ-IR). *Int Urogynecol J.* 2019;30(1):107-114. doi:10.1007/s00192-018-3718-z
4. Seksuele Gezondheid in Nederland 2017. https://rutgers.nl/onderzoeken/seksuele-gezondheid-in-nederland/. Accessed February 2, 2022.

**Supplementary file 2.**

1) External PFM assessment by visual inspection:
   (a) of the anal region including defects;
   (b) for the duration of 10 seconds of rest of all pelvic floor muscles;
   (c) for the duration of a maximum voluntary contraction of all pelvic floor muscles during three seconds followed by a maximum voluntary relaxation of all pelvic floor muscles;
   (d) for the duration of a cough and an abdominal straining movement.

2) Internal manual PFM examination of the external anal sphincter (EAS) and the puborectal muscle (PR) respectively by palpation with the right gloved index finger of the PFPT:
   (e) during 1 minute rest; manual palpation by the PFPT to detect tone and painful area's;
   (f) during a maximum voluntary contraction lasting three seconds and followed by a maximum voluntary relaxation;
   (g) during ten maximum voluntary contractions (each lasting three seconds) and each followed by a maximum voluntary relaxation;
   (h) during three endurance contractions of sub-maximum power (each lasting ten seconds) and each followed by a maximum voluntary relaxation;
   (i) during a cough and an abdominal straining movement.



**<u>Females</u>**

1) External PFM assessment by visual inspection:
   (a) of the vaginal region including defects;
   (b) for the duration of 10 seconds of rest of all pelvic floor muscles;
   (c) for the duration of a maximum voluntary contraction of all vaginal pelvic floor muscles during three seconds followed by a maximum voluntary relaxation of all vaginal pelvic floor muscles;
   (d) for the duration of a cough and an abdominal straining movement.

2) Internal digital PFM assessment of the vaginal pelvic floor muscles and left and right M. Obturatorius by palpation with the right gloved index finger of the PFPT:

   (a) during 1 minute rest; digital palpation by the PFPT to detect tone and painful area's (vaginal pelvic floor muscles); painfull area's (M. Obturatorius);

3) Internal digital PFM assessment of the vaginal pelvic floor muscles with the right gloved index and middle finger of the PFPT:
   (a) during a maximum voluntary contraction lasting three seconds and followed by a maximum voluntary relaxation;
   (b) during ten maximum voluntary contractions (each lasting three seconds) and each followed by a maximum voluntary relaxation;
   (c) during three endurance contractions of sub-maximum power (each lasting ten seconds) and each followed by a maximum voluntary relaxation;
   (d) during a cough and an abdominal straining movement.

4) Internal digital prolapse assessment by a Simplified Pelvic Organ Prolapse Quantification (S-POPQ) with the right gloved index finger of the PFPT to detect presence of prolapse (bladder, uterus, rectum) by Valsalva straining movements of the participant.

5) External PFM examination by visual inspection:
   (a) of the anal region including defects;
   (b) for the duration of 10 seconds of rest of all pelvic floor muscles;
   (c) for the duration of a maximum voluntary contraction of all pelvic floor msucles during three seconds followed by a maximum voluntary relaxation of all pelvic floor muscles;
   (d) for the duration of a cough and an abdominal straining movement.

2) Internal digital PFM assessment of the external anal sphincter (EAS) and the puborectal muscle respectively by palpation with the right gloved index finger of the PFPT:
   (a) during 1 minute rest; manual palpation by the PFPT to detect tone and painful area's;
   (b) during a maximum voluntary contraction lasting three seconds and followed by a maximum voluntary relaxation;
   (c) during ten maximum voluntary contractions (each lasting three seconds) and each followed by a maximum voluntary relaxation;

(d) during three endurance contractions of sub-maximum power (each lasting ten seconds) and each followed by a maximum voluntary relaxation;
(e) during a cough and an abdominal straining movement.

Subjects were allowed short rest periods of 3 seconds between each maximum voluntary contraction and 10 seconds between each sub-maximum endurance contraction of the vaginal pelvic floor muscles, the EAS and puborectal muscle. The instruction given on how to activate the vaginal pelvic floor muscles was “try to lift your vagina inwards”; for the EAS it was “try to squeeze your circular anal muscle as if you hold back bowel movements, passing flatus or gas”; for the puborectal muscle it was “try to lift your anal muscle inwards and forwards as if you hold back bowel movements, passing flatus or gas.” Instruction for sub-maximum power during endurance of the vaginal pelvic floor muscles, the EAS and puborectal muscle was “try to contract on 70% of your maximum power and hold this contraction for ten seconds”. Instruction for relaxation of the vaginal pelvic floor muscles, the EAS and the puborectal muscle was “try to perform a maximum relaxation after each maximum voluntary contraction or after each sub-maximum endurance contraction”. The instruction for the push moment of the vagina was “try to push your vagina”, for the EAS and the puborectal muscle was “try to push as if you are pushing out bowel”. Measurements were repeated if the researcher observed co-contraction of the muscles of the abdominal wall and / or the gluteal muscles and / or the muscles of the upper legs and/or the absence of an inward movement of the vaginal or anal region and perineum during contraction.

To avoid differences in instruction a tailored protocol was written and followed during all PFM assessments.

**Supplementary file 3. Items of digital pelvic floor muscle assessment of vaginal muscles, external anal sphincter and puborectal muscle, definition of normal function and codes of outcomes of pelvic floor musculature assessment for heatmaps**

| | Vaginal pelvic floor muscles | |
|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** |
| Stage POP | - **Stage 0 = no prolapse**<br>- Stage 1 = most distal part of the prolapse is > 1 cm. above the level of the remaining hymen<br>- Stage 2 = most distal part of the prolapse is 1 cm. above up to 1 cm. past the level of the remaining hymen<br>- Stage 3 = most distal part of the prolapse is > 1 cm. under the level of the remaining hymen<br>- Stage 4 = complete eversion of the vagina | - **0=0, stage 0**<br>- 0,25=1, stage 1<br>- 0,5=2, stage 2<br>- 0,75=3, stage 3<br>- 1=4, stage 4 |
| Cough | - **Yes, contraction in cephalad ventral direction**<br>- No, descend in dorso-caudal direction | **0 = yes**<br>1 = no |
| Tone | - **Normal**<br>- Decreased<br>- Increased | **0 = normal tone**<br>1 = decreased/increased tone |

| | Vaginal pelvic floor muscles | |
|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** |
| Voluntary contraction | - **Yes, circular closing and contraction in cephalad ventral direction (correct contraction (cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorso-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | **0 = yes**<br>0.5 = no, opening and descent (straining)<br>1 = no, no movement |
| Voluntary relaxation (Relaxation post contraction) | - **Complete relaxation to original rest tone, not delayed (Yes: relaxation felt directly after instruction; normal finding)**<br>- **Complete relaxation to original rest tone, delayed**<br>- Partial relaxation, not delayed<br>- Partial relaxation, delayed<br>- No relaxation (no: absent=non relaxation PFM) | **0 = complete (delayed) relaxation**<br>0.5 = partial (delayed) relaxation<br>1 = no relaxation |
| Strength: Maximum voluntary contraction measurement | - **Strong**<br>- **Normal (moderate)**<br>- Weak<br>- Absent | **0 = strong/normal (moderate)**<br>0.5 = weak<br>1 = absent |

| Vaginal pelvic floor muscles | | |
|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** |
| Frequency of maximum voluntary contraction (1 sec)<br>Repeatability of contraction<br>Number of rapid contractions performed | - **10 times**<br>- **7-9 times**<br>- 4-6 times<br>- 1-3 times<br>- 0 times | **0 = 7-10 times**<br>0.33 = 4-6 times<br>0.66 = 1-3 times<br>1 = 0 times |
| Endurance | - **7-10 seconds**<br>- 3-7 seconds<br>- 1-3 seconds<br>- 0-1 seconds | **0 = 7-10 sec**<br>0.33 = 3-6.99 sec<br>0.66 = 1-2.99 sec<br>1 = 0-0.99 sec |
| Palpation | - **Yes, 1 or 2 fingers**<br>- No, 0 fingers | **0 = 1 or 2 fingers**<br>1 = 0 fingers |
| Symmetry | - **Yes**<br>- No: left>right; right>left | **0 = yes symmetry**<br>1 = no symmetry |

| | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Tone | - **Normal**<br>- Decreased<br>- Increased | **0 = normal tone**<br>1 = decreased/ increased tone | - **Normal**<br>- Decreased<br>- Increased | 0 **= normal tone**<br>1 = decrease/ increase tone |
| Voluntary contraction (Direction of pelvic floor muscle movement) | - **Yes, circular closing and contraction in cephalad ventral direction (correct contraction (cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorsal-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>- No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | **0 = yes**<br>0.5 = no, opening and descent (straining)<br>1 = no, no movement | - **Yes, contraction in cephalad ventral direction (correct contraction (cephalad and ventral movement; pelvic floor elevation: normal finding)**<br>- No, descend in dorsal-caudal direction (straining; pelvic floor descent: palpation of downward movement of the PFM during attempted PFM contraction)<br>- No, no movement; (no contraction; no change. Absent: non-contracting PFM: during palpation there is no palpable voluntary or involuntary contraction of the PFM) | **0 = yes**<br>0.5 = no, descent (straining)<br>1 = no, no movement |

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| | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Voluntary relaxation (Relaxation post contraction) | - **Complete relaxation to original rest tone, not delayed (Yes: relaxation felt directly after instruction; normal finding)**<br>- **Complete relaxation to original rest tone, delayed**<br>- Partial relaxation, not delayed<br>- Partial relaxation, delayed<br>- No relaxation (no: absent=non relaxation PFM) | **0 = complete (delayed) relaxation**<br>0.5 = partial (delayed) relaxation<br>1 = no relaxation | - **Complete relaxation to original rest tone (Yes: relaxation felt directly after instruction; normal finding)**<br>- Partial relaxation<br>- No relaxation (no: absent=non relaxation PFM) | **0 = complete relaxation**<br>0.5 = partial relaxation<br>1 = no relaxation |
| Strength: Maximum voluntary contraction measurement (digital muscle test) | - **Strong**<br>- **Normal (moderate)**<br>- Weak<br>- Absent | **0 = strong/normal (moderate)**<br>0.5 = weak<br>1 = absent | - **Strong**<br>- **Normal (moderate)**<br>- Weak<br>- Absent | **0 = strong/ normal (moderate)**<br>0.5 = weak<br>1 = absent |

| | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Frequency of maximum voluntary contraction (1 sec) (Repeatability of contraction) Number of rapid contractions performed | - **10 times**<br>- **7-9 times**<br>- 4-6 times<br>- 1-3 times<br>- 0 times | **0 = 7-10 times**<br>0.33 = 4-6 times<br>0.66 = 1-3 times<br>1 = 0 times | - **10 times**<br>- **7-9 times**<br>- 4-6 times<br>- 1-3 times<br>- 0 times | **0 = 7-10 times**<br>0.33 = 4-6 times<br>0.66 = 1-3 times<br>1 = 0 times |
| Endurance (in categories) | - **7-10 seconds**<br>- 3-7 seconds<br>- 1-3 seconds<br>- 0-1 seconds | **0 = 7-10 sec**<br>0.33 = 3-6.99 sec<br>0.66 = 1-2.99 sec<br>1 = 0-0.99 sec | - **7-10 seconds**<br>- 3-7 seconds<br>- 1-3 seconds<br>- 0-1 seconds | **0 = 7-10 sec**<br>0.33 = 3-6.99 sec<br>0.66 = 1-2.99 sec<br>1 = 0-0.99 sec |
| Sphincter closed (at rest) | - **Yes, closed**<br>- No, not closed | **0 = yes**<br>1 = no | | |

| | External Anal Sphincter | | Puborectal muscle | |
|---|---|---|---|---|
| **Items of digital pelvic floor assessment** | **Description** | **Definition normal function (in heatmap)** | **Description** | **Definition normal function (in heatmap)** |
| Anorectal angle | | | - **Yes, increase of anorectal angle at contraction**<br>- No, no increase of anorectal angle at contraction | **0 = yes**<br>1 = no |

Note: normal function in bold.
Endurance = mean average of three endurance contractions (each with a maximum of ten seconds);
Anorectal angle = increase of anorectal angle during contraction.

# 6

# The association between pelvic floor muscle function and male lower urinary tract symptoms with and without concomitant pelvic floor symptoms

Françoise J.M. Notenboom-Nas, Grietje E. Knol-de Vries, Marijke C. Ph. Slieker-ten Hove, Michiel R. de Boer, Marco H. Blanker

## ABSTRACT

**Background**

Lower urinary tract symptoms (LUTS) are prevalent in males. LUTS are generally related to prostate disorders while the relation between male LUTS and pelvic floor muscle (PFM) function is still underexposed.

**Objectives**

To explore associations between PFM function in males and voiding and urinary incontinence (UI) symptoms (together with defecation problems and pelvic pain).

**Methods**

Data were used from 611 males who filled in questionnaires for a larger cohort study and from 199 males who participated in a digital PFM assessment. We explored the association between PFM function (tone, relaxation, maximum voluntary contraction (MVC) and endurance) and voiding and UI symptoms, by Kruskal-Wallis and Correlation tests. Secondly, we performed a latent class analysis (LCA) including age, body mass index, subscales for voiding and UI (ICIQ-MLUTS), fecal incontinence and constipation and pelvic pain and made cross-tabulations to show the association between PFM function and classes.

**Results**

No significant associations were found between PFM function and voiding and UI symptoms. LCA constructed 4 classes varying in sample size. Most PFM dysfunction for tone, relaxation and MVC both in the external anal sphincter and the puborectal muscle was found in the ‘young and healthy males’ (class 1). The eldest males having the most pelvic floor symptoms (class 4) showed less PFM dysfunction for tone in the external anal sphincter and the puborectal muscle and for relaxation in the external anal sphincter.

**Conclusions**

It is difficult to accurately assess and interpret male pelvic floor muscle function using digital rectal examination, which is commonly performed in clinical practice, since various factors influence outcomes.


Keywords: Digital assessment, lower urinary tract symptoms; male, pelvic floor musculature.

# 1. INTRODUCTION

Lower urinary tract symptoms (LUTS) such as storage, voiding and post micturition problems are prevailing complaints in men reducing quality of life.[1] Most studies describe LUTS in relation to prostate disorders, while there is a lack of research focusing on the relation between pelvic floor muscle (PFM) function and LUTS.[2]

We recently studied the association between on the one hand the number of pelvic floor symptoms, including LUTS and other pelvic floor symptoms such as defecation problems, sexual dysfunction and pelvic pain, and on the other hand PFM function, examined by digital internal PFM assessment.[3] This revealed no clear association between muscle function and symptoms, which could be explained by our choices for cut-off values for the presence or absence of LUTS and making no distinction between the different types of symptoms within the LUTS domain.[4] With our former approach, we could not rule out nor in, that any form of PFM dysfunction plays a role in male LUTS. A more in-depth exploration is warranted. Considering its anatomical location, it is of relevance to know whether the urogenital PFM could be a contributing factor to LUTS and, from a pathophysiological perspective, specific to voiding and urinary incontinence (UI) symptoms.[5] We expected that male PFM function could be associated with specific features of different LUTS (voiding and UI symptoms) and concomitant pelvic floor symptoms. When there is a relationship between PFM function and LUTS (and concomitant pelvic floor symptoms), a more targeted treatment for males could be composed.

The aim of the study is to explore the association between PFM function and LUTS (voiding and UI symptoms) together with bowel symptoms and pelvic pain.



# 2. MATERIALS & METHODS

## 2.1 Study design, setting and participants

We performed post hoc analyses on the data that were collected in a cross-sectional study in men with and without pelvic floor symptoms (Figure 1). For this study they filled in questionnaires on demographics and pelvic floor symptoms.[3] Terminal ill subjects, and subjects with decreased cognitive skills or psychological conditions precluding informed consent, or subjects too sick to participate according to general practitioners', were excluded. The study was approved by a medical ethical committee, and all participants provided written informed consent.[4]

## 2.2 Pelvic floor symptoms

Pelvic floor symptoms were determined as follows:

- LUTS: using continuous subscales of the International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS).[6] This form includes 13 questions (each scoring 0-4) to evaluate male LUTS and is separated in two sub-scales: voiding symptoms (scoring 0-20) and UI symptoms (scoring 0-24);
- Bowel symptoms: based on the Groningen Defecation and Fecal Continence questionnaire: using continuous subscales of Wexner fecal incontinence (FI) (scoring 0-20) and constipation (scoring 0-30)[7];
- Pain: as part of the pain questionnaire, using a dichotomous scale for having lower urinary tract pain or other pain in the pelvic region: yes or no.

## 2.3 PFM assessment

External and internal PFM assessment was performed, including digital palpation of the external anal sphincter and the puborectal muscle, by one experienced pelvic floor physical therapist (PFPT), who was blinded for the pelvic floor symptoms status. The following functions of the external anal sphincter and the puborectal muscle were assessed: tone (decreased tone, normal tone, increased tone), voluntary relaxation (complete (delayed) relaxation, partial (delayed) relaxation, no relaxation), maximum voluntary contraction (MVC) (strong, normal (moderate), weak, absent) and endurance (0-10 seconds, categorized afterwards in 0-1sec, 1-3sec, 3-7sec, 7-10sec). Full details of the PFM assessments can be found elsewhere.[3]

## 2.4 Statistical analysis

We first explored the association between PFM function and specific symptoms of LUTS, voiding and UI symptoms applying (non-parametric) Kruskal-Wallis and Correlation tests between PFM function (tone, relaxation, MVC and endurance) and ICIQ-MLUTS-subscales (voiding and incontinence). Secondly, to assess the association between PFM function and voiding and UI symptoms including concomitant pelvic

floor symptoms (i.e., FI, constipation, and pain), we performed latent class analyses (LCA), including both continuous and categorical variables, and subsequent cross-tabulations as detailed below.
LCA can be used to identify qualitatively different subgroups who often share certain outward characteristics. A planned LCA on PFM function resulted in two illogical classes possibly due to insufficient numbers of participants and large standard errors, which imply inconsistent results. We therefore performed an LCA based on questionnaire data of all males who provided informed consent for the main study to create classes (n=611). We performed five steps for LCA: 1) establish analytical sample (remove participants without data), 2) determine indicator variables, 3) data preparation and clean-up 4) estimate models and determine fit, 5) pick an optimal class solution that works best: statistical criteria and best judgement. [8] (Supplementary file 1). We included the following items: age, BMI, the voiding and incontinence subscales of the ICIQ-MLUTS, the Wexner incontinence and constipation subscales (all continuous scales), and pelvic pain (dichotomous scale).
The decision for the number of classes was based on the Akaike's information criterion (AIC), the Bayesian information criterion (BIC), the outcomes of the Entropy and the clinical relevance. In this process we also checked the influence of outliers, for which we visualized distribution of outcomes using boxplots (Figure 2).
Cross-tabulations were made, for those participants with PFM assessment (n = 199), to show the association between the classes from the LCA and the PFM function items tone, relaxation, MVC and endurance. These function items were chosen since these items showed > 10% dysfunction in one of our earlier studies [9] (Supplementary file 2).
Latent Class Analyses were performed by STATA/SE 17.0 and SPSS Statistics 28 was used for the other statistical analyses.



## 3. RESULTS

Part of the total group males (n=694) provided no data at all (n=76), and some no data on pelvic floor symptoms (n=7). For the LCA, we included subsequently data of 611 males who answered at least one questionnaire about pelvic floor symptoms, of whom 199 also participated in the PFM assessment study (Supplementary file 1).

### 3.1 Association between PFM function and voiding and UI symptoms

None of the associations between PFM function (both the external anal sphincter and puborectal muscle tone, relaxation, MVC and endurance) and the voiding and UI subscales of the ICIQ-MLUTS were significant (Table 1).

### 3.2 Latent Class Analysis

Based on the results of the AIC and the BIC, the outcomes of the Entropy and the clinical relevance we decided to continue our LCA with the following four classes:
**Class 1** (n=48): generally, young healthy men having no or few voiding and UI, none or few FI and none or few constipation symptoms, no pain;
**Class 2** (n=446): generally, older men having few or some voiding, none or few UI, none or few FI and none or few constipation symptoms, no pain;
**Class 3** (n=83): generally, men of intermediate age having some voiding, few UI, few FI and some constipation symptoms, and having pain symptoms;
**Class 4** (n=34): generally, eldest men having moderate voiding, some UI, few FI and few constipation symptoms, and having pain symptoms.

In the subsample, 199 participants with the pelvic floor muscle assessment were categorized to Class 1 (n=8), Class 2 (n=144), Class 3 (n=31), and Class 4 (n=16).
More details for total (n=611) and subgroup (n=199) are provided in Table 2 and in Supplementary file 3. Details of the AIC, BIC and Entropy are provided in Supplementary file 1.

### 3.3 Latent Classes and Pelvic Floor function Items in External Anal Sphincter and Puborectal Muscle

The outcomes of the pelvic floor function assessment for the four latent classes are shown in Figure 3A and 3B.

*3. 3. 1 Tone*

In the external anal sphincter, the highest percentage for an increased tone was found in Class 1 (50%), while Class 4 showed the highest percentage for normal tone (nearly 9 out of 10) and a decreased tone (12.5%). Also, in the puborectal muscle, Class 1 showed the highest percentage for an increased tone (62.5%), while Class 4 contained the highest percentage of males having a normal tone (75%). Class 3 showed the highest percentage for a decreased tone.

### *3. 3. 2 Relaxation*

In the external anal sphincter, males in Class 1 showed a partial (delayed) relaxation in 62.5 percent, which was much higher compared to Class 2 and 3 (nearly 1 out of 3) and Class 4 (no cases). The highest percentage for an absent relaxation was found in Class 4 (19%), while the highest percentage for a complete (delayed) relaxation of the external anal sphincter (81%) was also found in Class 4. In the puborectal muscle, the four classes showed similar percentages for a complete (delayed) relaxation (25% - 40%) and in class 1, 2 and 3 approximately half of the males showed a partial (delayed) relaxation, while this was only 1 out of 3 in Class 4. For the puborectal muscle, all classes contained males without relaxation, with the highest percentage found in Class 4.

### *3.3.3 Maximum Voluntary Contraction*

In the external anal sphincter, Class 1 showed the highest weak MVC (37.5%) and Class 4 showed the highest normal MVC (75%). In the puborectal muscle, approximately half of the males in Class 2, 3 and 4 showed a normal MVC. Half of the males in Class 1 and 4 showed a weak MVC, which was higher compared to Class 2 and 3 (1 out of 3). Males in Class 1 and 3 showed the highest percentages for an absent MVC in the puborectal muscle (respectively 12% and 10%), while males in Class 4 had no cases with an absent MVC.



### *3. 3. 4 Endurance*

In the external anal sphincter, Class 1, 2 and 3 showed a comparable normal endurance (7-10s) (approximately 8 out of 10), while this was lower in Class 4 (69%). All classes showed comparable low percentages for an endurance of 3-7s (10.4%-12.5%). In the puborectal muscle, all four classes showed high percentages for a normal endurance (approximately 4 out of 5), with a highest percentage in Class 1. Males in Class 1 and 4 showed the highest percentages (12.5%) for an absent or low endurance (0-1s).

## 4. DISCUSSION

The current study aimed to explore possible associations between PFM function, and voiding and UI symptoms (together with concomitant pelvic floor symptoms). We conducted an LCA to examine whether we could distinguish (latent) classes of males with varying age, BMI, and subscales of MLUTS-voiding and MLUTS-UI symptoms, FI, constipation and pelvic pain. We expected that the largest group of healthy elderly males without or few pelvic floor symptoms, would present no or less PFM dysfunction, and the small group with (a number of) pelvic floor symptoms would show more PFM dysfunction. The small group was no holdback for the LCA, since small groups may give direction considering results. However, this study did not demonstrate our expectations.
Overall, the study revealed that most PFM dysfunction for tone, relaxation and MVC both in the external anal sphincter and puborectal muscle was found in, the 'young and healthy males' (Class 1). The eldest males reporting the highest scores (Class 4) showed the least PFM dysfunction for tone in the external anal sphincter and puborectal muscle as well as for relaxation in the external anal sphincter. Males across all classes showed high percentages for a normal endurance (7-10s), in both the external anal sphincter and puborectal muscle, while in the puborectal muscle males in Class 1 and 4 showed the highest percentage for poor endurance.
The study's findings are discussed separately for tone, relaxation, MVC and endurance in both the external anal sphincter and puborectal muscle in relation to the characteristics of the four classes.
Contrary to expectations, males reporting the lowest scores on the pelvic floor symptoms questionnaires (Class 1) showed the highest percentages of increased tone, while males reporting the highest scores (Class 4) displayed the highest percentage of normal tone, in both the external anal sphincter and puborectal muscle. Additionally, in the external anal sphincter males in Class 4 showed the highest percentage of a decreased tone, which was in line with a previous study suggesting that the external anal sphincter thickness decreases with age.[5] Tone is difficult to measure digitally, since it depends on muscular control, the nervous system, muscle fiber elasticity, emotions, well-being and participant's tissue sensitivity.[10-12] In a recent study, results showed only limited evidence in increased tone in pelvic disorders. These results and our own, suggest

that interpreting tone is complex.[13] Still, in routine care, this is common practice.
The highest percentage of partial (delayed) relaxation in the external anal sphincter was found in the Class 1 and not in males in Class 3 or 4. In the puborectal muscle, Class 1, 2 and 3 showed similar percentages of a partial (delayed) relaxation, indicating that this issue is less depending on age or severity of pelvic floor symptoms. In line with our expectations, males in Class 4 exhibited the highest percentage of the inability to perform a complete relaxation in both the external anal sphincter and puborectal muscle. An inability to relax the puborectal muscle has been observed in males with chronic prostatitis/chronic pelvic pain.[14]
We unexpectedly found that males in Class 1 exhibited the highest percentages for a weak MVC in the external anal sphincter, instead of males having the highest scores on UI and FI (Class 4). The high percentages for a weak MVC in all classes we observed in the puborectal muscle, could be explained by the difficulty of consciously and voluntarily controlling and coordinating these deep PFM. Research showed that the same instruction for a MVC does not induce the same muscle contraction for all men.[15]
In all classes, high percentages were found for normal endurance, for both the external anal sphincter and puborectal muscle, with Class 1 having the highest percentages. In line with expectations, endurance below 7 seconds for the external anal sphincter and puborectal muscle, was most prevalent in males having the highest scores on voiding symptoms and UI (Class 4). Unexpectedly, for the puborectal muscle, Class 1 and Class 4 showed the same percentage of an endurance of <1 s.
We expected more PFM dysfunction in particular in the elderly males (Class 4). However, based on our findings for tone and relaxation in both muscles and for MVC in the external anal sphincter, it seems that an internal PFM assessment, in which the autonomic stress response may play a certain role, may be more stressing and uncomfortable for 'young and healthy males' (Class 1) compared to elderly males.[16] In line with our expectations we found that males in Class 4 displayed the highest percentage of inability to perform a complete relaxation, and showed the worst endurance, in both the external anal sphincter and puborectal muscle.
We emphasize that the measurement of PFM function is complex, and no standardization is available. Additionally, it should be realized that the PFM function is influenced by difficult to measure components such

as participants limited knowledge of bladder and bowel function, little awareness of the PFM, presence of flatus and feces in the anal canal, influence of setting and intimacy of the assessment, while higher cortical systems may influence PFM function too.[10-12,16-18]

Concerning strengths of the study, to date no study has explored the associations between the external anal sphincter and the puborectal muscle and the severity of pelvic floor symptoms in a general population of males. Secondly, we used the most common measurement tool for general practitioners and PFPTs; digital palpation. Thirdly, to prevent inter-rater disagreements, all participants were assessed by the same experienced PFPT and fourthly, confirmation-bias was precluded since the assessor was blinded for the type and severity of symptoms.[19]

This study has some limitations too. Due to the cross-sectional design, causality cannot be demonstrated. The number of cases in which pelvic floor muscle function using digital rectal examination could be analyzed (n=199) was one third of the number of cases that reported the questionnaire of LUTS (n=611). The absence of specific instructions for controlling the urogenital sphincter may have had impact on our outcomes.[20] Duration of symptoms was not specifically inquired nor included in our analyses. Prostate surgery, musculoskeletal back or hip pain were disregarded and may have had influence on our results.[21]

Further studies using additional measurement tools as flowmetry or electromyographic measurement are warranted to explore the complex relation between the PFM and male LUTS. In future, males with LUTS (and concomitant pelvic floor symptoms including sexual symptoms) presenting PFM dysfunction, might get a more optimal approach and treatment, including a purposeful rehabilitation program for dysfunctional PFM.

## 5. CONCLUSION

Male PFM function is difficult to assess using digital rectal assessment, but this is commonly performed in clinical practice to in- or exclude LUTS and / or other pelvic floor symptoms. In this study, LCA identified four distinguishable classes on pelvic floor symptoms, relevant and recognizable in practice. The ‘young and healthy males’ presenting the lowest scores on pelvic floor symptoms (Class 1), unexpectedly showed most PFM dysfunction, while the eldest males reporting the highest scores on pelvic floor symptoms (Class 4) showed the least PFM dysfunction. As expected, we found that the group of the elderly males having the highest scores on voiding symptoms and pelvic pain (Class 4) displayed the highest dysfunction on relaxation and endurance, in both the external anal sphincter and puborectal muscle. More urogenital studies are warranted to reveal the complexity of PFM function in relation to male LUTS.

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## TABLES

**Table 1.** Results for the association between voiding and incontinence subscales and pelvic floor muscle function items tone, relaxation, maximum voluntary contraction and endurance for the external anal sphincter and puborectal muscle

| | **External Anal Spincter** | | | | **Puborectal Muscle** | | | |
|---|---|---|---|---|---|---|---|---|
| | **MLUTS-voiding** | | **MLUTS-incontinence** | | **MLUTS-voiding** | | **MLUTS-incontinence** | |
| | | p-value | | p-value | | p-value | | p-value |
| **Tone** | | .898 | | .562 | | .829 | | .089 |
| Decreased | 3.5 (2-6) | | 2.5 (1-5) | | 3.5 (2-6) | | 1 (0-3.8) | |
| Normal | 4 (2-7) | | 2 (1-4) | | 4 (2-7) | | 2 (1-5) | |
| Increased | 4 (2-5) | | 2 (1-3) | | 4 (2-6.5) | | 2 (1-3) | |
| **Relaxation** | | .413 | | .318 | | .642 | | .434 |
| Complete (delayed) | 4 (2-7) | | 2 (1-4) | | 3 (2-7) | | 2 (1-4) | |
| Partial (delayed) | 3 (2-5) | | 1 (1-3) | | 4.5 (2-7) | | 2 (1-4) | |
| No relaxation | 5.5 (2.8-7.8) | | 3.5 (0-10.8) | | 4 (2-6) | | 2 (1-5) | |
| **MVC** | | .118 | | .157 | | .076 | | .094 |
| Strong | 3 (1-6) | | 1 (1-2.3) | | 2 (1.5-2.5) | | 1 (1-2) | |
| Normal | 5 (2-7) | | 2 (1-5) | | 4 (2-7) | | 2 (1-3.5) | |
| Weak/absent | 3 (2-6) | | 2 (1-4) | | 5 (2-7) | | 2 (1-5) | |

**Table 1.** *Continued.*

| | External Anal Spincter | | | | Puborectal Muscle | | | |
|---|---|---|---|---|---|---|---|---|
| | **MLUTS-voiding** | | **MLUTS-incontinence** | | **MLUTS-voiding** | | **MLUTS-incontinence** | |
| **Endurance** | | | | | | | | |
| 0-10 seconds | -.113 | .114 | -.025 | .727 | -.028 | .697 | -.080 | .265 |

MVC=maximum voluntary contraction; MLUTS=male lower urinary tract symptoms
For tone, relaxation and MVC Kruskall-Wallis tests, and for endurance Spearmans's Rho tests were performed.

**Table 2.** Patient characteristics based on pelvic floor symptoms questionnaires for the total group (n=611)

| | **Class 1** | **Class 2** | **Class 3** | **Class 4** |
|---|---|---|---|---|
| **Total group (n=611)** | **N=48** | **N=446** | **N=83** | **N=34** |
| Age (years) | 32.9 ± 8.9 | 65.4 ± 9.8 | 59.2 ± 14.1 | 69.9 ± 10.7 |
| | 16-47 | 36-92 | 24-86 | 45-88 |
| Body mass index (kg/m$^2$) | 24.7 ± 3.0 | 26.9 ± 3.7 | 28.0 ± 4.8 | 26.3 ± 3.9 |
| | 19.8-33.8 | 18.6-53.4 | 20.1-42.9 | 18.6-35.1 |
| MLUTS voiding (0-20) | 1 (0-2) | 3 (1-6) | 6 (3-9) | 9 (6-11) |
| MLUTS incontinence (0-24) | 0 (0-1) | 1 (0-3) | 3 (1-5) | 10 (8-11) |
| Wexner incontinence (0-20) | 0 (0-2) | 1 (0-3) | 3 (1-4) | 3 (2-6) |
| Wexner constipation (0-30) | 1 (0-3) | 0 (0-2) | 7 (6-9) | 2 (1-4) |
| Pelvic pain | 8.9 | 11.4 | 39.0 | 38.2 |

Data are displayed as *mean ± standard deviation* with *minimum-maximum* value for age and body mass index, *median (interquartile range)* for MLUTS- and Wexner scores, and *% yes* for pelvic pain.
MLUTS = male lower urinary tract symptoms.

# FIGURES

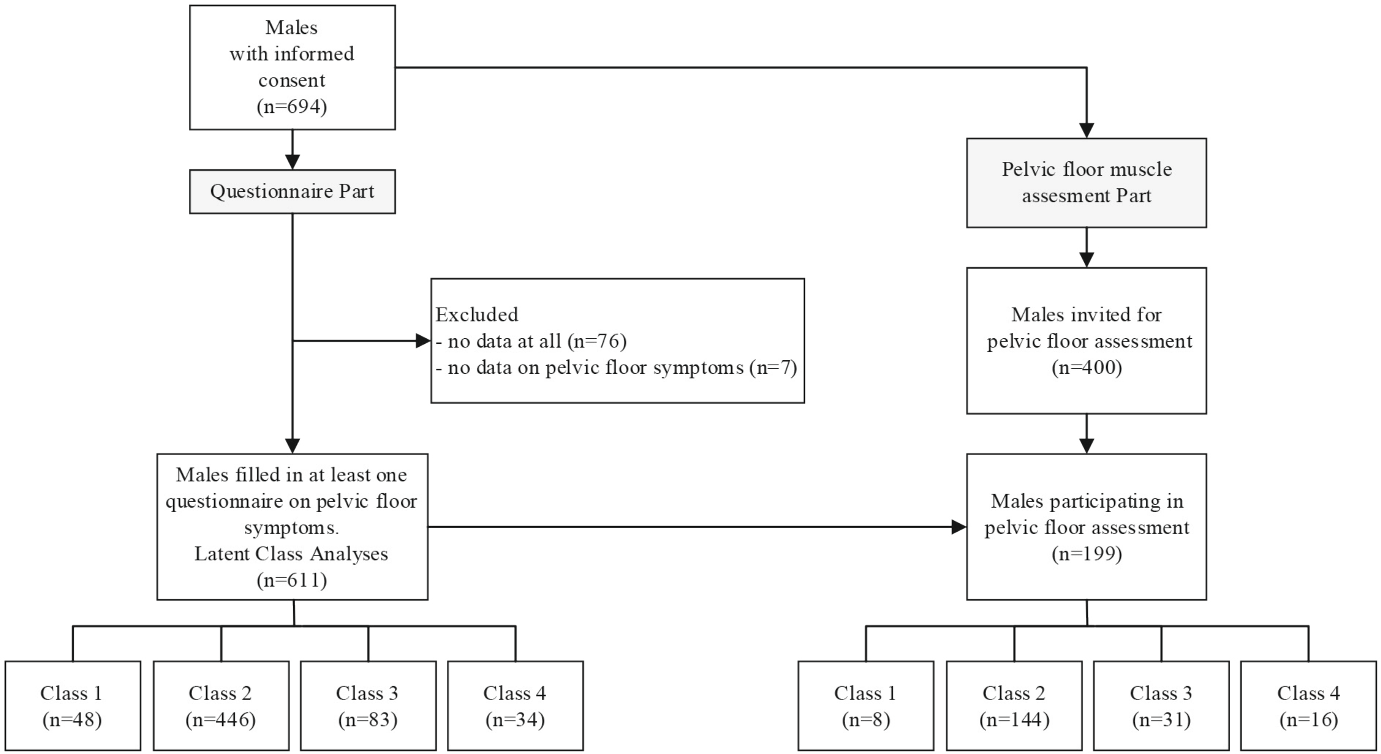



**Figure 1.** Flowchart

6

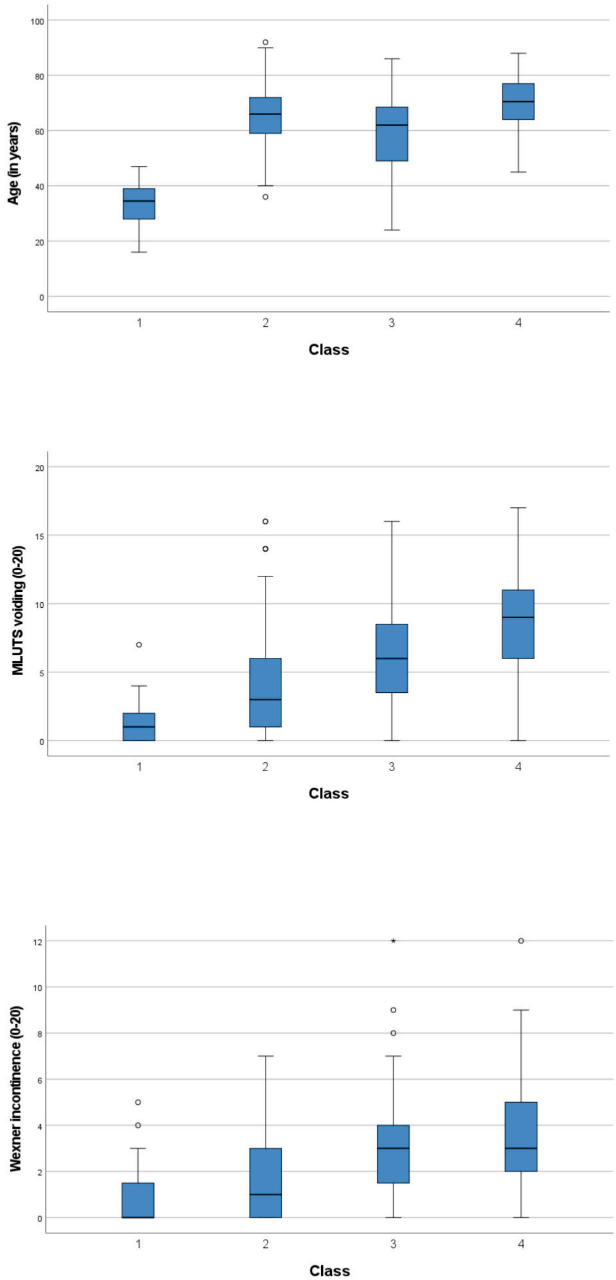
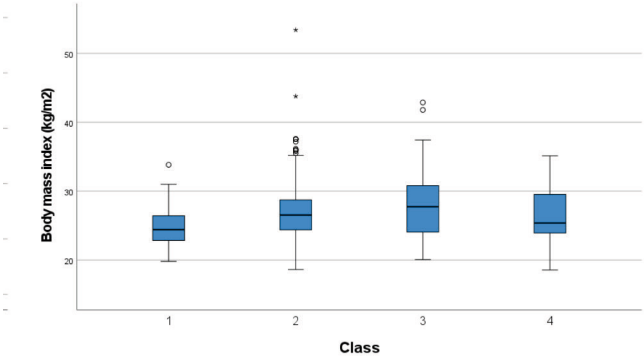
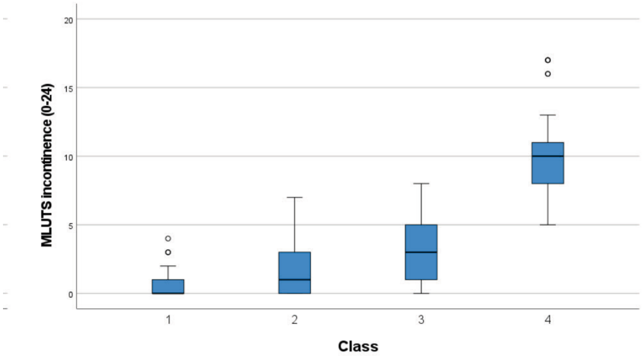
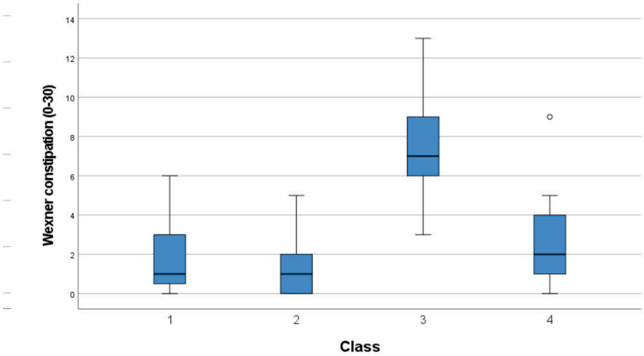



**Figure 2.** Boxplots for A. age, B. body mass index, C. MLUTS-voiding, D. MLUTS-incontinence, E. Wexner-incontinence, and F. Wexner-constipation, MLUTS = male lower urinary tract symptoms


Body mass index (kg/m2)
50
40
30
20
1
2
3
4
Class


MLUTS incontinence (0-24)
20
15
10
5
0
1
2
3
4
Class


Wexner constipation (0-30)
14
12
10
8
6
4
2
0
1
2
3
4
Class

6

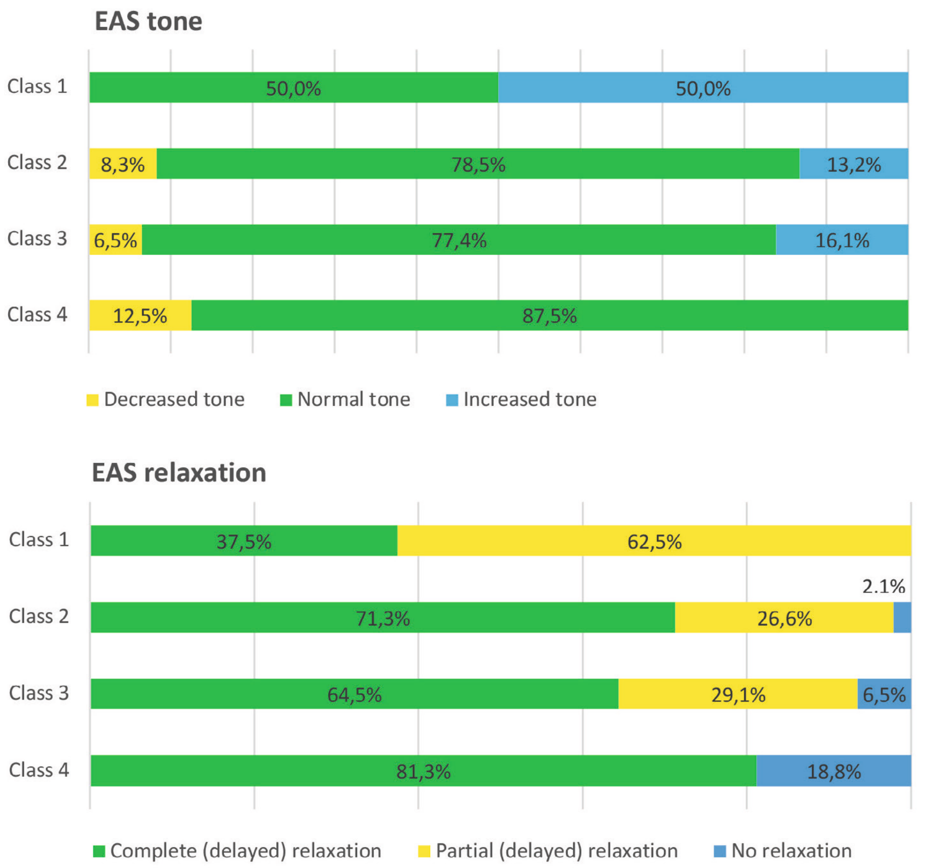
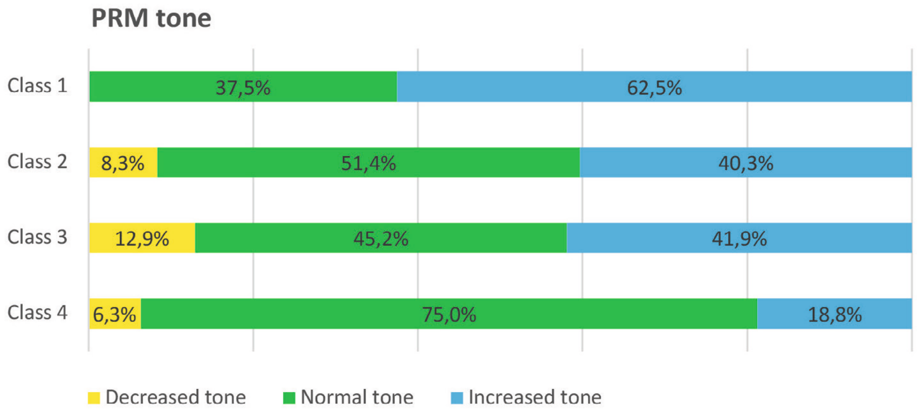
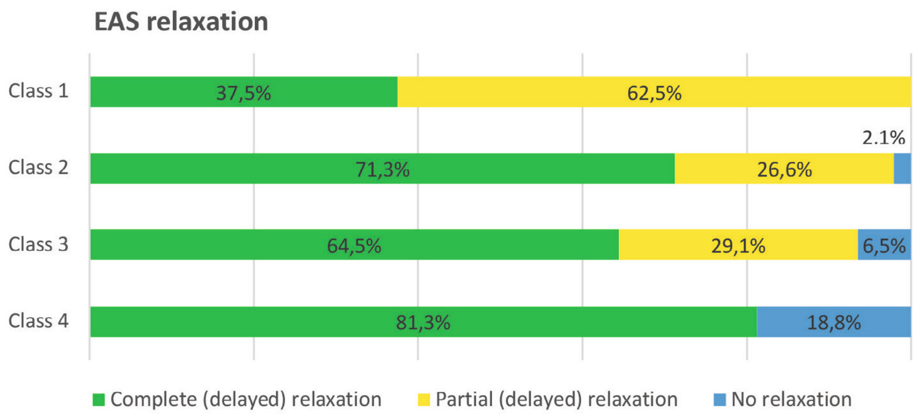



**Figure 3A.** Percentages within classes for external anal sphincter (EAS) and puborectal muscle (PRM) tone and relaxation.


PRM tone
Class 1
37,5%
62,5%
Class 2
8,3%
51,4%
40,3%
Class 3
12,9%
45,2%
41,9%
Class 4
6,3%
75,0%
18,8%
Decreased tone
Normal tone
Increased tone


EAS relaxation
Class 1
37,5%
62,5%
2.1%
Class 2
71,3%
26,6%
Class 3
64,5%
29,1%
6,5%
Class 4
81,3%
18,8%
Complete (delayed) relaxation
Partial (delayed) relaxation
No relaxation

6

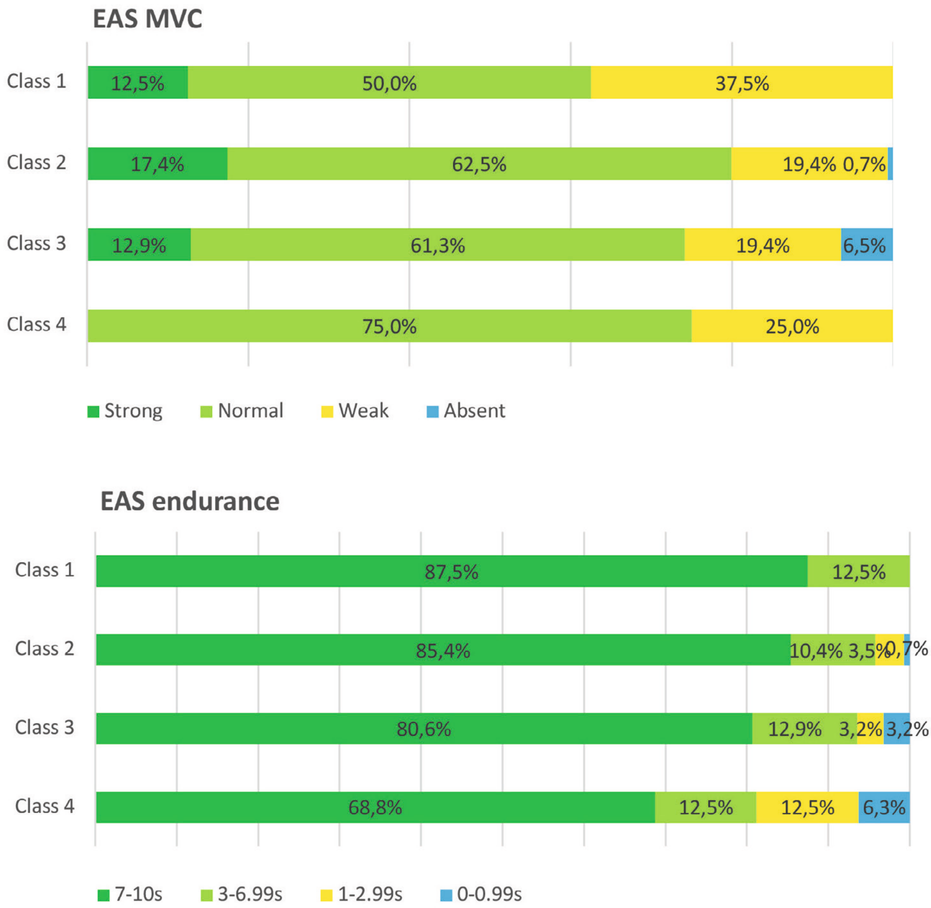
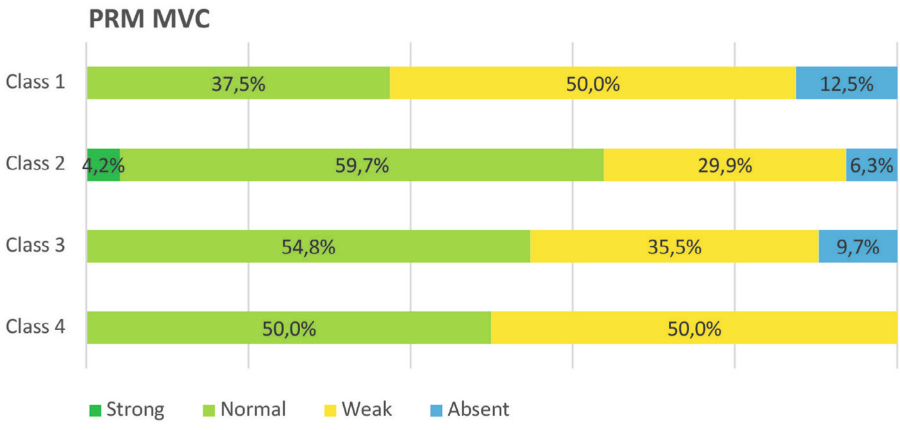
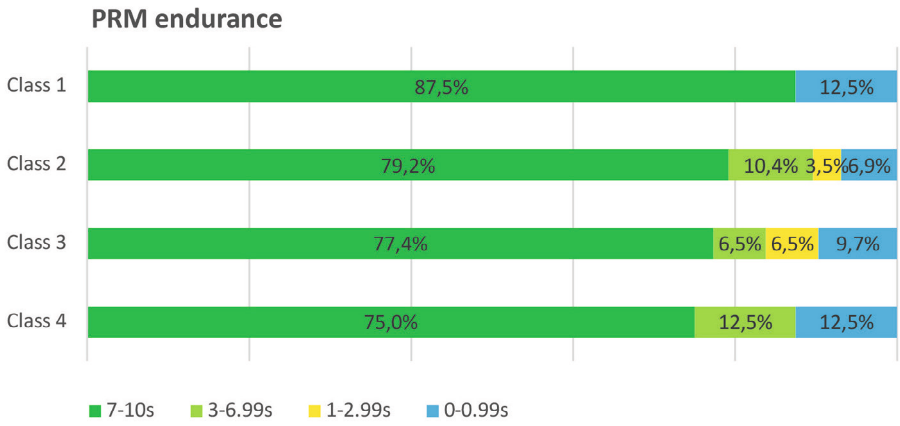



**Figure 3B.** Percentages within classes for external anal sphincter (EAS) and puborectal muscle (PRM) maximum voluntary contraction (MVC) and endurance.


PRM MVC
Class 1
Class 2
Class 3
Class 4
37,5%
50,0%
12,5%
4,2%
59,7%
29,9%
6,3%
54,8%
35,5%
9,7%
50,0%
50,0%
Strong
Normal
Weak
Absent


PRM endurance
Class 1
Class 2
Class 3
Class 4
87,5%
12,5%
79,2%
10,4%
3,5%
6,9%
77,4%
6,5%
6,5%
9,7%
75,0%
12,5%
12,5%
7-10s
3-6.99s
1-2.99s
0-0.99s

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# SUPPLEMENTARY FILES

## Supplementary file 1. Latent Class Analysis Roadmap

### <u>Part A. Data completeness / goodness of fit dataset</u>

**1. Establish analytical sample**
Check missings in all variables.
<u>Results:</u>
- N=694 men with informed consent
  *minus* N=76 men who had no data at all
  -> N=618 men with data

**2. Determine indicator variables**
- Lower urinary tract symptoms (subscale voiding, subscale incontinence)
- Defecation problems (subscale constipation, subscale incontinence)
- Pelvic pain (yes/no)
- Age (in years)
- Body mass index (BMI; kg/$m^2$)

Make choices concerning the number of classes. More classes lead to smaller groups but more distinction, less classes leads to larger groups but less distinction.

**3. Data preparation & clean-up**
Make choices concerning the missings of variables. Which variables should be complete?
<u>Results:</u>
- N=5 only data for age (no data on BMI and pelvic floor symptoms)
- N=2 only data for age and BMI (no data on pelvic floor symptoms)
- All other participants at least had data on 1 type of pelvic floor symptoms
  ->N=611 (n=199 participating in a pelvic floor muscle assessment)
  ->N=571 with complete data on age, BMI, all PFS (n=191 with physical exam)

**4. Estimate models & determine fit**
<u>Performing LCA in STATA – select dataset – enter syntax:</u>

```
gsem (var 1 var 2 var 3 etc <- _cons), lclass(C a*)
estat lcmean
estat lcprob
predict classpost*, classposteriorpr
list in 1, abbrev(10)
predict cpost*, classposteriorpr
egen max = rowmax(cpost*)
generate predclass = 1 if cpost1==max
replace predclass = 2 if cpost2==max
replace predclass = 3 if cpost3==max
replace predclass = 4 if cpost4==max
estat lcgof
ssc install lcaentropy
lcaentropy
```

<u>Explanation</u>:

- a*= number of classes
- gsem= generalized structural equation model
- In case the variable outcome is dichotome insert “i.” in front of the variable
- *estat lcmean*: latent class marginal means; reports a table of the marginal predicted means of the outcome within each latent class
- *estat lcprob*: latent class marginal probability: reports a table of the marginal predicted latent class probabilities
- *predict classpost*, classposteriorpr*: calculates predicted posterior probabilities for each latent class
- *list in 1, abbrev(10)*: list of abbreviations

  *estat lcgof*: reports the goodness of fit

  *Akaike Information Criterion (AIC):* An index of how well a model fits, which seeks to balance
  the complexity of the model against the sample size. Values closer to 0 indicate better fit.
  *Bayesian Information Criterion (BIC):* An index of how well a model fits, which seeks to
  balance the complexity of the model against the sample size. Values closer to 0 indicate better fit.
  *Entropy:* A measure of separation between the latent classes generated in a model. A higher entropy value represents a greater degree of

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distinction between classes. Values >0.8 indicate high degree of separation between classes.

Action: perform 4 analysis and determine Goodness-of-fit for:

- n=611, 3 classes lclass(C 3)
- n=571, 3 classes
- n=611, 4 classes lclass(C 4)
- N=571, 4 classes

**5. Pick an optimal class solution that works best: statistical criteria and best judgement**

- Comparing outcomes for 3 and 4 classes and for datasets n=571 and n=611 (are the same men included in the same class?)
- Comparing AIC / BIC & entropy for 3 and 4 classes
- Clinical relevance (Do your findings match clinical practice? How do you define your classes?)
- Determine the numbers (n=) of men in the classes

**Results and conclusion Part A.:**

| | AIC | BIC | Entropy | N= |
|---|---|---|---|---|
| N=611<br>3 classes | 19886.222 | 20014.260 | .812261 | N=66 class 1<br>N=437 class 2<br>N=108 class 3 |
| N=571<br>3 classes | 18771.486 | 18897.560 | .817998 | N=61 class 1<br>N=404 class 2<br>N=106 class 3 |
| N=611,<br>4 classes | 19618.211 | 19781.570 | .892867 | N=48 class 1<br>N=446 class 2<br>N=83 class 3<br>N=34 class 4 |
| N=571,<br>4 classes | 18509.541 | 18670.395 | .900534 | N=42 class 1<br>N=412 class 2<br>N=85 class 3<br>N=32 class 4 |

<u>Conclusion:</u>

- Same men are in same classes. Deleting men (n=611-> n=571) has no large influence on outcomes.
- 4 classes differentiated more than 3 classes -> 4 classes more clinically relevant

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**<u>Part B. Robustness</u>**

**Data preparation & clean-up**

<u>Check outliers:</u>

Perform the LCA without the outliers to check differences in your findings.

- Make boxplots and histograms to verify
- Find the extremes in de Stem-and-Leaf Plots
- Decide which outliers/extremes should be deleted
  Outliers (circles in boxplots):
  -low potential outlier: score is more than 1.5 IQR but at most 3 IQR below quartile 1;
  -high potential outlier: score is more than 1.5 IQR but at most 3 IQR above quartile 3.
  Extreme values (asterisks (*) in boxplots):
  -low extreme value: score is more than 3 IQR below quartile 1;
  -high extreme value: score is more than 3 IQR above quartile 3.

Adjusting startvalues
Draws can be adjusted. Compare to the original.

- gsem (var 1 var 2 var 3 etc <- _cons), lclass(C 4) startvalues(randomid, draws(25) seed(15))

Elaborate to less restricted model

- gsem (var 1 var 2 var 3 etc <- _cons), lclass(C 4) lcinvariant(none) covstructure(e._OEn, unstructured)

Results:

- When leaving out the 'outliers' for LUTS this seems to have some influence on determining classes
- Based on statistical criteria we determined 'Outliers' but these 'Outliers' are normal (and not extreme) values

**Estimate models & determine fit**

| CLASS | Original | 25 draws | 50 draws | 100 draws |
|---|---|---|---|---|
| 1 | 48 | 83 | 83 | 83 |
| 2 | 446 | 48 | 48 | 48 |
| 3 | 83 | 446 | 446 | 446 |
| 4 | 34 | 34 | 34 | 34 |
| Entropy | 0.892867 | 0.892867 | 0.892867 | 0.892867 |

Conclusion: Same men in same classes (although in other order)

**Pick an optimal class solution that works best: statistical criteria and best judgement**

- Outcomes are rather robust so we can use the 4 classes from the dataset with n=611 men
- As a next step we can analyse the association between those classes and pelvic floor muscle function (from the n=199 men participated in the pelvic floor muscle assessment study)

**Supplementary file 2. Crosstabs for percentages within Classes for External Anal Sphincter and Puborectal Muscle for tone, voluntary relaxation, maximum voluntary contraction and endurance.**

**TONE**

| | EAS | | | PRM | | |
|---|---|---|---|---|---|---|
| **CLASS** | **Decreased tone** | **Normal tone** | **Increased tone** | **Decreased tone** | **Normal tone** | **Increased tone** |
| 1 | 0.0% | 50.0% | 50.0% | 0.0% | 37.5% | 62.5% |
| 2 | 8.3% | 78.5% | 13.2% | 8.3% | 51.4% | 40.3% |
| 3 | 6.5% | 77.4% | 16.1% | 12.9% | 45.2% | 41.9% |
| 4 | 12.5% | 87.5% | 0.0% | 6.3% | 75.0% | 18.8% |

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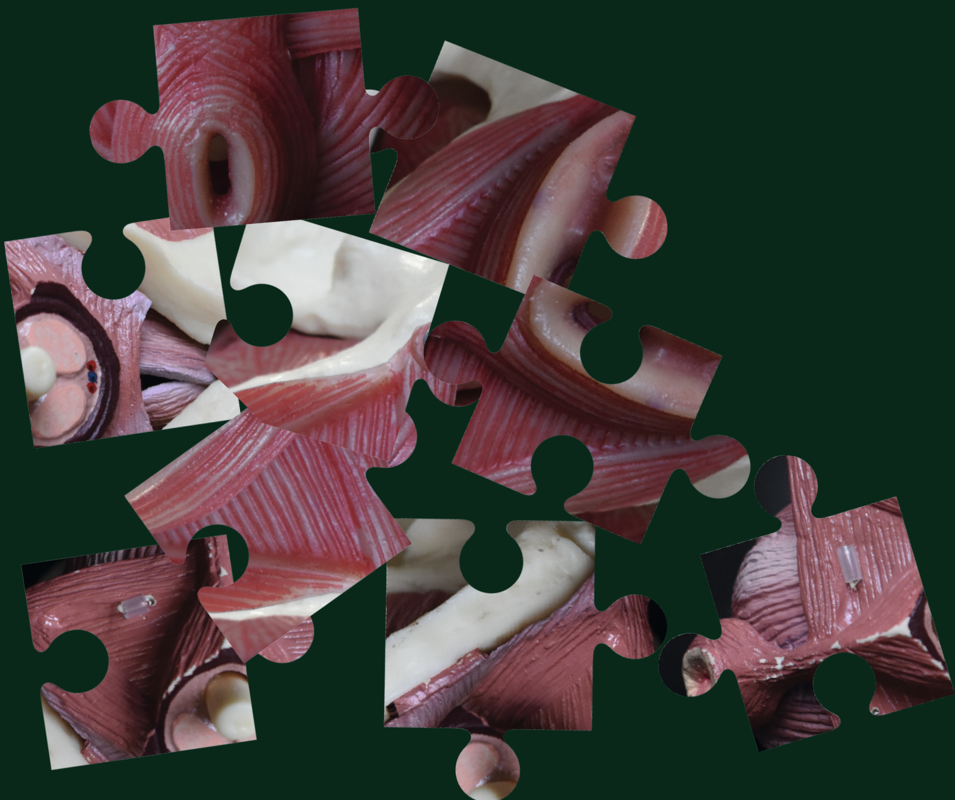
**Supplementary file 3. Patient characteristics based on Pelvic Floor Symptoms questionnaires for total group (N=611) and subgroup (N=199)**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Class 1** | | **Class 2** | | **Class 3** | | **Class 4** | |
| **Total group (N=611)** | **N=48** | | **N=446** | | **N=83** | | **N=34** | |
| **Subgroup (N=199)** | | **Class 1 N=8** | | **Class 2 N=144** | | **Class 3 N=31** | | **Class 4 N=16** |
| Age (years) | 32.9 ± 8.9 | 34.1 ± 5.3 | 65.4 ± 9.8 | 64.9 ± 10.2 | 59.2 ± 14.1 | 57.4 ± 14.0 | 69.9 ± 10.7 | 71.4 ± 7.7 |
| | 16-47 | 27-42 | 36-92 | 36-90 | 24-86 | 28-83 | 45-88 | 57-83 |
| Body mass index (kg/$m^2$) | 24.7 ± 3.0 | 24.7 ± 2.8 | 26.9 ± 3.7 | 26.4 ± 3.4 | 28.0 ± 4.8 | 27.4 ± 4.5 | 26.3 ± 3.9 | 26.3 ± 4.0 |
| | 19.8-33.8 | 21.5-28.7 | 18.6-53.4 | 19.1-37.6 | 20.1-42.9 | 20.1-37.4 | 18.6-35.1 | 19.0-35.1 |
| MLUTS voiding (0-20) | 1 (0-2) | 0 (0-3) | 3 (1-6) | 3 (2-6) | 6 (3-9) | 7 (5-10) | 9 (6-11) | 9 (6-11) |
| MLUTS incontinence (0-24) | 0 (0-1) | 1 (0-2) | 1 (0-3) | 2 (1-3) | 3 (1-5) | 3 (1-5) | 10 (8-11) | 11 (8-13) |
| Wexner incontinence (0-20) | 0 (0-2) | 2 (0-3) | 1 (0-3) | 2 (1-3) | 3 (1-4) | 4 (2-4) | 3 (2-6) | 4 (2-6) |
| Wexner constipation (0-30) | 1 (0-3) | 2 (0-3) | 0 (0-2) | 1 (0-2) | 7 (6-9) | 7 (7-9) | 2 (1-4) | 2 (1-4) |
| Pelvic Pain | 8.9 | 12.5 | 11.4 | 12.7 | 39.0 | 51.6 | 38.2 | 56.3 |

Data are displayed as *mean ± standard deviation* with *minimum-maximum* value for **age and body mass index**, *median (interquartile range)* for **MLUTS**- and **Wexner scores**, and *% yes* for **pelvic pain**



# 7

# General discussion

# GENERAL DISCUSSION

## 1. THIS THESIS

The main objectives of this thesis were to explore in community-dwelling males and females:

- concomitant pelvic floor signs and pelvic floor symptoms (PFS),
- the relationships within and between the pelvic floor musculature (PFM),
- the relationship between the PFM and a number of PFS,
- the differences and similarities between the male and female PFM by the number and type of PFS;
- for males, the associations between PFM function and lower urinary tract symptoms (LUTS) with and without concomitant PFS (defecation problems and pelvic pain).

## 2. BACKGROUND

### 2.1 Pelvic floor symptoms

Pelvic floor symptoms (PFS) prevail both in males and females and may reduce quality of life.[1,2] PFS cover a number of LUTS (e.g., voiding and urinary incontinence), defecation problems (fecal incontinence, constipation, functional obstruction), sexual symptoms (erectile dysfunction, ejaculation problems, pain during intercourse), pelvic pain and in females, pelvic organ prolapse (POP) symptoms.[3-5] The content of PFS is well-known but a clear definition for male and female PFS is still inconclusive.[6,7] Studies regarding PFS are mainly focused on one or two PFS. However, recent studies found that in both sexes PFS often co-occur.[8,9] In males, PFS are generally attributed to a dysfunction of the lower urinary tract and sexual dysfunction, and to a limited extend to defecation problems.[10]

### 2.2 Pelvic floor anatomy

The pelvic anatomy comprises the PFM, the bladder, intestines and rectum, in females the vagina and uterus and in males the prostate, and is surrounded by ligaments, fascia and connective tissues, pelvic nerves and vessels.[11] There is scarcity of research focusing on the relationship between the PFM and PFS in males, and in females between PFM function and concomitant PFS. This is remarkable since the PFM, generally assumed to act as a functional unity, is anatomically located close to the bladder, prostate and intestines playing an important role in urinary and bowel processes, and in sexuality and childbirth.[12,13]

The PFM comprise four layers which are attached to the bony pelvis and contains superficial and deep laying musculature. The PFM and adjacent tissues include the ischiocavernosus muscle, the bulbospongiosus (bulbocavernosus) muscle, superficial transverse perineal muscle, the external anal sphincter (EAS), the perineum (tissue between the urethra and the anus), the urogenital diaphragm or triangular ligament and perineal membrane, the muscular pelvic diaphragm (levator ani and coccygeus) and the endopelvic fascia.[14] Most studies indicate that the levator ani muscle consists of the iliococcygeus muscle, the pubococcygeus muscle and the puborectal muscle (PRM), but recent studies dispute if the PRM is part of the levator ani.[15] Considering connections between the EAS and the PRM, pelvic floor research remains inconclusive and may be associated with variations in muscle morphology.[14,16,17]

The nervous system of the PFM is complex. The pudendal nerve (ventral branches of S2-S4 of the sacral plexus) has three sub divisions and provides the somatic innervation for the anterior PFM (the bulbospongiosus and ischiocavernosus muscles) including the urethral sphincter, penis and clitoris, and the perineum, and the posterior superficial EAS. The nerve roots of S3-S5 are thought to innervate directly the muscles of the levator ani, but the PRM is innervated by the levator ani nerve (S3-S4) and the pudendal nerve.[13,16] Functionally, the pudendal nerve contributes to micturition, defecation and sexual function.[18,19]

### 2.3 Pelvic floor musculature function

Research demonstrated that male and female PFM function is complex and dependent on several physiological, cortical and social processes.[20,21] In interaction with the bladder and intestines, voluntary or involuntary contraction and relaxation of the PFM induce respectively continence of urine and feces, micturition and defecation, while the PFM plays an important role too in male and female sexuality.[12,20,22] It seems therefore eligible to explore the role of the PFM in male and female PFS.

### 2.4 Pelvic floor musculature dysfunction and pelvic floor symptoms

In clinical practice, patients with incorrect micturition or bowel behavior, possibly related to social and /or environmental situations, or patients suffering from (sexual) trauma or stress, often show a situational or even a persistent involuntary PFM contraction. This frequently leads to an increase of tone and a dysfunction of voluntary relaxation, maximum voluntary contraction (MVC) and endurance in the PFM. As a result of PFM dysfunction and incorrect behavior, these patients often report certain PFS, e.g., hesitation, urgency, post urinary dribble, urinary or fecal incontinence, constipation and / or pain symptoms during intercourse. Based on these clinical experiences it is of interest too, to explore relationships between PFM dysfunction and PFS.

### 2.5 Internal digital pelvic floor musculature assessment

The internal digital assessment of the PFM in males and females is a commonly used tool in daily practice for those health care providers who are qualified, competent and registered, such as medical doctors and pelvic floor physiotherapists (PFPTs). However, medical doctors perform a short PFM assessment according to gynecological and urological guidelines, while the digital PFM assessment of the PFPT, who is a specifically educated for the anatomy and function of the PFM, consists of a comprehensive and complete digital PFM assessment.[12,23-28] A digital PFM assessment is indicated for all complaints in the pelvic area and for exclusion of pathological processes or anomalies in the anal or vaginal region. Assessment of the PFM is important for the evaluation of sensibility of pelvic tissues, awareness or consciousness of the muscles of the pelvic floor and for the evaluation of voluntary and involuntary contractions of the PFM.[6,7] For a proper internal digital assessment of the PFM, in males the EAS and the PRM, and additionally in females the vaginal PFM should be separately assessed. Although the EAS, the PRM and the vaginal PFM are close to each other, the EAS and the superficial vaginal PFM have a more closing function, while the PRM has in particular a lifting function.[29] Separate assessment of the EAS, the PRM and the vaginal PFM may result in different function outcomes for these muscles, and seems therefore essential for further treatment. Assessment of PFM function consist for the evaluation of several items comprising pain (clockwise palpated), tone, voluntary contraction, MVC, (complete) voluntary relaxation, frequency of MVC, endurance and, dependent of the instruction, the contraction of the PFM before cough (involuntary (no instruction to pre-contract before cough) or voluntary (with instruction to pre-contract before cough)). Besides, during PFM function, coordination of the PFM and compensation by peri-pelvic musculature should be observed. Additionally, in females, POP gradation should be performed by the Pelvic Organ Prolapse-Quantification (POP-Q) or the S-POP (Simplified Pelvic Organ Prolapse) and is used to evaluate the prolapse of the anterior, middle and posterior compartments.[30-32] It should be noticed that complaints in the low back, in the pelvic girdle, hip joints, sacral-iliac joints, as well as respiration disorders and position of the pelvis may also influence outcomes of the internal digital PFM assessment, but were, for the scope of this study, not included.[33,34]

To date, no 'gold standard' is available for male and female PFM function.[35] Frawley and colleagues recently updated the terminology for the internal digital PFM assessment extensively, which is a big step forward to a clear and defined description and interpretation of PFM function.[36] It contributed in particular to an update of terms and definitions, procedures of the digital PFM assessment including interpretation of results, and contributed to improvement of diagnostics. An important modification regards the nomenclature of the 'internal digital PFM assessment', which was changed into 'internal assessment per vaginam (PV) or per rectum (PR) by digital palpation'. As the manuscript of Frawley was published during this PhD trajectory, we used the nomenclature which was, according to the ICS guidelines, customary at that moment in all our articles and this discussion.

We realize that a digital internal PFM assessment is a subjective measurement method and may therefore be a point of discussion. Objective internal measurement methods, such as electromyography (EMG), pressure measurement, ultrasound, are commonly used in scientific studies, since devices determine, if properly performed and well-instructed applied, precise and accurate results.[37] However, it should be realized that objective measurement methods are often not available for GPs and are used very limited by medical specialists. PFPTs use EMG as assessment of PFM function, but is performed after digital assessment of the PFM. It applies to both objective and subjective measurements methods, that the experience and assessment skills of the assessor may be determinative for the outcomes of digital PFM assessment. Outcomes may also be dependent on patients motives e.g., anxiety for their symptoms, shame and trust or distrust in the assessor.[38]

Other factors of influence on outcomes apply for both objective and subjective measurement methods, such as the understanding of the assessors' instruction and the knowledge of the location of the PFM and PFM function by the participant or patient.[39] Additionally, during both assessments' urgency for urine, flatus or feces, sensitivity or pain in the pelvic area or in other parts of the body, and position (supine of sight-lying) might be of influence on outcomes.[40] Objective and subjective measurement findings may also be influenced by earlier PFM, urological or bowel assessments and may be influenced by emotion and sexual experiences.[20] Both measurement methods may be influenced by stress reaction induced by the intimacy of the PFM assessment too, which might be more present during a digital PFM assessment. Important, a digital PFM assessment is not a routine examination, and is only conducted after informed consent. Patients' history e.g., sexual abuse may be a preclusion, but medical doctors and PFPTs are educated to advise the desirability or need of a digital PFM assessment.[41]

## 3. WHY THIS STUDY?

This research was part of a larger observational cohort study assessing PFS in community-dwelling males and females in a Dutch medium-sized municipality. Main goals of this overall study were to explore, within a defined cohort, data on concurrent PFS in both males and females, using validated questionnaires.[42-46] Despite the extensive female pelvic floor research related to childbirth, we found for females a gap in the report of concomitant PFS, and PFM function in relation to multiple PFS.[9,47,48] For males, research on concurrent PFS and PFM function is undoubtfully scarce and mostly focused on prostate surgery, sexual dysfunction and LUTS.[49,50] To fill this gap, we explored concomitant PFS in both sexes, and conducted a digital PFM assessment in males and females.
To assess the relation between PFM function and PFS we invited participants with and without PFS, and focused initially on an in-depth exploration of the male and female PFM. Additionally, we explored the association between male and female PFM function and a number of PFS. Comparison between female and male PFM function is valuable, since the pelvic region and the PFM in males and females are different in anatomy and function.[11]

Furthermore, we compared the differences between the male and female PFM function by number and type of PFS (LUTS, defecation problems, sexual dysfunction and pain) and explored the association between PFM (dys)function and male LUTS (and defecation problems and pelvic pain). The digital PFM assessment we applied for the current study was according to the latest recommendations of the International Continence Society (ICS).[6,7] We used the initial digital PFM assessment of Slieker et al. and the generally used digital PFM assessments in the Netherlands.[51] Our PFM assessment was subsequently discussed with a research group of GPs and PFPTs before the final version was accepted, and the data collection was started.

## 4. MAIN FINDINGS AND DISCUSSION

### 4.1 Concomitant pelvic floor signs and pelvic floor symptoms (PFS)

In ***Chapter 2*** we explored the occurrence PFS in community-dwelling males and females. About one third of both males and females reported having two or more concomitant PFS. In females, sexual dysfunction and pelvic pain, and sexual dysfunction and defecation problems were most prevalent clusters, followed by LUTS and defecation problems, and LUTS, defecation problems and pelvic pain. Pelvic pain was reported more in females compared to males, and in 40-45% it was present simultaneously with defecation problems, sexual dysfunction and LUTS. Females reported POP only in combination with other PFS. This is not remarkable, since the presence of POP symptoms often reflect changes in the vaginal and pelvic anatomy and therefore, POP symptoms often occur in combination with other PFS.[52]

In males, LUTS and sexual dysfunction, LUTS and defecation problems (almost 50%), and LUTS, sexual dysfunction and defecation problems were the most prevalent PFS clusters. Pelvic pain was often found in co-occurrence with other PFS. Our findings, showing large overlap between the different types of PFS, are not surprising. The pelvic organs are close to each other having an interplay during micturition, defecation and during sexuality.[52,53]

Some limitations on *Chapter 2* need to be considered before drawing firm conclusions. The older age of the participants compared to the general population may induce certain PFS.[1,54-56] Therefore, we may have found other clusters of PFS in younger males and females. Due to response bias, we omit prevalence rates for all PFS. We expect that consideration for overlap in PFS is already common in GP and PFPT practice, but appropriate attention for all PFS is desirable in the consultation of male and female PFS. A need for further research on concomitant PFS in both males and females seems desirable. According to the differences we found between male and female PFS clusters, research in females should focus on the concurrency of sexual dysfunction and pelvic pain or sexual dysfunction and defecation problems together with UI and / or POP symptoms, so incorporating all types of PFS. Male pelvic floor research should give more attention to the concurrency of defecation problems and pelvic pain together with LUTS and sexual dysfunction.

### 4.2 Male and female pelvic floor assessment studies

Considering the anatomy of the PFM, we hypothesized that a dysfunction of one pelvic floor muscle could coincide with dysfunction in another pelvic floor muscle (in males the EAS and PRM; in females the EAS, the PRM and the vaginal PFM). Also, we hypothesized that abnormalities in certain aspects of muscle function (e.g., relaxation) would coincide with other dysfunctions of that same muscle (e.g., MVC). Assuming the functional unity of the PFM, we expected that male and female PFM dysfunction would be associated with symptoms, and that more (severe) dysfunction would be associated with more (and more severe) PFS.
In ***Chapter 3*** we explored the PFM in 199 males with and without PFS. We found high percentages of agreement (>90%) between the EAS and the PRM for voluntary contraction and frequency of MVC. In contrast, we found low percentages of agreement between the EAS and PRM for voluntary relaxation. Apparently, voluntary contraction and the frequency of MVC seems to be more of a simultaneous action between the EAS and the PRM, while this is not or less the case for any form of voluntary relaxation. Furthermore, we found that a dysfunctional tone in the PRM was associated with a dysfunctional voluntary relaxation and MVC, and less change in the anorectal angle during contraction and relaxation.
However, it is important to realize that the assessment of tone in males and females is challenging since no validated scales for grading of tone are available.[57] Tone is multifactorial and dependent of several physical, neurological and physiological factors such as emotional states, anxiety, history of parity in females, traumatic events, sexual

function and tenderness or pain arising from the PFM or connective pelvic tissues. Furthermore, tone is a continuum fluctuating from lower to higher tone and dependent of both the active (contractile) and the passive (elastic and viscoelastic) components of the muscles, which cannot be discriminated by palpation alone. Therefore, in the tone-scale no rating can be indicated as 'normal (average).[6,7,36,58] Besides, several difficult to measure factors such as urgency for urine, flatus or bowel, and the environment and temperature may influence tone during PFM assessment. PFM assessment of tone by an objective measuring device might therefore add valuable information. We indicate that our findings regarding tone should be interpreted with caution.
As we found no clear pattern of association between the EAS and the PRM, the question arises whether we can consider the EAS and the PFM as a functional unity, as former studies reported.[14,16,17] Furthermore, we found a one-directional pattern of the EAS towards the PRM. In other words, when having dysfunction within the EAS, in most cases there is dysfunction within the PRM, while dysfunction within the PRM is not always related to dysfunction within the EAS. This pattern was most pronounced for voluntary relaxation, tone and MVC.
Remarkably we found that 33% of all males reported no symptoms, while 80% of those males showed some PFM dysfunction. Possibly these males did not recognize or ignored their PFS, PFM dysfunction did not result in experienced symptoms, or dysfunction of the PFM was only present during the PFM assessment. Primary adverse muscle reactions in the peri-pelvic or other body muscles, and holding breath, may have influenced PFM function too, since a digital insertion is contradictory to the defecation process and for males even more unnatural.
In ***Chapter 4*** we performed a comparable analysis in 187 community-dwelling females. For the female muscle combinations (vaginal PFM-EAS, vaginal PFM-PRM, EAS-PRM) we found highest agreements (>90%) for voluntary contraction and the frequency of MVC. At first glance this may not be surprising given the simple instruction and the assumed functional unity of the PFM. However, several female studies indicate that without a proper instruction, it is difficult to perform a voluntary contraction of the PFM.[59] For the same three muscle combinations, we found lower agreements (~50%) for normal tone, and for strong or normal MVC. As discussed above, tone is complex to assess and apparently a strong or normal MVC in one muscle may imply a dysfunctional MVC in the other two muscles.[6,7,36,58,59] In the EAS, in almost 80% a dysfunction

for voluntary relaxation was present together with a dysfunction of the MVC. We are not aware of similar research, but a previous study in females with and without provoked vestibulodynia, showed relations between MVC and relaxation after voluntary contraction during vaginal palpation.[60] In the PRM, high agreement was found between a dysfunction for MVC, endurance and anorectal angle, and a dysfunction for voluntary relaxation. To date, we found no similar studies exploring associations within the PFM. However, in one study, assessing PFM morphometric differences between continent and incontinent females, the function of the MVC was correlated with the anorectal angle, which was in line with our findings.[61]

Within the vaginal PFM a dysfunctional musculature response on coughing, without the instruction to pre-contract, was one of the most common PFM dysfunctions during the vaginal PFM assessment. This finding was in line with a former study, which found that elderly females showed an inappropriate PFM contraction when coughing.[62] Furthermore, we often found POP signs during the PFM assessment. POP signs are common in multi- or even single-para, but do not always correlate with POP symptoms.[63] Factors of influence for POP signs may be insufficient PFM support for the pelvic organs and /or inappropriate ligamentous structures.[64] In our study only a few females reported POP symptoms, while most of them had a POP stage of one or higher. Apparently, females with a POP stage less than 2, did not report or ignored their POP symptoms, which was in line with another previous study.[65] Furthermore, in other females with a POP stage less than 2, POP signs did not give any POP symptoms at all.

Since we found only some weak patterns of association for voluntary relaxation, MVC and endurance between the female PFM, questions may arise regarding connections between the vaginal and anorectal PFM. Therefore, we strongly recommend both a vaginal and an anorectal digital PFM assessment in females with PFS. PFPTs should be, according to these findings, convinced that both assessments of the PFM are essential in PFS consultation.

Both in the male and female digital PFM assessment studies we did not find, contrary to our expectations, a clear dose-response relationship between PFM dysfunction and (the number of) PFS. We expected that participants showing more PFM dysfunction would have more or the most PFS compared to those having less PFM dysfunction. Furthermore, for both sexes we found that the PRM showed more and more (severe)

PFM dysfunction compared to the EAS (and in females the vaginal PFM). An explanation for these findings might be the location of the PRM, deeper and less known and findable than the superficial EAS or, in females the vaginal PFM.[66,67] Besides, the PRM may by its deep location be more influenced by dysfunction of the peri-pelvic or other muscles and the diaphragm, something we did not assess in this study.[33]
However, our results still provide possible pieces of the puzzle and new areas for future studies, unravelling the complexity of male and female PFM function in relation to PFS.
In ***Chapter 5*** we compared the male and female PFM function in relation to PFS. We expected, according to the variety between the male and female urogenital and PFM anatomy, differences between both sexes. Since pregnancy and delivery are risk factors for PFM dysfunction, we expected that females reported more PFS.
Overall, we found that females more often had decreased tone, whereas males more often had increased tone. Males more often showed impaired relaxation, a stronger MVC, and a normal endurance. The increase of tone we found in males is difficult to explain, and evidence on male and female PFM tone is still scarce.[68,69] An explanation for the increase of tone in males might be coherent to the nature of the assessment, which may give other reactions in males compared to females. We found that especially males with two or more PFS performed worse in relaxation of the PRM. These findings might be contributed to participants with pelvic pain, since in a former study it was found that 88% of the males with pelvic pain was unable to relax the PFM, but it was not specified in which part of the PFM.[70] Concerning MVC and the number of PFS, females more often showed a weak MVC of the EAS, compared to males. A weak MVC may be associated with obstetric anal sphincter injuries (OASIS), as result of vaginal delivery or having anal sex.[71] Females having sexual dysfunction and pelvic pain, more often showed a weak MVC, compared to males, in particular in the PRM. Apparently, strength of the deep PFM has more influence on these PFS, compared to the superficial PFM in females. This is in line with findings of a study in females having an increased tone and pelvic pain, in which strength and length of the deeper located levator ani muscle improved after a PFPT rehabilitation.[72]
In general, females showed more dysfunction for endurance, compared to males. However, males with sexual dysfunction and pelvic pain showed a higher percentage for a dysfunctional endurance (0-3 out of 10s) in the PRM, compared to females, indicating that pain in males

may influence endurance in the deep lying PFM. This is in line with a previous study, in which endurance was measured with EMG.[73]
In ***Chapter 6*** we further explored the association between male PFM function and LUTS (voiding and UI symptoms) together with defecation problems and pelvic pain. We expected that males presenting the most PFM dysfunction would show the highest scores on LUTS (voiding and UI symptoms) and concomitant PFS.
In chapter 4 we found no clear association between male PFM function and the number of PFS. We therefore searched for another approach to explore male PFM dysfunction and specific PFS, such as voiding and UI symptoms. Since latent class analyses (LCA) may identify qualitatively different subgroups within populations who often share certain outward characteristics, we chose this procedure for exploring relationships between PFM dysfunction and certain PFS. Our LCA created four classes. Class 1, contained 'the young and healthy males', having the least symptoms. Class 2, the largest group, and Class 3 including older males, demonstrated more symptoms, and Class 4, in general the eldest males, showed most symptoms. Sexual dysfunction was not included since not all males were sexually active and would make our complex analysis even more complicated.
Highest percentages of increased tone were found in the younger males (class 1), while the oldest males (class 4), showed the highest percentages on normal tone for both in the EAS and the PRM. As described above, PFM tone may be dependent of several factors, what makes findings for tone point of discussion.[20,33,36,74]
In line with our expectations, males having the most voiding symptoms and pelvic pain (Class 4), due to possibly chronic prostatitis/chronic pelvic pain, showed the highest percentage of an incomplete relaxation of the EAS and the PRM.[75] Contrary to our expectations, males in Class 1 showed the highest percentages for a weak MVC in the EAS and in the PRM, which we cannot explain. All classes showed a high percentage for a weak MVC, which we attributed to the deep location and the lesser awareness of the PRM. [76]Not surprisingly, males in Class 4, exhibited in line with our expectations, most frequently had an endurance less than 7 seconds for both the EAS and the PRM.

### 4.3 Overall strengths and limitations male and female PFM assessment studies

A limitation for both the male and female study was the mean age of the participants, which was 63.0 ± 12.5 years for males and 58.6 ± 14.1 years for females respectively. Therefore, we could only collect limited data concerning younger participants.

In both studies we did not find, contrary to our expectations, a clear dose-response relationship between PFM dysfunction and the number of PFS. We expected that participants showing more PFM dysfunction would have more or the most PFS compared to those having less PFM dysfunction. Furthermore, this cross-sectional study could not establish causal relationships.

As we performed an internal digital PFM assessment specifically for the evaluation of PFM function by PFPTs in relation to concomitant PFS, we did not use specific urological measurement devices to report the (fe) male urethral/rhabdo sphincter function. Former studies reported that this muscle is partly responsible for urinary continence and the process of micturition.[77,78]

In absence of established cut-off values, we used the highest quartiles of the LUTS and defecation questionnaires for the presence of PFS. Other, stringent cut-off values could have influenced our outcomes. We initially assessed only the number of PFS and omitted the severity of the PFS, but in the final chapter we explored PFM function in relation to the severity of male LUTS (and concurrent PFS).

Our choice for one PFPT prevented inter-rater dissimilarities, but perhaps this may have implied systematic errors, since all assessments were equally performed without interim evaluation by a second assessor. Regarding male PFM assessment inter-rater and intra-rater reliability, to date no research studied these topics and seems to illustrate the existing lack in male PFM assessment studies again.[79] Inter- and intra-reliability for female digital PFM assessment has been studied already for some decades. Some studies indicate that as result of subjectivity of the different digital palpation procedures and a low inter-rater reliability, female PFM assessment show unsatisfactory reproducibility. Other research reports that a digital female PFM assessment shows moderate face validity and intra-rater reliability and is appropriate for clinical practice.[80-83]

Since we conducted an explorative study, we did not perform sample size calculation and assumed that with 200 males and 200 females, outcomes

of both PFS and PFM assessment, we would include sufficient variability allowing to compare subgroups. Larger participant-groups were not feasible within the time-span of the study.
Respondent bias might have been subject to the study too. Reasons to participate may have been different, e.g., interest in scientific research, or pelvic floor research, interest in their own PFM function with or without PFS, or searching for a digital PFM assessment by an assessor who was not affiliated to their GPs practice.
We did not assess the duration of PFM dysfunction and PFS in our analyses. This may be a discussion point, as having PFM dysfunction on a long-term might have more impact on the presence of PFS compared to a PFM dysfunction just recently started. Adding such information would require a much larger sample size, which was deemed unfeasible.
Finally, for our findings concerning the comparison between male and female PFM dysfunction, the vaginal PFM may have influenced the EAS and the PRM, something we could not rule out. Besides, the PRM may be more influenced by dysfunction of the peri-pelvic or even other muscles, and the diaphragm, something we did not assess in this study.[33]
Despite the limitations above, strengths may be indicated as follows:
This is the first study assessing PFM function in relation to multiple PFS in both males and females. This enabled us to compare the outcomes between male and female PFM function, and to assess male PFM function in relation to voiding and UI symptoms (and concomitant PFS). Secondly, the small difference (<5 years) in mean age and comparable numbers in each group (for the total number of PFS) allowed us to make a comparison between males and females, which was advantageous for the study. Thirdly, both sexes were sampled from the same general population. Fourthly, we used a tool for PFM assessment which is easily and commonly used in daily practice by GPs and PFPTs. Fifthly, to improve intra-rater reliability and transparency, we described all steps in the male and female PFM assessment. Since the digital PFM assessment was performed by a single PFPT, inter-rater reliability was no issue. Sixthly, since the PFPT was blinded to the PFS, and participants were asked not to inform his or her PFS status, we reduced the risk of observer bias (in particular confirmation bias). Referring to this last point, in the daily practice of GPs or PFPTs, observer bias is likely, since the status of the patient is already known, before assessing PFM function. Seventhly, we used heatmaps and an LCA in an attempt to create order in the complexity of male and female PFM function in relation to PFS.

This unique study contributes to the unravelling of the complexity of male and female PFM function in relation to PFS.

## 5. GENERALIZABILITY RESULTS

We realize that the results of this study are not generalizable to general or specific populations of patients seeking for help for PFS at their GP, urologist, gynecologist, proctologist or PFPT. Participants in this research comprised males and females in a general population, willing to take part in a scientific study. Seeking help for PFS was not part of the selection procedure. To attain equal groups for the number of PFS, participants for the PFM assessment study were purposively selected from the group of participants who completed the PFS questionnaires in the overall study. Therefore, certain groups may have been overrepresented. Since the nature of the study might be too inconvenient for younger people, only participants aged ≥21 were invited. The skewed age distribution prevents generalization to populations of younger males and females with PFS. We indicate that no normal values exist for male and female PFM function. Still, the benefit of our sampling procedure is that the contrast between participant categories (comparing those with very limited symptoms with the group with most symptoms) was most pronounced, allowing comparisons to be made.

## 6. CLINICAL IMPLICATIONS



According to our findings, health care providers should be aware that different types of PFS often present simultaneously. It is therefore desirable that all types of PFS should be inquired, during history taking. A recent study showed that patients seeking help for one PFS may have other PFS which they do not report.[84]
We found that males without symptoms not always show a normal PFM function, which may imply that males not notice or ignore certain PFS. On the other hand, in males having PFS, we should be cautious to assert that in those males PFM dysfunction is a real dysfunction responsible for their PFS, or that maybe other factors are accountable for the PFS, and that the PFM dysfunction may only be present during the digital PFM assessment.

In this study we found no clear dose-response relationship between the presence of PFM dysfunction and the number of PFS in both sexes, but we recommend that patients having more than one PFS a digital PFM assessment should be considered. If needed, a referral to a specialist in PFM (dys)function is possible In the Netherlands, PFPTs are the most experienced care providers for this.
Previous PFM research showed that a digital PFM assessment may contribute to increased PFM awareness.[85] An improvement in PFM awareness might contribute to an improvement of PFM function, which in turn might lead to a decrease of PFS. We were unable to show that in females a digital PFM assessment of both the anorectal and vaginal PFM may have impact on the reduction of PFS, as no follow-up took place.
Based on our results we do recommend the assessment of both the anorectal and vaginal PFM. We further advise that in both males and females a proper and complete anorectal PFM assessment should be performed in side-lying position. Concerning the digital PFM assessment, we further advise that every PFPT should apply the new terminology and description of PFM function.[36]
Cough responses should be given full attention too in PFM assessment, since we found a high percentage PFM dysfunction to a cough response in females. This might have been due to the given instruction (no instruction to voluntary contract the PFM), or aging. Explanation by PFPTs about the effect of increase of intra-abdominal pressure should therefore always be part of PFM treatment, in particular in elderly females.
Finally, medical doctors and PFPTs and pelvic floor health care providers should be aware of the subjectivity of PFM assessment. On that point frequent performance of a PFM assessment seems to be evident.

## 7. FUTURE RESEARCH

In the past, most pelvic floor research focused on a single or at most two PFS, but based on our results, future research should be more focused on the co-occurrence of PFS in both males and females. Additionally, pelvic floor research should focus on the relationships between PFM function and multiple and concurrent PFS, in which duration of PFM dysfunction and PFS, and severity of PFS should be included. Furthermore, it would be very interesting to assess whether a complete digital PFM assessment improves the understanding and awareness of PFM function, leading to more effective pelvic floor physical therapy and a reduction of PFS. Researchers should also decide which measurement methods they will employ for answering their research question and should be aware of the influence of multiple physiological and psychological factors, and the intimacy of a digital PFM assessment. They should also realize that a digital PFM assessment is the first practical measurement tool in clinical practice and objective measurement tools are often not available. Based on the new terminology of Frawley et al, in future efforts should be made to study which parts of the male and female digital PFM assessment should be adjusted and standardized, making a digital PFM assessment more suitable and acceptable for pelvic floor scientific research. Developing scales for PFM tone may be a particular subject too for further PFM research.[86] According to this author's opinion, research on prevention of PFS and male and female PFM dysfunction may be an even more important issue.

## 8. GENERAL CONCLUSION

In this male and female PFM assessment study we found no clear associations between PFM function and PFS, which might be due to our analysis methods, the complex puzzle of male and female PFM function and additional influencing factors. A digital PFM assessment is subjective but the first practical measurement tool in clinical practice of GPs and PFPTs. Research of male and female PFM function in relation to concurrent PFS may add to the understanding and improvement of consultation for PFS.

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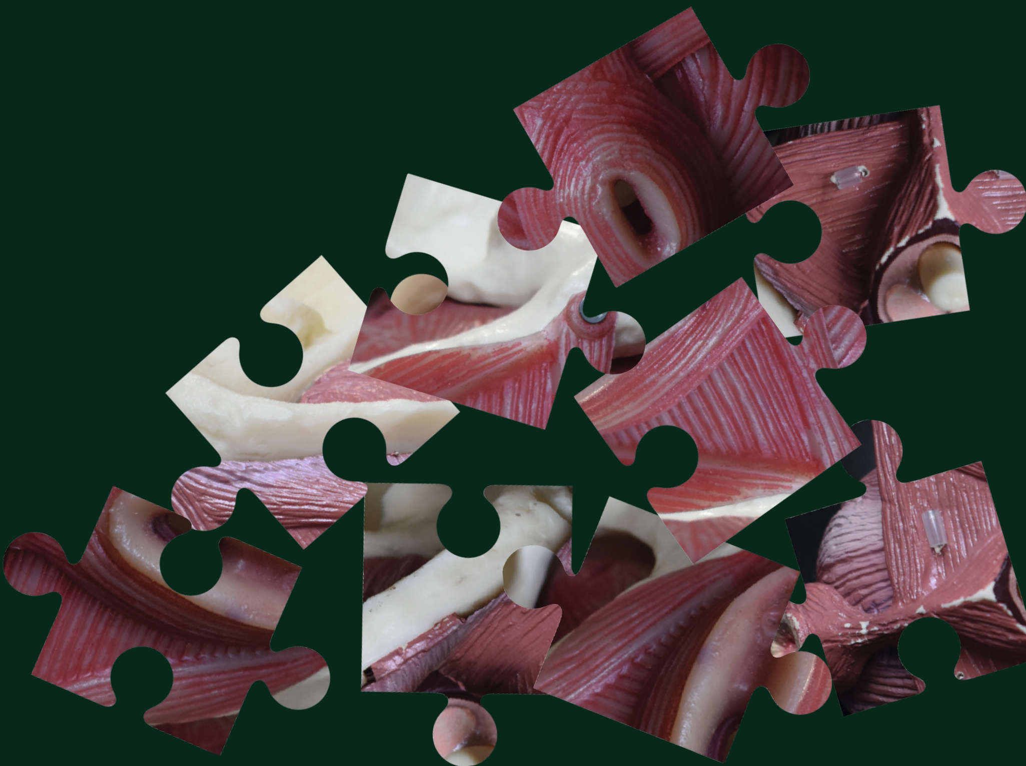

# A

# Appendices

## SCIENTIFIC SUMMARY

### Background

Pelvic floor symptoms (PFS) are prevailing in males and females and often reduce quality of life. PFS comprise lower urinary tract symptoms (LUTS; e.g., urinary incontinence (UI), urgency, voiding problems), defecation problems (fecal incontinence (FI), obstipation), sexual dysfunction (erectile and / or ejaculation problems; pain during intercourse, arousal problems), pelvic pain and additionally in females, pelvic organ prolapse (POP) symptoms.
The pelvic floor is a complex unit of pelvic floor muscles (PFM), ligaments, nerves and adjacent tissues. It plays an important role in the storage and passage of urine and feces, sexuality, and support to the pelvic organs (bladder, intestines, prostate and uterus). A dysfunction of the pelvic organs might lead to PFS, while PFM may also play a role in PFS, since they are close to the pelvic organs.
Research on female PFS has mostly been focused on UI and / or POP symptoms, sometimes together with FI. However, research on concomitant female PFS is scarce. Female PFM (dys) function is often described in relation to childbirth and UI, but an in-depth exploration of the relation between female PFM function and (all types) of PFS is lacking in current female pelvic floor research. Research on male PFS, is focused primarily on LUTS and sexual dysfunction, while male research on concurrent PFS is still underexposed. Research on male PFM function is undoubtfully scarce and is often studied in relation to prostatectomy or the chronic pelvic pain syndrome.
To fill these gaps in male and female pelvic floor research, a large observational population-based cohort study was conducted. In this study among inhabitants of a Dutch municipal area, males and females aged ≥ 16 years completed validated questionnaires on PFS in 2019, 2020 and 2021. A total of 11,724 inhabitants were invited, among which 566 males and 839 females completed all PFS questionnaires. From these males and females, with and without PFS, 400 males and 608 females aged ≥21 years were invited for an additional assessment concerning PFM function. In total 199 males and 187 females underwent an internal digital PFM assessment in accordance to protocols of pelvic floor physical therapy in the Netherlands, and the most recent International Continence Society (ICS) recommendations. In males, the external anal sphincter (EAS) and the puborectal muscle (PRM) were assessed,

and in females the vaginal PFM and prolapse staging were evaluated, in addition to abovementioned muscles, During the PFM assessment the following items of PFM function were assessed: tone, voluntary contraction, voluntary relaxation, maximal voluntary contraction (MVC), frequency of 10 MVC's, and endurance (3 times a maximum of 10 seconds).
With the data of the PFS questionnaires and the PFM assessment we explored:
a) the concurrency of PFS in males and females;
b) the function of the different PFM and the comparison of the different function-items within and between the different PFM, and the relation between PFM function and the total number of PFS in males and females;
c) the similarities and differences between male and female PFM function by the number and type of PFS;
d) the relation between male PFM function and LUTS and other PFS (defecation problems and pelvic pain).

**Results**
***Chapter 2*** describes concomitant PFS in community-dwelling males and females. In both male and female participants, approximately one out of three reported no PFS, and one out of three reported two or more PFS.
The most prevalent clusters of PFS in females were: sexual dysfunction and pelvic pain, sexual dysfunction and defecation problems, and LUTS with defecation problems with or without pelvic pain.
The most prevalent clusters in males were sexual dysfunction and LUTS, defecation problems and LUTS, and sexual dysfunction, LUTS and defecation problems. We found that females reported pelvic pain more often than males. Pelvic pain in males was reported in almost 85% in combination with other PFS.

In ***Chapter 3*** we explored the associations within and between the EAS and the PRM, and the relation between PFM (dys-) function in relation to the total number of PFS, in 199 males with and without PFS. Overall, one out of five males had a completely normal PFM function. Among 66 males without PFS, 80% showed some PFM dysfunction. The PRM showed both more and more severe dysfunction compared to the EAS. We found no clear dose-response relationship between PFM (dys-) function and the number of PFS.

In ***Chapter 4*** we explored the associations within and between the EAS, the PRM and the vaginal PFM and prolapse staging, and the relation between PFM function and the total number of PFS, in 187 females with and without PFS.
Females often showed at least some degree of prolapse. Additionally, dysfunction of the vaginal PFM appeared on cough response, while most dysfunction of the PRM appeared on assessing tone and voluntary relaxation. We found high percentages of association suggestive of patterns within each specific PFM, while for the same conditions, we found low percentages of association between the different PFM. The PRM showed more, and more severe dysfunction compared to the EAS or the vaginal PFM. In females we also found no dose-response relationship between PFM dysfunction and the number of PFS.

In ***Chapter 5*** we compared male and female PFM function. Similarities and differences in male and female PFM function were assessed with respect to tone, voluntary relaxation, MVC and endurance by the number and type (LUTS, defecation problems, sexual dysfunction and pelvic pain) of PFS. Compared with females, males more often showed an increased EAS and PRM tone during assessments. Compared with males, females more often showed a weaker MVC of the EAS and a dysfunctional endurance of both muscles; additionally, those without PFS or one PFS, and those with sexual dysfunction and pelvic pain, more often showed a weak MVC of the PRM.

In ***Chapter 6*** we explored the relationship between male PFM function and LUTS and concomitant PFS (defecation problems and pelvic pain). No significant associations were found between PFM function and voiding and UI symptoms. A latent class analysis (LCA) constructed 4 Classes varying in sample size. Most PFM dysfunction for tone, voluntary relaxation and MVC, both in the EAS and the PRM, was found in the 'young and healthy males' (Class 1). The eldest males having the most PFS (Class 4) showed less PFM dysfunction for tone in the EAS and the PRM and for voluntary relaxation in the EAS.

**Clinical implications and future research**
According to our findings, health care providers should be aware that different types of PFS often present simultaneously and should address all PFS during consultation.

Health care providers in pelvic floor dysfunction and researchers should be aware that physiological and emotional factors, and the intimacy of a digital PFM assessment might influence outcomes of PFM evaluation. In this study we found no clear dose-response relationship between PFM dysfunction and the number of PFS in both sexes. We recommend that in patients having more than one PFS, a digital PFM assessment should be considered. In the Netherlands, pelvic floor physical therapists are educated and trained for performing PFM assessment and are therefore the most experienced care providers for such an assessment. Since, in females, we only found weak associations between the function-items of the different PFM, we recommend, when a complete PFM assessment is indicated, that both a digital vaginal and anorectal PFM assessment should be performed.
Future research should focus more on the co-occurrence of PFS in both males and females, and on the relationships between PFM function and all types of (concurrent) PFS, in which the duration of PFM dysfunction and PFS, and severity of PFS should be included. Furthermore, future research should study the possible impact of a digital PFM assessment on the awareness of PFM function, and the subsequent possible positive effect on the severity of PFS. Besides, it would be helpful to look at potential adjustments in the digital PFM assessment so that it would be more suitable for pelvic floor scientific research.

**General conclusion**

In this male and female internal digital PFM assessment study we found no clear associations between PFM function and PFS, which might be due to the complex puzzle of male and female PFM function and additional influencing factors. A digital PFM assessment of a GP or a pelvic floor physical therapist is subjective, but the first practical measurement tool to assess PFM function in clinical practice. Research of male and female PFM function in relation to concurrent PFS may add to an improvement of knowledge of PFM function and PFS, and in the future possibly to a better treatment for PFS.

## NEDERLANDSE SAMENVATTING

### Achtergrond

Bekkenbodemklachten komen vaak voor bij zowel vrouwen als mannen en leiden in veel gevallen tot een vermindering van de kwaliteit van leven. Bekkenbodemklachten bestaan uit 'lower urinary tract symptoms' (LUTS) klachten (o.a. urine-incontinentie (UI)), aandrang- en plasklachten), ontlastingsklachten (ontlastingsverlies, obstipatie), seksuele klachten (erectiestoornissen, zaadlozingsproblemen, pijn bij penetratie, opwindingsstoornissen), pijnklachten in het bekkengebied en bij vrouwen verzakkingsklachten.

De bekkenbodem is een complexe eenheid van spieren, banden, zenuwen en bindweefsel, en speelt een belangrijke rol bij de doorgang en opslag van urine en ontlasting, de seksualiteit, en de ondersteuning van de bekkenorganen (blaas, darmen, prostaat en baarmoeder). Een disfunctie van de bekkenorganen kan leiden tot bekkenbodemklachten, maar ook kunnen de bekkenbodemspieren door hun ligging hier een rol in spelen.

Bekkenbodemonderzoek bij vrouwen is voornamelijk gericht op UI en verzakkingsklachten, soms tezamen met ontlastingsverlies, maar onderzoek naar samen voorkomende bekkenbodemklachten is schaars. Een disfunctie van de bekkenbodemspieren bij vrouwen wordt vaak onderzocht in relatie tot geboorte en UI, maar diepgaand onderzoek naar de relatie tussen de bekkenbodemspierfunctie en (alle typen) bekkenbodemklachten mist nog. Onderzoek naar bekkenbodemklachten bij mannen is voornamelijk gericht op LUTS klachten en seksuele klachten, maar onderzoek naar samen voorkomende bekkenbodemklachten bij mannen is ook nog steeds onderbelicht. Onderzoek van de bekkenbodemspierfunctie bij mannen is zeer schaars, en richt zich meestal alleen op de functie van de bekkenbodemspieren na een prostaatverwijdering of in relatie tot chronische pijnklachten.

Om deze lacunes in het bekkenbodemonderzoek bij mannen en vrouwen op te vullen, werd een onderzoek uitgevoerd, waarbij in 2019, 2020 en 2021 mannen en vrouwen van 16 jaar en ouder uit een Nederlandse gemeente vragenlijsten over bekkenbodemklachten invulden. In totaal werden 11.724 inwoners uitgenodigd om mee te doen, waarvan 566 mannen en 839 vrouwen de vragenlijsten volledig invulden.

Van deze groep mannen en vrouwen, met en zonder bekkenbodemklachten, werden 400 mannen en 608 vrouwen, ouder

dan 21 jaar, uitgenodigd voor aanvullend onderzoek bestaande uit een inwendig onderzoek naar de bekkenbodemspierfunctie. Dit inwendig manueel onderzoek naar de bekkenbodemspierfunctie bij uiteindelijk 199 mannen en 187 vrouwen, werd verricht overeenkomstig protocollen betreffende inwendig bekkenbodemonderzoek in Nederland en de meest recent aanbevelingen van de International Continence Society (ICS). Bij mannen werd de anale sluitspier (externe anale sfincter) en de diepe anale bekkenbodemintrekspier (m. puborectalis) onderzocht. Bij vrouwen werden naast eerdergenoemde spieren, ook de vaginale bekkenbodemspieren en de mate van een verzakking onderzocht. Tijdens het bekkenbodemonderzoek werden onder andere de volgende items van de spierfunctie onderzocht: spierspanning (tonus), bewuste aanspanning, bewuste ontspanning, maximale aanspankracht, frequentie van 10 maximale aanspanningen en de duurkracht (3 maal maximaal 10 seconden).
Met de gegevens van de bekkenbodemvragenlijsten en het inwendige onderzoek van de bekkenbodemspierfunctie werd het volgende onderzocht:
a) het samen voorkomen van bekkenbodemklachten bij mannen en vrouwen;
b) de functies van verschillende bekkenbodemspieren en de vergelijking van de verschillende functie-items binnen de bekkenbodemspieren en tussen de verschillende bekkenbodemspieren, en de relatie tussen de bekkenbodemspierfunctie en het aantal bekkenbodemklachten bij mannen en vrouwen;
c) de overeenkomsten en verschillen tussen de bekkenbodemspierfunctie bij mannen en vrouwen in relatie tot het aantal en type bekkenbodemklachten;
d) de relatie tussen de bekkenbodemspierfunctie en LUTS klachten, en andere bekkenbodemklachten (ontlastingsklachten en pijnklachten in het bekkengebied) bij mannen.

**Resultaten**
***Hoofdstuk 2*** beschrijft het samen voorkomen van bekkenbodemklachten bij mannen en vrouwen. Bij zowel de mannelijke als de vrouwelijke deelnemers, meldde ongeveer één op de drie geen klachten, en één op de drie twee of meer bekkenbodemklachten.
De meest voorkomende clusters van bekkenbodemklachten bij vrouwen waren: seksuele klachten met pijnklachten in het bekkengebied,

seksuele klachten met ontlastingsklachten, en LUTS klachten met ontlastingsklachten, al dan niet met pijnklachten in het bekkengebied. De meest voorkomende clusters bij mannen waren seksuele klachten en LUTS klachten, ontlastingsklachten en LUTS klachten, en seksuele klachten met zowel LUTS klachten en ontlastingsklachten. Vrouwen hadden vaker pijnklachten dan mannen. Pijnklachten bij mannen kwamen bijna altijd (85%) in combinatie met andere klachten voor.

***Hoofdstuk 3*** beschrijft bij 199 mannen de associaties binnen en tussen de anale sluitspier en de diepe anale bekkenbodemintrekspier, en de relatie tussen de bekkenbodemspierfunctie en het totaal aantal bekkenbodemklachten. We vonden dat één op de vijf mannen een normale bekkenbodemspierfunctie had. Van de 66 mannen zonder bekkenbodemklachten had 80% toch enige mate van bekkenbodemspierdisfunctie. De diepe anale bekkenbodemintrekspier had vaker en meer een disfunctie dan de anale sluitspier. In deze studie vonden we geen duidelijke relatie tussen een disfunctie van de bekkenbodemspieren en het totaal aantal bekkenbodemklachten.

***Hoofdstuk 4*** beschrijft bij 187 vrouwen met en zonder bekkenbodemklachten en de associaties binnen en tussen de anale sluitspier, de diepe anale bekkenbodemintrekspier en de vaginale bekkenbodemspieren, de mate van een verzakking, en de relatie tussen de bekkenbodemspierfunctie en het totaal aantal bekkenbodemklachten. Bij vrouwen werd vaak een mate van verzakking gevonden. Daarnaast werd er een disfunctie van de vaginale bekkenbodemspieren gevonden bij hoesten, terwijl de meeste dysfunctie werd gevonden in de spierspanning (tonus) en de bewuste ontspanning van de diepe anale bekkenbodemintrekspier. We vonden binnen de bekkenbodemspieren een hoog percentage van associatie tussen de functie-items, maar een laag percentage van associatie tussen de functie-items van de verschillende bekkenbodemspieren. Verder vonden we vaker en meer disfunctie van de diepe anale bekkenbodemintrekspier in vergelijking met de anale sluitspier of de vaginale bekkenbodemspieren. Ook werd bij de vrouwen geen relatie tussen een disfunctie van de bekkenbodemspieren en het totaal aantal bekkenbodemklachten gevonden.

***Hoofdstuk 5*** beschrijft de overeenkomsten en verschillen van de bekkenbodemspierfunctie tussen mannen en vrouwen, waarbij we keken naar spierspanning, bewuste ontspanning, maximale aanspankracht en duurkracht in relatie tot het aantal en het type bekkenbodemklachten (LUTS klachten, ontlastingsklachten, seksuele klachten en pijn in het

bekkengebied). Vergeleken met vrouwen lieten mannen vaker een toegenomen spierspanning zien van de anale sluitspier en de diepe anale bekkenbodemintrekspier. Vergeleken met mannen lieten vrouwen vaker een afname zien van de maximale aanspankracht van de anale sluitspier en een afname van de duurkracht van beide bekkenbodemspieren, waarbij vrouwen met geen of één bekkenbodemklacht, seksuele klachten en pijn in het bekkenbodemgebied, vaker een afname lieten zien van de maximale aanspankracht van de diepe anale bekkenbodemintrekspier.
***Hoofdstuk 6*** beschrijft de relatie tussen de bekkenbodemspierfunctie en LUTS klachten met daarbij andere voorkomende bekkenbodemklachten (ontlastingsklachten en pijn in het bekkengebied) bij mannen. We vonden geen significante associaties tussen de bekkenbodemspierfunctie en plasklachten en UI. Een latent class analyse construeerde 4 klassen voor bekkenbodemklachten welke in grootte verschilden. We vonden de meeste disfuncties in de bekkenbodemspierfunctie voor spierspanning, bewuste ontspanning en de maximale aanspankracht, in zowel de anale sluitspier als de diepe anale bekkenbodemintrekspier in de groep 'jonge en gezonde mannen' (klasse 1). De oudste mannen met de meeste bekkenbodemklachten (klasse 4) vertoonden minder disfuncties in de bekkenbodemspieren voor spierspanning in de anale sluitspier en de diepe anale bekkenbodemintrekspier, en voor bewuste ontspanning in de anale sluitspier.

**Klinische implicaties en toekomstig onderzoek**
Gebaseerd op onze bevindingen zouden hulpverleners van bekkenbodempatiënten zich bewust moeten zijn dat bekkenbodemklachten vaak samen voorkomen en zouden alle bekkenbodemklachten uitgevraagd moeten worden tijdens het consult van de patiënt.
Hulpverleners van bekkenbodempatiënten, en onderzoekers, moeten zich bewust zijn dat de uitkomsten van een inwendig onderzoek naar de bekkenbodemspierfunctie beïnvloed kunnen worden door fysieke en emotionele factoren en door de intimiteit van het onderzoek.
In deze studie vonden we zowel bij mannen als bij vrouwen geen duidelijke relatie tussen een disfunctie van de bekkenbodemspieren en het aantal bekkenbodemklachten. We adviseren dat bij patiënten met meer dan één bekkenbodemklacht overwogen moet worden of een inwendig onderzoek van de bekkenbodemspierfunctie moet plaatsvinden. In Nederland zijn bekkenfysiotherapeuten opgeleid en getraind voor inwendig onderzoek

naar de bekkenbodemspierfunctie en zijn daarmee specialisten op dit gebied. Omdat bij vrouwen weinig overeenstemming is gevonden tussen de functie-items van de verschillende bekkenbodemspieren, adviseren we verder dat, wanneer een compleet onderzoek naar de bekkenbodemspierfunctie is geïndiceerd, zowel een inwendig onderzoek van de anale als van de vaginale bekkenbodemspierfunctie zou moeten plaatsvinden.
Toekomstig bekkenbodemonderzoek bij mannen en vrouwen zou zich meer moeten richten op het gelijktijdig voorkomen van bekkenbodemklachten, en de relatie tussen de functies van de bekkenbodemspieren en alle typen (samen voorkomende) bekkenbodemklachten, waarbij de duur van de disfuncties van de bekkenbodemspieren en de duur van de bekkenbodemklachten, alsmede de ernst van de bekkenbodemklachten zouden moeten worden meegenomen in het onderzoek.
Verder zou toekomstig bekkenbodemonderzoek zich moeten richten op de impact van het inwendig onderzoek van de bekkenbodemspierfunctie op de bewustwording van de bekkenbodemspierfunctie en een mogelijke daaropvolgende afname van de bekkenbodemklachten, en tevens hoe het inwendig onderzoek van de bekkenbodemspierfunctie zou moeten worden aangepast, zodat het geschikter is voor wetenschappelijk bekkenbodemonderzoek.

**Algemene conclusie**

In deze studie betreffende een inwendig manueel onderzoek van de bekkenbodemspierfunctie bij mannen en vrouwen vonden we geen duidelijke relatie tussen de functies van de bekkenbodemspieren en het aantal bekkenbodemklachten, wat beïnvloed zou kunnen zijn door de complexiteit van de bekkenbodemspierfunctie en diverse andere factoren. Echter, een inwendig manueel onderzoek van de bekkenbodemspierfunctie, zowel van de huisarts als van de bekkenfysiotherapeut, is subjectief, maar het eerste praktische meetinstrument in de dagelijkse praktijk.
Studies naar de bekkenbodemspierfunctie bij mannen en vrouwen in relatie tot samen voorkomende bekkenbodemklachten zouden kunnen bijdragen aan betere kennis van de bekkenbodemspierfunctie en bekkenbodemklachten, waardoor patiënten in de toekomst mogelijk een betere behandeling van deze klachten kunnen krijgen.

## LIST OF PUBLICATIONS

1. **Exploring pelvic floor muscle activity in men with lower urinary tract symptoms.**
   Vrolijks RO, Notenboom-Nas FJM, de Boer D, Schouten T, Timmerman A, Zijlstra A, Witte LPW, Knol-de Vries GE, Blanker MH. Neurourol Urodyn. 2020 Feb;39(2):732-737. doi: 10.1002/nau.24267. Epub 2020 Jan 3. PMID: 31899809
2. **Exploring pelvic floor muscle function in men with and without pelvic floor symptoms: A population-based study.**
   Notenboom-Nas FJM, Knol-de Vries GE, Beijer L, Tolsma Y, Slieker-Ten Hove MCP, Dekker JH, van Koeveringe GA, Blanker MH. Neurourol Urodyn. 2022 Nov;41(8):1739-1748. doi: 10.1002/nau.24996. Epub 2022 Jul 25. PMID: 35876473
3. **Exploring concomitant pelvic floor symptoms in community-dwelling females and males.**
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Françoise.

## ABOUT THE AUTHOR

Françoise was born on the 9th of July 1961 in Paramaribo, Suriname, as daughter of Pieter Nas, a geodetic engineer and Marieke Nas-Wijffels, a librarian. After the family moved back to the Netherlands, she grew up in Zoetermeer, where she finished her high school at the Erasmus College in 1980. After one year-in-between, she started in 1981 with the study Physiotherapy at the Hogeschool Leiden and completed her studies in 1985.
Between 1986 and 1989 she worked in several physiotherapy practices in Rotterdam and Capelle aan de IJssel. In 1987 she married to Ton and the couple moved to Houten. In 1989 their first daughter Merel, and in 1992 her second daughter Hester, were born and she decided to stop working temporarily as a physiotherapist. However, by following a course 'Pre- and Postpartum Education' during her first pregnancy, she started giving lessons in peri-partum care in 1990 and continued this for 10 years. In 1994 she started working again as an all-round physiotherapist and from 1995 until 1999 she worked in two physiotherapy practices in Houten. After moving to Zutphen in 2000, she worked for 6 years in a practice in Lochem. During these years she followed several additional courses for education on pelvic floor dysfunction and pelvic floor symptoms. Because of her special interest for pelvic floor dysfunction, she started in 2003 the specialized education for pelvic floor physical therapy in Rotterdam, which was supervised by Mrs. dr. Marijke Slieker, one of her copromotores. After graduation in 2005, she continued her work as one of the first officially registered pelvic floor physical therapists in the Netherlands. Subsequently she worked in a practice in Apeldoorn for 12,5 years and gained her experience in pelvic floor physical therapy. During this period, she was part of several multidisciplinary teams and followed again numerous courses on pelvic floor dysfunction. Because of her interest in scientific research, she decided in 2011 to start Clinical Health Sciences at the University of Medical Sciences in Utrecht and finished this master degree in 2015. After graduating she worked on a short project as a researcher at the University Medical Center in Maastricht, still continuing her work as a pelvic floor physical therapist for 2 days a week.
In March 2019 she started as a junior researcher for the Coevorden-study at the Department of Primary and Long-term Care of the UMC Groningen. This junior researchership was extended in December 2020

in a PhD-trajectory, while she continued working part-time as a pelvic floor physical therapist in Brummen until the end of 2022. After Ton en Françoise moved to Ommen, she continued in Juli 2023 her part-time work as a pelvic floor physical therapist at Physiotherapy De Carrousel in Ommen, and completed her PhD-trajectory. In July of 2024 she started as a professional reference at the Dutch Paramedical Institute making pelvic floor scientific research more accessible for Dutch pelvic floor physical therapists.