

**DOES A REGULAR MENSTRUAL TAMPON OR AN INTRAVAGINAL PESSARY  
MITIGATE URINE LEAKAGE WHILE RUNNING AMONG FEMALES WHO  
EXPERIENCE EXERCISE-INDUCED URINARY INCONTINENCE?**

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## Abstract

Exercise-induced urinary incontinence (EI-UI), urine leakage experienced predominantly during exercise, affects nearly 40% of females who participate in high-impact activities and is a common barrier to exercise participation. In this randomized assessor-blind crossover trial, 30 adult females with EI-UI completed three standardized treadmill protocols: one without intervention, one with a self-fitted Uresta® pessary, and one with a regular menstrual tampon, with the latter two administered in randomized order. The primary outcome was the EI-UI Severity Index, a composite of self-reported leakage frequency and perceived volume during the run. Secondary outcomes included pad weight gain during the run, exercise-induced pelvic floor tissue strain assessed via transperineal ultrasound imaging, and user self-reported experience. Both devices significantly reduced EI-UI Severity Index scores compared to no intervention, with the pessary offering significantly greater symptom reduction compared to the tampon. The pessary significantly reduced pad weight gain while the tampon did not. Neither device influenced the extent of exercise-induced pelvic floor tissue strain. These findings support the use of the self-fitted Uresta® pessary and a regular menstrual tampon as effective, self-administered conservative management strategies for EI-UI in active females, with the pessary being superior to a menstrual tampon.

*Keywords:* urinary incontinence, conservative management, pessary, female runner, physiotherapy

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## **Statement of Contributions**

This study was conducted by a research team led by Dr. Linda McLean, who served as the Principal Investigator and supervised this thesis. I, Grace Collins, executed the study and led data collection, working alongside Dr. Marina Petter Rodrigues and Dr. Sabine Vesting, two post-doctoral researchers and pelvic health physiotherapists.

Dr. Linda McLean contributed to the conception and design of the study, provided guidance on participant eligibility criteria and data collection procedures, mentored the statistical analysis and provided revisions to manuscript drafts.

I, Grace Collins, conducted participant recruitment and screening to verify eligibility for the trial. I performed the majority of the data collection, including all ultrasound imaging and instruction of the standardized treadmill running protocol. I conducted the statistical analysis of all outcomes and wrote all chapters of this thesis, incorporating feedback from Dr. Linda McLean.

Dr. Marina Petter Rodrigues was one of the two pelvic health physiotherapists who supported participants during device self-fitting and insertion prior to use during laboratory visits. She also served as the second assessor, conducting transperineal ultrasound assessments and image analysis in 11 participants, and contributed to discussions on participant eligibility.

Dr. Sabine Vesting was the second of two pelvic health physiotherapists who supported participants during device self-fitting and insertion prior to use during the laboratory visits.

Undergraduate student volunteer research assistants played an essential role in the standardized treadmill protocol, recording participants' self-reported leakage responses during the run and measuring pad weight gain to maintain blinding of the primary assessor to condition allocation.

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For those who are unfamiliar with my path: after 2 years as a research assistant knee-deep in three projects on exercise-induced urinary incontinence, continuing to figure out my next step and seeking a new challenge, Dr. Linda McLean encouraged me to pursue a Master of Science degree under her wing... accelerated in one year. I had already been working on the project that became my thesis, with most of the data already collected. In shifting my role to graduate student, I've been able to learn and teach pelvic floor ultrasound, tap into the academic writer in me, present my work at national and international conferences, and meet so many intelligent leaders in women's health.

With that, I would first like to thank Dr. Linda McLean for the opportunity to learn, grow, and conduct research in the exceptional environment that is the Motor Function Measurement (MFM) lab. It has been an honour to be part of an internationally recognized team. I'm even more honoured to be guided by someone whose brilliance and relentless work ethic are matched by the kindness and humanity she brings into every room. You have a gift for seeing potential in people and then holding them to it. You teach beyond your words and have shown me what strong, compassionate female leadership looks like. As you have shared so poetically: "I never predicted

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## **List of Abbreviations**

|                   |                                                                                          |
|-------------------|------------------------------------------------------------------------------------------|
| <b>3D</b>         | Three-dimensional                                                                        |
| <b>ARA</b>        | Anorectal angle                                                                          |
| <b>BMI</b>        | Body mass index                                                                          |
| <b>BNH</b>        | Bladder neck height                                                                      |
| <b>BV</b>         | Bladder volume                                                                           |
| <b>CI</b>         | Confidence interval                                                                      |
| <b>EI-UI</b>      | Exercise-induced urinary incontinence                                                    |
| <b>EMM</b>        | Estimated marginal mean                                                                  |
| <b>EPI</b>        | Estimated percent improvement                                                            |
| <b>ICIQ-UI SF</b> | International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form |
| <b>IQR</b>        | Interquartile range                                                                      |
| <b>LHA</b>        | Levator hiatus area                                                                      |
| <b>LMEM</b>       | Linear mixed-effects model                                                               |
| <b>LPL</b>        | Levator plate length                                                                     |
| <b>OR</b>         | Odds ratio                                                                               |
| <b>PF</b>         | Pelvic floor                                                                             |
| <b>PFM</b>        | Pelvic floor muscle                                                                      |
| <b>PFMT</b>       | Pelvic floor muscle training                                                             |
| <b>PSQ</b>        | Patient Satisfaction Questionnaire                                                       |
| <b>RPE</b>        | Rating of perceived exertion                                                             |
| <b>SD</b>         | Standard deviation                                                                       |
| <b>SUI</b>        | Stress urinary incontinence                                                              |
| <b>UI</b>         | Urinary incontinence                                                                     |
| <b>UUI</b>        | Urgency urinary incontinence                                                             |
| <b>USI</b>        | Ultrasound imaging                                                                       |

## **Chapter 1. Introduction**

Exercise-induced urinary incontinence (EI-UI) is a prevalent and under-recognized condition affecting physically active females, particularly those participating in running and high-impact sports (Almousa & Bandin Van Loon, 2019; Brennand et al., 2017; Teixeira et al., 2018). Despite its high prevalence, EI-UI frequently goes unmanaged: more than half of affected females reduce or avoid physical activity as a result (Brennand et al., 2017; Brown & Miller, 2001; Nygaard et al., 2005), compounding the individual and societal burden of a treatable condition. Given the well-established physical and psychological benefits of regular exercise (Garber et al., 2011; Ji et al., 2024), addressing EI-UI is both a clinical and public health priority.

Pelvic floor muscle training (PFMT) is recommended as first-line therapy for stress urinary incontinence (SUI) broadly; however, evidence supporting its effectiveness specifically for EI-UI is limited (Petter Rodrigues et al., 2024). Published evidence suggests that passive tissue support deficits, rather than pelvic floor muscle (PFM) weakness, may be central to EI-UI pathophysiology (Bérubé & McLean, 2023; dos Santos et al., 2019; Gan et al., 2025), reinforcing interest in interventions that provide direct mechanical urethral support during exercise. Intravaginal devices, including incontinence pessaries, are a conservative, readily accessible management strategy that may mitigate EI-UI through urethral compression and enhanced bladder neck support (DeLancey, 1994; Komesu et al., 2008). Preliminary evidence supports their effectiveness during exercise (Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993); however, existing studies are limited by small sample sizes, non-standardized exercise protocols, and reliance on pad testing as a primary outcome, an outcome measure of questionable validity during exercise due to confounding variables of perspiration and vaginal fluids (Petter Rodrigues et al., 2024, 2025). No

prior study has combined objective and subjective leakage assessment with evaluation of pelvic floor morphometry and user experience within a randomized crossover design.

The primary aim of this study was to determine whether a self-fitted pessary and/or a regular menstrual tampon reduces EI-UI severity during a standardized treadmill running protocol when compared to no intervention. Secondary aims were to (1) compare differences in objective urine leakage measured via a treadmill-based pad test performed with no intervention, with a menstrual tampon and with an intravaginal pessary; (2) examine the effects of intravaginal devices on exercise-induced pelvic floor tissue strain; (3) evaluate acute user experience including satisfaction and perceived improvement with each intervention; and (4) assess short-term device use and user experience over a four-week follow-up period.

## **Chapter 2. Literature Review**

### **2.1 Defining Exercise-Induced Urinary Incontinence**

Urinary incontinence (UI), defined by the International Continence Society (ICS) as the involuntary loss of urine, most commonly presents as stress urinary incontinence (SUI) but also presents as urgency urinary incontinence (UUI) or a combination of both (Haylen et al., 2010). SUI is described as involuntary leakage synchronous with effort or physical exertion, sneezing, or coughing (Haylen et al., 2010). Despite being grouped together, exercise differs in its biomechanical demands, underlying mechanisms, and response to treatment, warranting its consideration as a distinct clinical entity. Although exercise-induced urinary incontinence (EI-UI) is not a standardized ICS term, it is used throughout this work to describe involuntary urine loss occurring specifically during physical exercise, distinguishing this population from the broader SUI definition.

### **2.2 Prevalence and Impact of Urinary Incontinence in Physically Active Females**

SUI affects over 30% of females aged 18 to 60 years (Nygaard et al., 2005), with prevalence ranging from 10% to 80% among athletes depending on the intensity of the activity (Almoussa & Van Loon, 2019; Lourenco et al., 2018; Pires et al., 2020; Teixeira et al., 2018). Rates are highest in high-impact activities involving running and jumping, which impose repetitive and rapid loading on the pelvic floor (Brennand et al., 2017; Goldstick & Constantini, 2014). Among recreational and competitive runners specifically, reported prevalence ranges from 31% to 44% (Lourenco et al., 2018; Pires et al., 2020; Teixeira et al., 2018), highlighting that running is a particularly leakage-provoking activity. Many females normalize leakage as an expected consequence of exercise or aging, or avoid seeking care due to embarrassment, fear of invasive

treatments, or limited awareness of conservative management options (Cheater & Castleden, 2000). Thus, EI-UI remains underreported and undertreated.

The consequences of EI-UI extend well beyond a localized symptom and represent a significant public health concern. UI independently impairs quality of life and negatively affects physical, social, sexual, and mental health (Chow et al., 2022; Senra & Pereira, 2015). In the context of exercise specifically, 25-50% of affected females reduce or avoid physical activities that provoke leakage (Brennand et al., 2017; Brown & Miller, 2001; Nygaard et al., 2005). This is a harmful outcome given that regular physical activity reduces all-cause mortality and risk of cardiovascular disease, diabetes, and osteoporosis (Borer, 2005; Ji et al., 2024). EI-UI therefore drives women away from the very behaviours most beneficial to their long-term health.

### **2.3 Pathophysiology of Exercise-Induced Urinary Incontinence**

The precise mechanisms underlying EI-UI remain poorly understood. Current conceptual frameworks of SUI suggest that its pathophysiology depends on two interdependent subsystems: a sphincteric system and a support system (DeLancey & Ashton-Miller, 2004). The sphincteric system maintains urethral closure pressure above bladder pressure at rest and during elevations in intra-abdominal pressure (DeLancey & Ashton-Miller, 2004). The support system provides the structural foundation upon which this sphincteric response depends. The urethra and bladder neck rest upon a hammock-like supportive layer composed of the anterior vaginal wall and its connective tissue attachments to the pelvic bones and muscles (DeLancey, 1994; DeLancey & Ashton-Miller, 2004). During rises in intra-abdominal pressure, caudal displacement of the urethra against this firm supportive layer causes urethral compression, maintaining continence. When support is insufficient, excessive bladder neck descent and inadequate external urethral compression leads to urine leakage (DeLancey, 1994).

During high-impact activities such as running, the pelvic floor is subjected to substantially greater and more repetitive loading than during activities of daily living, potentially exceeding the capacity of these support structures. It has been hypothesized that EI-UI in active females may reflect weakened or poorly functioning PFMs, whereby insufficient muscular support during exercise allows for involuntary urine loss (Bø, 2004). However, more recent evidence challenges this hypothesis. Female athletes with EI-UI demonstrate greater voluntary PFM contractile function than continent athletes but also greater tissue compliance (Bérubé & McLean, 2023; dos Santos et al., 2019). Importantly, no differences in PFM activity during running have been found between continent and incontinent females (Leitner et al., 2017), nor in pelvic floor kinematics (Leitner et al., 2018). This evidence suggests that deficits in the passive supportive structures rather than impaired voluntary muscle contractility may be more central to EI-UI in active females, highlighting the mechanistic rationale for interventions that provide direct mechanical support to the bladder neck and urethra during exercise.

## **2.4 Risk Factors for Urinary Incontinence**

The etiology of SUI is multifactorial. Established factors for SUI include age, obesity, pregnancy and childbirth, assisted vaginal delivery, menopause, and prior gynecological surgery (Luber, 2004). The decline in estrogen associated with menopause negatively affects muscle mass, connective tissue integrity, and urethral sphincter function (Sipilä et al., 2020). At the structural level, urethral hypermobility and excessive bladder neck descent during increases in intra-abdominal pressure are recognized morphological risk factors for SUI, and can be assessed via three-dimensional (3D) transperineal ultrasound (Dietz et al., 2002; Dietz, 2004).

Notably, EI-UI is not limited to older or parous females. High prevalence has been well documented in young, nulliparous, elite female athletes (Almousa & Bandin Van Loon, 2019;

Nygaard et al., 1994), suggesting that high-impact loading can challenge continence mechanisms independently of age- or childbirth-related pelvic floor changes. The relationship between physical activity and SUI is complex: moderate exercise may confer protective effects through pelvic floor hypertrophy, while repetitive high-impact loading may exceed the supportive capacity of the pelvic floor in susceptible individuals (Bø, 2004). Traditional risk factors for SUI do not fully account for EI-SUI in active females, highlighting the need for interventions to be tested specifically in this population.

## **2.5 Pelvic Floor Anatomy and Function During Running**

The levator ani muscles surround a central aperture, the levator hiatus, through which the urethra, vagina, and rectum pass. The size of this opening and position of the pelvic organs within it are key determinants of pelvic organ support (Bérubé & McLean, 2024; DeLancey & Ashton-Miller, 2004). 3D transperineal ultrasound imaging enables non-invasive, real-time assessment of pelvic floor morphology and is well-established for evaluating structural parameters including the levator hiatus area (LHA), levator plate length (LPL), and bladder neck height (BNH) (Dietz, 2004; Dietz et al., 2005). Imaging is performed by placing a curvilinear ultrasound transducer at the perineum, providing views of the pelvic floor in the midsagittal and transverse planes.

Following a single bout of treadmill running, significant transient changes in all three of these parameters have been observed: a larger LHA, an elongated LPL, and a more caudal bladder neck position compared to pre-run baseline measures (Bérubé & McLean, 2024). Importantly, these morphological changes were observed in all female runners regardless of continence status, suggesting that running imposes acute strain on the passive supportive tissues of the pelvic floor universally (Bérubé & McLean, 2024). Throughout this thesis, pelvic floor tissue strain refers to transient, exercise-induced lengthening of the passive pelvic floor support structures reflected by

increases in LHA and LPL and decreases in BNH. Strain in this context does not assume structural damage or injury to the tissue. The finding that PFM function, assessed via active muscle contraction, was not significantly affected after running while morphological changes were, further supports the notion that the passive supportive system, rather than muscle fatigue or weakness, may be the primary change induced during high-impact exercise.

## **2.6 Conservative Interventions for Exercise-Induced Urinary Incontinence**

Conservative treatment is the first-line approach for SUI, including PFMT, lifestyle modifications, and intravaginal devices (Dumoulin et al., 2015, 2018; Imamura et al., 2015; Nekkanti et al., 2022; Waetjen et al., 2003). Invasive surgical interventions are reserved for cases where conservative management fails (Chapple & Dmochowski, 2019; Ford et al., 2015).

Lifestyle interventions such as weight loss, fluid intake modification, and reduction of caffeinated drinks are commonly recommended for the management of UI (NICE, 2019) despite a lack of strong supporting evidence from clinical trials. A Cochrane review (Imamura et al., 2015) of randomized and quasi-randomized trials found limited evidence from 11 studies demonstrating ‘low’ to ‘very low’ quality data to suggest any significant effect of weight loss and fluid or caffeine modification on improving UI symptoms. As such, there is not enough evidence to suggest that lifestyle interventions are effective for general SUI nor EI-UI.

PFMT is the first-line non-surgical management approach for general UI (NICE, 2019), with short-term cure rates of 44-80% based on pad test outcomes of less than 2g of urine leakage (Dumoulin et al., 2018) and sustained benefits at long-term follow-up (Bø & Hilde, 2013). However, evidence supporting PFMT specifically for EI-UI in active females is limited (Petter Rodrigues et al., 2024). Randomized controlled trials in active female populations suggest that PFMT may reduce EI-UI compared to no intervention (Ferreira et al., 2014; Pires et al., 2020),

with greater benefit observed when training is supervised by a physiotherapist (Sousa et al., 2015). Nonetheless, these results should be interpreted with caution due to small sample sizes, heterogeneous methodologies, and limited reporting of exercise protocols and outcome measures (Petter Rodrigues et al., 2024).

Urethral bulking agents are another treatment option, typically reserved for individuals with moderate to severe SUI who do not improve with other conservative treatment strategies. However, these interventions are not specifically designed for the management of EI-UI. The two classes of urethral bulking agents used in the treatment of general SUI include particulate bulking agents and homogenous gel-type bulking agents. Following periurethral injection, these agents aim to increase urethral coaptation and resistance, thereby improving closure pressure and continence during rises in intra-abdominal pressure (Chapple & Dmochowski, 2019). Systematic reviews evaluating the efficacy of urethral bulking agents for the treatment of SUI in women reveal a 50% improvement rate, decreasing after long-term follow-up with frequent need for repeat injections (Capobianco et al., 2020; Hoe et al., 2021). Although not consistently reported, the reported incidence of adverse events has been variable, from less than 1% to 62.5% and include acute urinary retention, urinary tract infection, dyspareunia, and erosion of the agent through the surrounding tissue (Hoe et al., 2021).

Surgical intervention for SUI also tends to be reserved for those who do not experience successful conservative intervention. The most common surgical intervention for general SUI is the insertion of a mid-urethral sling, which involves placing a narrow 1cm strip of biocompatible mesh beneath the mid-urethra through either the retropubic or obturator space (Ford et al., 2015). Both techniques demonstrate high effectiveness, with pooled objective and subjective cure rates exceeding 80% in women with complicated or recurrent SUI (Kim et al., 2019). However, mid-

urethral sling procedures carry considerable risks. Intraoperative complications include bladder, urethral, or vaginal perforation, vascular or bowel injury, hematoma, and neurological injury (Kim et al., 2019). Postoperative complications including de novo urinary urgency, voiding dysfunction, mesh erosion, and urine retention are comparable between mid-urethral sling approaches (Kim et al., 2019). For elite athletes, surgical management is generally not recommended given the context-specific nature of symptoms (Bø, 2004). Moreover, young athletes may hesitate to undergo surgery due to postoperative recovery time, temporary or prolonged training restrictions, and the risk of complications that could interfere with sport participation. Similarly, aging athletes may be concerned about comorbidities, slower healing, or postoperative voiding dysfunction affecting daily function and quality of life. As a result, the potential trade-off between continence improvement and functional or health-related risks may reduce the appeal of surgical interventions compared with non-invasive alternatives. Accordingly, there is growing interest in conservative strategies.

Intravaginal pessaries have long been used as a conservative treatment for pelvic organ prolapse (Shah et al., 2006), and have more recently been implemented in the management of general SUI (Nygaard, 1995). Incontinence pessaries are typically silicone or rubber devices that support the urethra and bladder by increasing urethral length and resistance, supporting the bladder, and gently compressing the urethra through the anterior vaginal wall (Al-Shaikh et al., 2018; Komesu et al., 2008). While many pessaries require a burdensome fitting procedure with a health care provider, self-fitted pessaries are readily available and offer an accessible and convenient alternative. Menstrual tampons are not designed for continence support but have been studied by some researchers as an alternative to a pessary, with some evidence of effectiveness (Diez-Itza et al., 2025; Gephart et al., 2018; Nygaard, 1995).

Despite supportive evidence on the effectiveness of intravaginal devices for general SUI (Diez-Itza et al., 2025; Farrell et al., 2007; Lovatsis et al., 2017) and being recommended for use during exercise (NICE, 2019), few studies have evaluated their effectiveness specifically for EI-UI. Small intervention and repeated-measures studies suggest that both pessaries and tampons may improve EI-UI symptoms (Campbell et al., 2023; Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993). Nygaard & Zinsmeister (1993) demonstrated that women with EI-UI (n=9) who wore a Hodge pessary during their regular exercise session (running, aerobics, trampoline, walking, or golfing) had reduced urine leakage compared to no intervention. Leakage was measured using a home-based pad test, in which an absorbent pad was weighed before and after the exercise session. Similarly, Campbell et al. (2023) reported improvements in EI-UI when women (n=40) used the Uresta® self-fitted pessary during their regular exercise routines over 12 months; however, no control group was included. Two repeated-measures studies compared the effectiveness of two or more intravaginal devices to no intervention (Gephart et al., 2018; Nygaard, 1995). Nygaard (1995) used a prospective, single-blind crossover design in which women (n=18) completed three standardized 40-minute aerobics sessions wearing a Hodge pessary, a super tampon, or no device. Urine loss was quantified using via pad weight gain during the activity, and women lost significantly less urine with both devices when compared to no intervention, supporting both devices as viable non-surgical options for managing EI-UI. Using a prospective cohort design with randomized intervention order, Gephart et al. (2018) compared three intravaginal devices (tampon, a “disposable vaginal insert”, and a ring pessary) against no intervention during CrossFit exercise sets in women with SUI (n=18). Urine loss measured by pad weight gain was significantly reduced with all three devices compared to no intervention, with the vaginal insert producing the greatest reduction in urine leakage. No further pairwise comparisons

were provided. These studies provide preliminary evidence that intravaginal devices reduce EI-UI during exercise; however, both were limited by small sample sizes, neither provided detail on fitting procedures, and limited detail was provided regarding the exercise conducted by participants (Petter Rodrigues et al., 2024). Furthermore, both studies relied exclusively on pad weight gain to quantify urine leakage, a method that has since been identified as inadequate for use during exercise (Petter Rodrigues et al., 2025).

Accessible, conservative management strategies are needed for EI-UI experienced by female athletes. Current evidence suggests that intravaginal devices, including pessaries and tampons, may provide immediate mechanical support and reduce urine leakage during exercise; however, the evidence is limited by small samples, reliance on pad test outcomes, and lacks methodological clarity. Further research is needed to establish the effectiveness of these devices during exercise and to determine whether the weight of the device influences the transient strain experienced by the pelvic floor tissues.

## **2.7 Assessment of Exercise-Induced Urinary Incontinence**

When evaluating intravaginal device effectiveness, researchers have used a range of outcome measures, including pad tests, questionnaires, and voiding diaries (Avery et al., 2004; Campbell et al., 2023; Jimenez-Cidre et al., 2015; Nekkanti et al., 2022; Nygaard & Heit, 2004; Sandvik et al., 1993, 2006; Seckiner et al., 2007). However, no single measure has been established as the gold standard for assessing both acute EI-UI during a standardized exercise bout or symptom patterns over a short- or long-term follow-up period. Both assessments are critical when evaluating the effectiveness of interventions used during exercise.

### ***2.7.1 Objective Measurement of Urine Leakage During Exercise***

The pad test is one of the most widely used objective measures of urine leakage in both clinical care and research, with the 1-hour and 24-hour protocols being the most commonly implemented (Krhut et al., 2014). A 1-hour pad test is considered positive for UI if the pad weight gain exceeds 2g. However, the 1-hour pad test has low reproducibility (Lose et al., 1986) and is typically used for diagnosis of SUI rather than to assess leakage severity (Krhut et al., 2014). Furthermore, the validity of a pad test applied specifically during treadmill running is questionable due to contamination from sweat and vaginal fluids (Petter Rodrigues et al., 2025). Exercise-based pad tests have been reported as primary outcomes in several studies that have investigated conservative interventions for EI/UI (Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993). Using these tests, the distributions of pad weight gain have been reportedly wide and skewed (Nygaard & Zinsmeister, 1993), and authors have considered pad weight gains of >2g as evidence of EI/UI (dos Santos et al., 2019). When interpreting pad weight gain of the 1-hour pad test for general SUI, an increase of 1-10g is considered mild incontinence, 11-50g moderate incontinence, and >50g severe (Krhut et al., 2014). However, substantial pad weight increases have been observed in continent runners during a 37-minute treadmill running protocol, with gains approaching 20g (Petter Rodrigues et al., 2025), suggesting that pad weight gain may overestimate EI/UI during running. These limitations highlight the need to improve on the objective measures of EI/UI used to evaluate treatment outcomes.

### ***2.7.2 Subjective Assessment of Urine Leakage During Exercise***

Bladder diaries are regarded as reliable and valid tools for measuring UI symptoms in clinical and research contexts. Standardized formats, such as the 3-day International Consultation on Incontinence Questionnaire (ICIQ) bladder diary, demonstrate feasibility and reliability for

documenting voiding frequency, fluid intake, pad use, and incontinence episodes over multiple days (Jimenez-Cidre et al., 2015). However, bladder diaries are designed to capture habitual urinary patterns and day-to-day symptom variability rather than leakage occurring during a controlled, single exercise bout. As such, they are not well-suited to studies conducted in a laboratory setting.

The Incontinence Severity Index reported by Sandvik et al. (1993) is based on a bladder diary and combines leakage frequency and perceived volume. The Incontinence Severity Index has been validated against the 24-hour pad test in general SUI populations (Sandvik et al., 1993, 2006), and, while not designed for acute, exercise-specific use, modification of this questionnaire to a single exercise bout is a conceptually appropriate approach for capturing EI/UI severity over an acute bout of exercise.

### ***2.7.3 Patient-Reported Satisfaction and Improvement***

In addition to symptom quantification, patient-reported measures such as satisfaction and perception of improvement provide insight into the clinical acceptability of an intervention (Howell & Concato, 2004; Richard, 2000).

The Patient Estimated Percent Improvement (EPI) scale is a validated measure of improvement in urinary incontinence symptoms, with scores ranging from 0% (no improvement) to 100% (complete improvement), and demonstrates strong correlations with changes in the bladder diary, the Incontinence Impact Questionnaire, and patient desire for continued treatment (Burgio et al., 2006).

Similarly, the Patient Satisfaction Questionnaire (PSQ) assesses satisfaction on a three-point scale ('not at all', 'somewhat', and 'completely') and reflects patient-centered treatment success (Burgio et al., 2006).

## **2.8 Gaps in the Literature & Study Rationale**

The literature reveals several critical gaps. First, no adequately powered, randomized study has evaluated the effectiveness of intravaginal devices when used during exercise to mitigate urine leakage using outcomes beyond pad weight. Second, no study has examined whether intravaginal devices alter the transient pelvic floor morphometric changes induced by running, raising unanswered questions about device safety during high-impact exercise. Third, the self-fitted Uresta® pessary has not been evaluated against a no-device control for its effectiveness regarding the mitigation of urine leakage during exercise.

Running and brisk walking were selected as the target activities for this study given their high participation rates and associated leakage prevalence, their compatibility with standardized laboratory testing, and the absence of prior intervention research including this population specifically, which instead recruited broadly mixed or unspecific activity types.

The present study was designed to address these gaps. The primary objective was to compare EI-UI Severity Index scores during a standardized treadmill protocol across three conditions (no intravaginal support, a regular menstrual tampon, and a self-fitted Uresta® pessary) among females who report experiencing EI-UI during every bout of running or brisk walking. Secondary objectives were to (1) quantify differences in urine leakage volume across conditions using a treadmill-based pad test, (2) compare exercise-induced changes in pelvic organ support across conditions (3) evaluate participant-reported satisfaction and perceived improvement with each intravaginal device, and (4) assess short-term device adoption at a four-week follow-up.

## **Chapter 3. Effects of a Self-Fitted Pessary and Menstrual Tampon on Exercise-Induced Urinary Incontinence During Running: A Randomized Crossover Trial**

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### **3.1 Introduction**

Exercise-induced urinary incontinence (EI-UI), defined as involuntary urine loss occurring specifically during physical exercise, affects 10-80% of physically active females with higher rates for high-impact activities including running (Almousa & Bandin Van Loon, 2019; Lourenco et al., 2018; Pires et al., 2020; Teixeira et al., 2018). More than half of affected females reduce or avoid exercise as a direct consequence of urine leakage (Brennand et al., 2017; Brown & Miller, 2001), compounding the burden of an otherwise treatable condition. Despite its high prevalence and impact, there is currently limited knowledge on effective conservative interventions specifically for EI-UI, and management is largely informed from broader stress urinary incontinence (SUI) guidelines (NICE, 2019). Current clinical guidelines support supervised pelvic floor muscle training (PFMT) as first-line conservative care for SUI or mixed UI, with surgical options considered when symptoms remain bothersome despite conservative therapy (Kobashi et al., 2023; NICE, 2019; SOGC, 2006). However, the literature does not support a strong recommendation for PFMT in active females with EI-UI (Petter Rodrigues et al., 2025; Skaug et al., 2024).

Intravaginal devices, including incontinence pessaries and menstrual tampons, may mitigate EI-UI by augmenting urethral support during exercise. These devices are thought to reinforce the anterior vaginal wall, supporting urethral compression during rises in intra-abdominal pressure (DeLancey, 1994; Komesu et al., 2008). Small studies have reported reductions in pad weight gain when both pessaries and tampons are used during aerobic and CrossFit training

(Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993). However, these studies were limited by small samples, non-standardized exercise protocols, and reliance on pad weight gain as evidence of leakage, an outcome measure of questionable validity during exercise due to confounding perspiration and vaginal fluids (Petter Rodrigues et al., 2025). Whether the weight of intravaginal devices may add to the transient strain observed in the pelvic floor tissues after exercise (Bérubé & McLean, 2024) also remains unknown.

This study addressed these gaps in the literature by comparing a self-fitted Uresta® pessary and a regular menstrual tampon against a no-device control in an assessor-blind randomized crossover trial. The primary aims were to evaluate the effect of each device on EI/UI severity during a standardized treadmill protocol and to compare the effectiveness between the devices. Secondary aims were to assess differences among conditions in the extent of pad weight gain observed during exercise, the amount of exercise-induced pelvic floor tissue strain observed after running, user satisfaction and perceived improvement in symptoms with each intravaginal device, and device adoption over a four-week follow-up period.

## **3.2 Methods**

This study was registered (NCT07103161) and received approval from the University of Ottawa Research Ethics Board (H-06-22-8153). All participants provided written informed consent prior to engaging in any study activities.

### ***3.2.1 Design***

This was an assessor-blind randomized crossover trial.

### ***3.2.2 Participant Recruitment and Eligibility***

Physically active female participants  $\geq 18$  years old who regularly ran or brisk walked were recruited from the Ottawa-Gatineau region using flyers distributed across the University of Ottawa campus, physiotherapy clinics, and local running events, recruitment materials posted on social media, and word of mouth. Inclusion required self-reported urine leakage during every bout of running or brisk walking to ensure leakage would occur during the laboratory-based treadmill-exercise protocol. Brisk walking was included alongside running to broaden the eligible population, as recruitment proved to be challenging given the requirement for leakage during every exercise bout. Exclusion criteria were pregnancy or  $< 6$  months postpartum, prior incontinence surgery, urgency-predominant urinary incontinence, confounding cardiac, pulmonary, metabolic, or neurological conditions, a lower body injury limiting walking or running ability or comfort, or pain experienced with tampon use or during gynecologic examinations. Participants with a hysterectomy were not excluded as hysterectomy does not affect Uresta® pessary fitting outcomes (Farrell et al., 2007).

An a priori power calculation (G\*Power 3.1.9.6) was performed based on the within-subject study reported by Nygaard & Zinsmeister (1993), where the pad test was used as the primary outcome. An estimated minimum sample size of  $n=16$  was determined for paired comparisons between each intervention and the control (no intervention) (Cohen's  $d = 1.55$ ,  $\alpha = 0.05$ , power = 0.80). A target of  $n=30$  was set to account for comparisons between the tampon and the pessary intervention.

### ***3.2.3 Interventions***

Pessary: A Uresta® Bladder Support Starter Kit (sizes 2-6) was provided to participants, with written instructions on how to self-fit the device at home or in the laboratory. Proper fit was

defined as the device being pain-free and unnoticeable once inserted. A pelvic health physiotherapist with pessary fitting experience was available for participants to consult at any point while they were self-fitting the device. Prior to using the pessary in the laboratory-based session, participants completed jumping jacks, body weight squats, and two-legged hops to confirm device position and sizing. The most common fit was size 4 (50.0%, n = 13), followed by size 5 (26.9%, n = 7), size 3 (15.4%, n = 4), and size 6 (7.7%, n = 2).

Tampon: A Playtex Sport® regular tampon was provided to the participant to insert into their vagina using the applicator provided.

### ***3.2.4 Laboratory Protocol***

Participants were instructed to follow the same preparation instructions prior to each of three laboratory visits: to refrain from moderate-to-vigorous physical activity on the day of testing; to avoid caffeine for at least three hours prior to the visit; to void their bladder one hour prior to their scheduled visit and to consume 200mL of water after voiding.

Participants attended three laboratory-based visits (Figure 1), completing the protocol with no device first (visit 1), then with the pessary and the tampon in randomized order (visits 2-3) via coin-toss allocation. Participants with regular menstrual cycles completed all three visits within the first ten days of their menstrual cycle. Those who were postmenopausal or amenorrheic completed all three visits within a 10-day timeframe. All visits followed the same protocol (Figure 2), except for the intervention worn during running.

Pre-exercise bladder volume was standardized to 100-200mL and estimated with the participant supine using 3D transabdominal ultrasound (GE Voluson S6; RAB6-RS curvilinear transducer, GE Healthcare, Toronto, Canada). Next, with the participant in quiet standing, the assessor acquired three 3D transperineal ultrasound images, adjusting the probe to view the

symphysis pubis, urethra, bladder neck, bladder, and anorectal angle, with a single focal point located at the level of the anorectal junction following the protocol described by Bérubé et al. (2025).

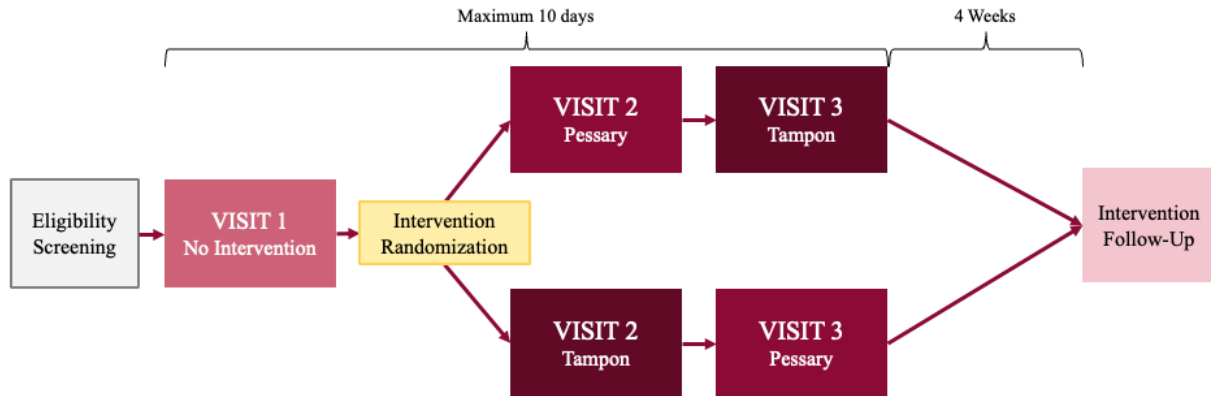
Following the pre-exercise ultrasonography, participants removed residual ultrasound gel from the perineal area, changed into athletic clothing and footwear, removed a pre-weighed absorbent pad from a paper bag and adhered it to their undergarment, and fastened a Fitbit® device to their wrist. Prior to the exercise session in visit 2, a research assistant performed a coin flip to determine the order of intervention assignment for visits 2 and 3, with each intravaginal device (tampon and pessary) assigned to one side of the coin.

Participants completed a 38-minute standardized protocol on a NordicTrack Commercial 2450 treadmill, adapted from Bérubé and McLean (2024), comprising a 6-minute warm-up, a 30-minute run, and a 2-minute cool-down.

The warm-up included increasing the belt speed by a minimum of 1km/hr every 2 minutes until the participant reached a belt speed that was at least 6 km/h and at which they reported it to be “somewhat hard” on the Borg Rate of Perceived Exertion (RPE) scale. The 30-minute run began at this point and included a 25-minute steady-state run/brisk walk at this pace, followed by a 5-minute challenge (Figure 2). The challenge began at minute 25, where participants were asked to increase their speed to reach a rating of ‘very hard’ (Borg RPE = 17) for the final 5-minutes of the run. The Borg RPE scale was selected to standardize exertion given its high correlation with heart rate during treadmill running and walking (Dias et al., 2014). Further, participants who reported typically experiencing urine leakage when walking/running on an incline or decline were instructed to adjust the treadmill gradient accordingly, and this was recorded such that the same gradient was used at all three visits.

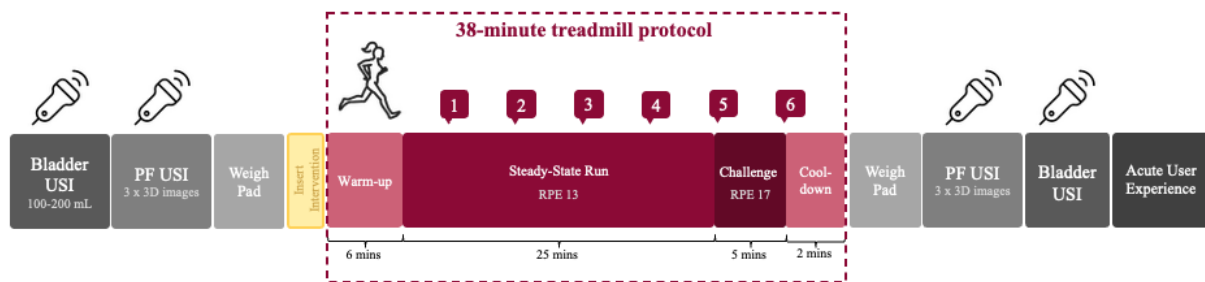
Throughout the 30-minute monitored run, a research assistant asked participants every 5 minutes to confirm their Borg RPE and to report whether they experienced any urine leakage in the previous 5-minute interval, recording yes (1) or no (0). If yes, participants described the amount of urine loss as ‘drops’ (1), ‘squirts’ (2), or a ‘gush or more’ (3) (adapted from Sandvik et al., 1993, 2006). Following the 30-minute run, participants reduced their speed to a slow jog or walk for a 2-minute cool-down period. The research assistant obtained the total step count and average heart rate from the Fitbit.

As quickly as possible after the cool-down, the participant returned to the assessment room, removed the pad and placed it back in the paper bag for weighing, changed out of their athletic clothing and donned the gown, refraining from sitting throughout. During visits 2 and 3, participants also removed the assigned device (tampon or pessary) at this time. Used tampons were placed in the garbage and covered while pessaries were returned to the participant’s belongings to keep the assessor blinded to the intervention. A research assistant weighed the pad in the paper bag. Participants then rated their satisfaction and perceived improvement with the respective device on a scale of 0% (not at all satisfied/no improvement) to 100% (completely satisfied/completely improved). The participant indicated whether they intended to use the device at home (yes / no). The assessor returned to the assessment room to repeat the transperineal and transabdominal ultrasonography. After the third laboratory visit, participants received no specific instructions regarding future use of either device but were sent home with the Uresta® pessary and a supply of tampons.



**Figure 1.** Participation timeline.

Visit 1 was the no-intervention control, while visits 2 and 3 involved running with a tampon and pessary in randomized order. The 4-week follow-up included the intervention follow-up questionnaire.



**Figure 2.** Laboratory visit protocol.

Sequence of assessments completed at each laboratory visit, including transabdominal ultrasound imaging (USI) for bladder volume standardization between 100-200mL, transperineal USI to assess pelvic floor morphology, a 38-minute standardized treadmill protocol, and repeated post-run imaging. The treadmill protocol consisted of a 6-minute warm-up, a 30-minute leakage-monitored run, and a 2-minute cool-down. Leakage was reported every 5-minutes during the 30-minute run. Satisfaction and perceived improvement were recorded after intervention visits.

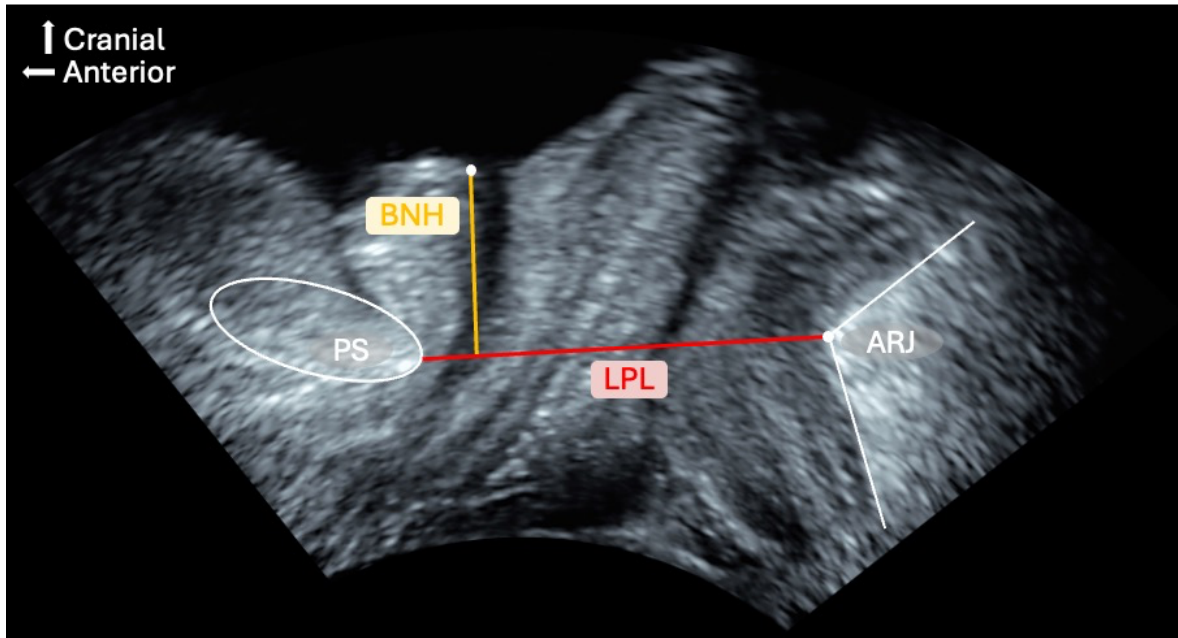
### 3.2.5 Four-Week Follow-Up Assessment

Four weeks after the third laboratory visit, participants completed an intervention follow-up questionnaire (Appendix A) assessing tampon and/or pessary use during their exercise routines over four weeks post-participation. Several questions assessing the user's experience with the device were asked.

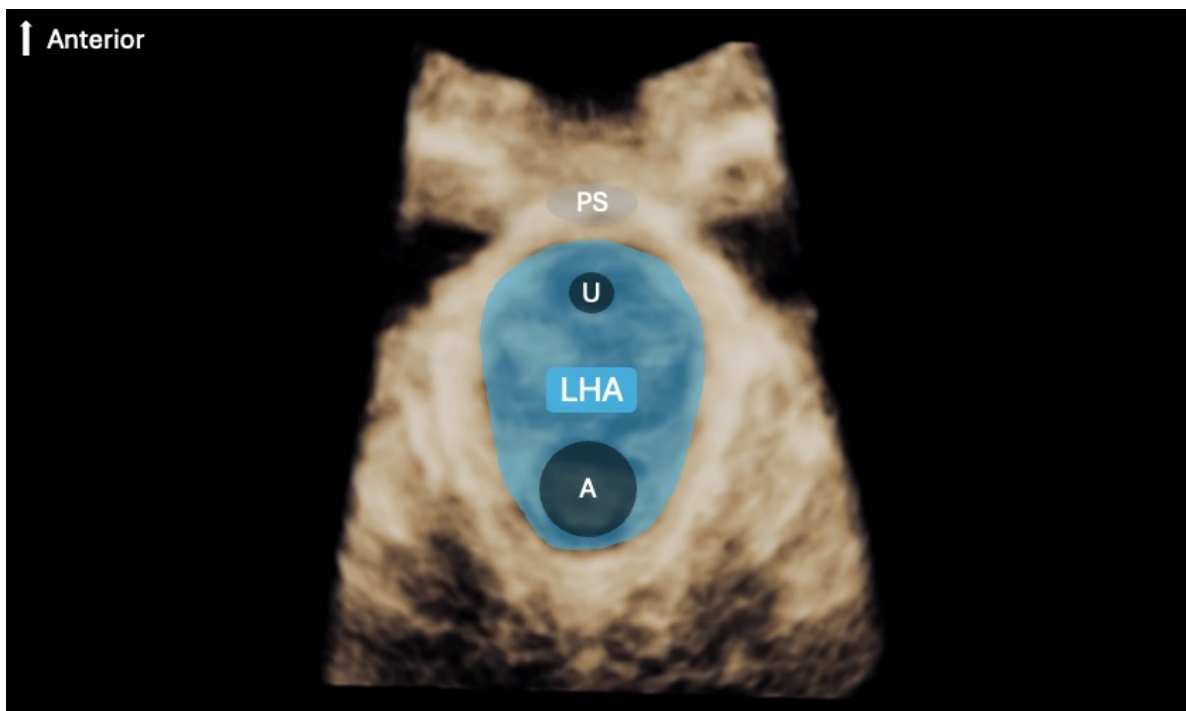
### ***3.2.6 Ultrasound Image Processing***

All 3D transperineal ultrasound images were processed offline using 4DView software (GE Healthcare Canada Inc, Mississauga, ON, Canada). Each 3D image was manipulated to obtain the optimal 2D plane, defined as the plane of minimal hiatal dimension, allowing clear visualization of the anatomical landmarks required for each measurement, following standardized approaches (Dietz et al., 2005).

In the midsagittal plane (Figure 3), the levator plate length (LPL) was measured as the linear distance between the hyperechoic posterior border of the symphysis pubis and the hyperechoic anorectal junction (Dietz et al., 2005). In the same plane, bladder neck height (BNH) was measured as the orthogonal distance from the anterior margin of the bladder neck to the levator plate line (Brooks et al., 2021). The levator hiatus area (LHA) was obtained in the plane of minimal hiatal dimensions (Figure 4) by placing the axis of rotation at the inferoposterior margin of the symphysis pubis and rotating the midsagittal plane image until the levator hiatus was observed in the transverse plane. A rendered volume of 5 mm thickness was used to obtain the dimensions of the levator hiatus (Dietz et al., 2011).



**Figure 3.** Midsagittal transperineal ultrasound image. Image acquired in standing. Linear measurements are displayed: levator plate length (LPL) in red and bladder neck height (BNH) in yellow. ARJ, anorectal junction; PS, pubic symphysis.



**Figure 4.** Transverse transperineal ultrasound image. Image acquired in standing. The levator hiatus area (LHA) in blue was acquired in the plane of minimal hiatal dimensions. A, anal canal; U, urethra; PS, pubic symphysis.

This measurement process was repeated for each of the three 3D images obtained at each time point (before and after running) at all three visits (no device, tampon, pessary). The mean of each variable (LPL, BNH, LHA) at each time point (pre- and post-running) was retained for statistical analysis. These averaged values were used to compare pelvic floor morphometry before and after running within each condition and determine whether the magnitude of the change differed across conditions.

### 3.2.7 Outcome Measures

The primary outcome measure was the EI-UI Severity Index. This measure is conceptually consistent with the validated Incontinence Severity Index in which leakage frequency and amount reported using a bladder diary are multiplied to quantify symptom severity (Sandvik et al., 2006). For each treadmill session, the EI-UI Severity Index score was calculated by multiplying the proportion of 5-minute intervals with reported leakage (i.e., the number of intervals with leakage divided by 6) by the median leakage amount across all intervals, rated on a three-point scale: drop(s) = 1, squirt(s) = 2, or more/gush = 3 (Table 1). Scores ranged from 0 to 3, with the maximum score reflecting a report of more/gush leakage in all 6 intervals.

**Table 1.** EI-UI Severity Index assessment items.

Items administered every 5-minutes during the 30-minute leakage-monitored portion (25-minute steady-state run and a 5-minute challenge phase) of the 38-minute treadmill protocol. Verbal responses of leakage frequency and volume were used to derive the EI-UI Severity Index score for each exercise bout.

|                                                                     |              |
|---------------------------------------------------------------------|--------------|
| (1) In the previous five minutes, did you experience urine leakage? |              |
| 1                                                                   | Yes          |
| 2                                                                   | No           |
| (2) How much urine did you lose?                                    |              |
| 1                                                                   | Drops        |
| 2                                                                   | Squirts      |
| 3                                                                   | More or Gush |

Secondary outcome measures included (1) pad weight gain; (2) exercise-induced changes in pelvic floor morphometry (LPL, BNH, LHA); (3) participant reported satisfaction and perception of improvement (0-100%) with each intravaginal device, and (4) predicted and actual device use after a 4-week period, along with user experience across four domains. These domains include clinical effectiveness (perceived EI-UI reduction), usability (insertion ease, removal ease, and voiding ability), tolerability (comfort and absence of bleeding/discharge), and acceptability (satisfaction and intent to continue use).

Pad weight gain accrued during the standardized treadmill protocol under each study condition was calculated as post-exercise minus pre-exercise pad weight. Although the pad test has questionable validity for use during exercise protocols (Petter Rodrigues et al., 2025), it is the current gold standard measure of severity for general SUI (Krhut et al., 2014) and has been used in other studies, thus serves as a basis for comparison to the literature (Campbell et al., 2023; Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993).

Exercise-induced changes in pelvic organ support were assessed via 3D B-mode transperineal ultrasound imaging acquired before and after each exercise bout following the protocol described by Bérubé et al. (2025). Three morphological variables were assessed: LPL, BNH, LHA, each measured using standardized, valid, and reliable methods (Dietz et al., 2002, 2005; Majida et al., 2010; Shek & Dietz, 2008). All ultrasound imaging was performed by two assessors: a pelvic health physiotherapist with over five years of clinical experience and more than two years of experience using transperineal ultrasound imaging, and the primary author, who completed six months of supervised training under this physiotherapist prior to conducting imaging independently. The same assessor performed all ultrasound imaging across the three visits attended by a given participant. As all comparisons were made within participants across

conditions, and intra-rater reliability of transperineal ultrasound of pelvic floor morphometry is well-established (Shek & Dietz, 2008), measurement consistency across operators was not expected to meaningfully affect the findings.

Participant-reported satisfaction and perceived improvement with each intravaginal device were acquired immediately following the exercise bout using a scale ranging from 0% (not at all satisfied/no improvement) to 100% (completely satisfied/completely improved). Following visits 2 and 3, participants were also asked to report whether they predicted using the device as a means of managing EI/UI in the future (yes/no).

Short-term device use and metrics of user experience following participation were assessed through a custom online questionnaire (Appendix A). The questionnaire assessed frequency of device use (pessary, tampon, both, or neither) during exercise over the 4-week period following their third laboratory visit. Satisfaction with the device, perceived improvement in urinary symptoms during running/brisk walking, device comfort, ease of insertion and removal, and intention to continue using the device were each rated on a visual analogue scale from 0 to 100%, where 0 represented the worst and 100 the best possible experience.

### ***3.2.8 Statistical Analysis***

All statistical analyses were conducted using R version 4.4.2 (R Foundation for Statistical Computing, Vienna, Austria), with  $\alpha = 0.05$ . Descriptive statistics are reported as mean and standard deviation or frequencies and proportions. Running parameters (speed, time, and distance) and bladder volume were each examined using linear mixed-effects models (LMEM) to confirm standardization across conditions. Sensitivity analyses were conducted to determine whether visit order influenced EI/UI Severity Index or pad weight gain. For each outcome, a base linear mixed effect model including intervention condition was compared with a second model that also

included visit order as a covariate. Likelihood ratio tests were used to determine whether adding visit order improved model fit.

EI-UI Severity Index scores were right-skewed and thus square root transformed to achieve a normal distribution prior to analysis using a LMEM with intervention condition as a fixed effect and participant ID as a random intercept. Similarly, pad weight gain distribution was right-skewed and thus log-transformed with confirmed normality prior to analysis using the same LMEM structure. Back-transformed estimated marginal means (EMMs) for EI-UI Severity Index scores and pad weight gain was conducted for reporting. Effect sizes for all LMEMs are reported as partial eta-squared ( $\eta^2_p$ ). The association between EI-UI Severity Index and pad weight gain was examined using Spearman rank correlations stratified by intervention condition. Satisfaction and perceived improvement ratings were compared between tampon and pessary conditions using paired Wilcoxon signed-rank tests with effect sizes reported as rank-biserial correlations.

Pelvic floor morphometry outcomes were analyzed using LMEMs with timepoint (pre-run, post-run), intervention condition, and their interaction as fixed effects and participant ID as a random intercept. Pairwise comparisons between intervention conditions used Tukey adjustment.

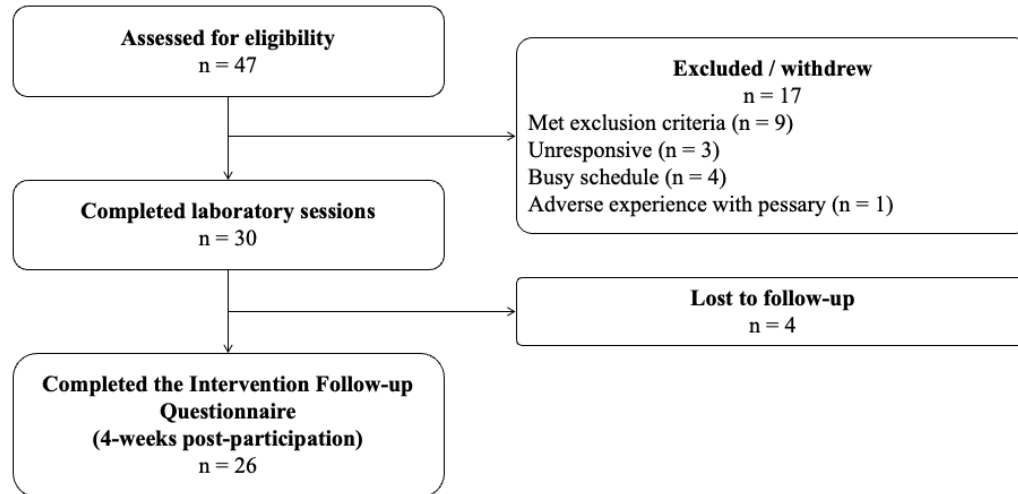
Predicted device use was modelled using a binomial logistic regression with intervention condition as the sole predictor. A mixed-effects structure was initially specified with a random intercept for participant ID; however, the random effect variance was estimated at zero (singular fit), and the model was refitted as a standard general linear model. Odds ratios and 95% confidence intervals were obtained. Actual device use was modelled using the same approach, with intervention condition as the sole predictor. The influence of EI-UI Severity Index and pad weight gain on predicted and actual device use was further examined using separate binomial generalized linear models, stratified by intervention condition.

Device adoption was additionally summarized descriptively as the proportion of participants reporting pessary use, tampon use, or no device use during the 4-week follow-up period. Among device adopters, user experience domain items (clinical effectiveness, usability, tolerability, and acceptability) rated on a 0-100% visual analogue scale, were summarized as median and interquartile range.

### **3.3 Results**

#### ***3.3.1 Sample Demographics***

Of 47 individuals who completed the eligibility screening, 17 declined participation or were deemed ineligible (Figure 5). One participant withdrew after experiencing mild vaginal bleeding during pessary self-fitting, prior to completing the laboratory running trials. Given this adverse experience, the study assessor and participant agreed it was appropriate to prioritize care for vaginal dryness and withdraw from the study. Thirty participants completed all three laboratory sessions, and 26 participants completed the 4-week Intervention Follow-up questionnaire. Participant characteristics are summarized in Table 2. The sample had a mean (standard deviation, SD) age of 46 (10) years and a mean (SD) BMI of 23.3 (2.8) kg/m<sup>2</sup>. Eighty percent of participants were parous, and one-third of participants were in menopause. Two participants who reported no leakage during the no-intervention visit were excluded from the EI-UI Severity Index, pad weight gain, and satisfaction and perceived improvement outcome measures. Four participants with insufficient ultrasound image quality were excluded from morphometry analyses.



**Figure 5.** Participant flow diagram.

**Table 2.** Baseline demographic and obstetric characteristics of participants enrolled.

|                                   | Mean / n | SD / % |
|-----------------------------------|----------|--------|
| Age, years (mean, SD)             | 46       | 10     |
| BMI, kg/m <sup>2</sup> (mean, SD) | 23.3     | 2.8    |
| Parous (n, %)                     | 24       | 80%    |
| Parity (mean, SD)                 | 1.6      | 1.0    |
| Forceps (n, %)                    | 5        | 16.7%  |
| Suction (n, %)                    | 4        | 13.3%  |
| Menopause                         | 10       | 33%    |

*BMI* body mass index, *SD* standard deviation

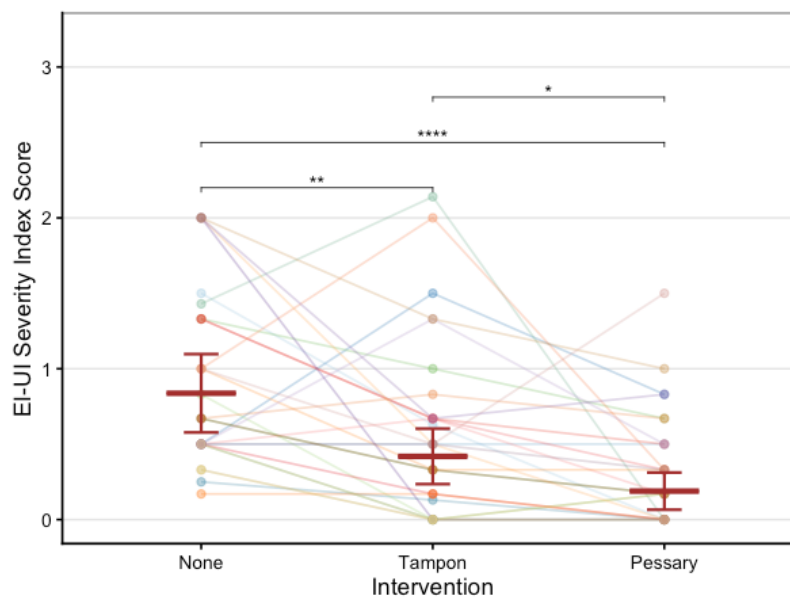
### 3.3.2 Protocol Standardization: Exercise Performance and Bladder Volume

Exercise performance was consistent across conditions. Median running distance was 4.09 km (IQR = 0.81) with a median speed of 8.00 km/hour (IQR = 2.30). No significant differences across conditions were observed in distance or speed ( $p > 0.14$ ). Pre- and post-run bladder volumes were comparable across the control, pessary, and tampon conditions (Table B1; Appendix B), with no significant differences observed for either pre-run bladder volume,  $F(2, 87) = 0.29$ ,  $p = 0.748$ ,

partial  $\eta^2 = 0.007$ , or post-run bladder volume,  $F(2, 43.1) = 0.38, p = 0.683$ , partial  $\eta^2 = 0.02$ . These findings confirm that bladder filling state was standardized across conditions and did not confound EI-UI outcomes.

### 3.3.3 EI-UI Severity Index

EI-UI Severity Index scores differed significantly across intervention conditions ( $F(2, 54) = 17.97, p < 0.001, \eta^2p = 0.40$ ). Post-hoc comparisons revealed that EI-UI Severity Index scores were significantly lower with both the pessary ( $d = 1.6, p < 0.001$ ) and the tampon ( $d = 0.89, p = 0.005$ ) compared with no device. The pessary also produced significantly lower EI-UI Severity Index scores than the tampon ( $d = 0.71, p = 0.035$ ; Figure 6). Back-transformed estimated marginal means are reported in Table B1 (Appendix B). Running speed did not significantly predict EI-UI Severity Index ( $F(1, 27.66) = 0.89, p = 0.355, \eta^2p = 0.03$ ) nor did it interact with intervention condition ( $F(2, 52.25) = 0.30, p = 0.742, \eta^2p = 0.01$ ), indicating that the effect of intervention on EI-UI Severity Index was robust across the range of exercise speeds observed in this sample.

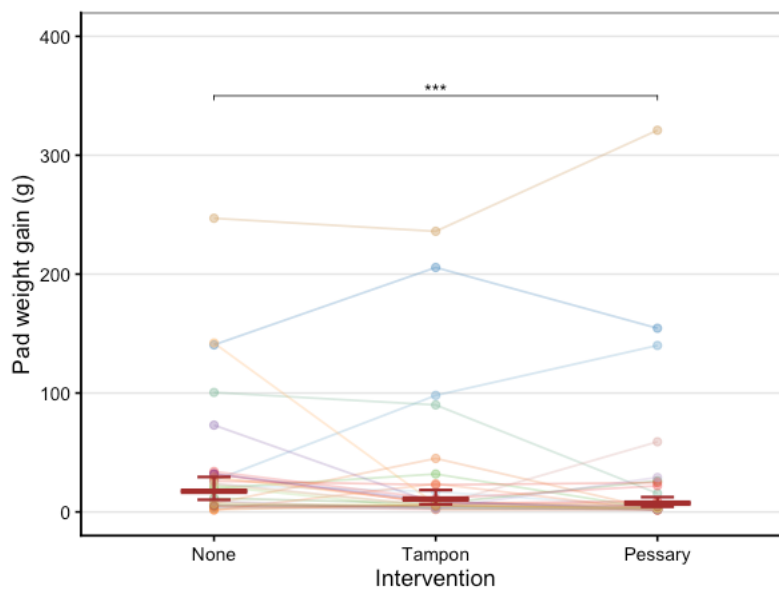


**Figure 6.** EI-UI Severity Index scores across intervention conditions.

Individual and mean EI-UI Severity Index scores for the no-intervention, tampon, and pessary conditions in female recreational runners or brisk walkers ( $n = 28$ ). Coloured lines represent individual participant scores. Dark red horizontal and vertical lines indicate estimated marginal means  $\pm$  95% confidence intervals back-transformed from the square root transformation. \*Statistically significant difference between interventions ( $p < 0.05$ ). \*\*\*Statistically significant difference between interventions ( $p < 0.001$ ). \*\*\*\*Statistically significant difference between interventions ( $p < 0.0001$ ).

### 3.3.4 Pad Weight Gain

Pad weight gain differed significantly across intervention conditions ( $F(2, 54) = 6.41, p = 0.003, \eta^2p = 0.19$ ). Post-hoc comparisons revealed that pad weight gain was significantly lower with the pessary than with no device ( $d = 0.96, p = 0.002$ ). The tampon did not differ significantly from either no device ( $d = 0.52, p = 0.133$ ) or the pessary ( $d = 0.43, p = 0.246$ ). Back-transformed estimated marginal means are reported in Table B1; Appendix B.



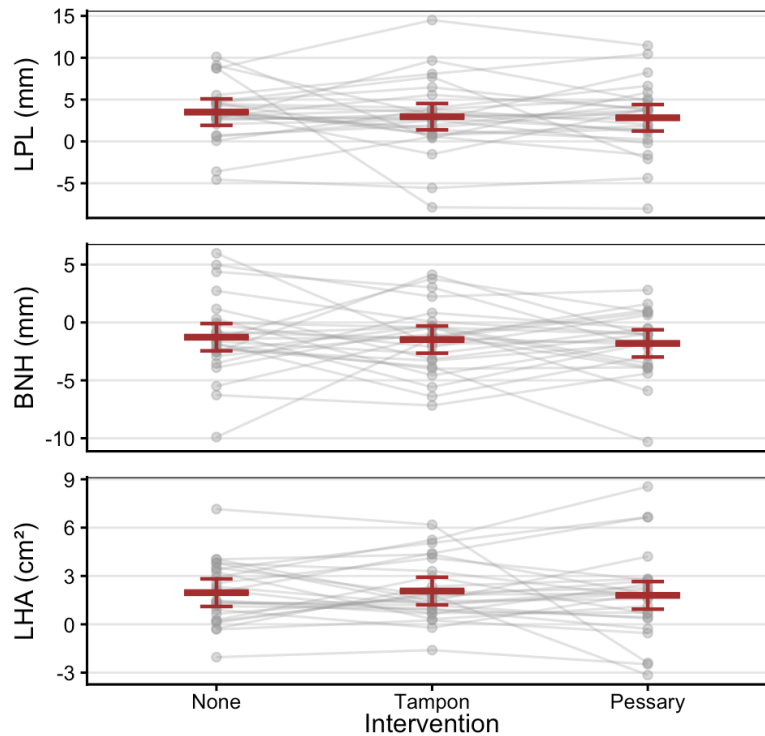
**Figure 7.** Pad weight gain across intervention conditions.

Individual and mean pad weight gain (g) for the no-intervention, tampon, and pessary conditions in female recreational runners ( $n = 28$ ). Coloured lines represent individual participant trajectories. Dark red horizontal and vertical lines indicate estimated marginal means  $\pm$  95% confidence intervals back-transformed from the log scale. \*\*\*Statistically significant difference between interventions ( $p < 0.001$ ).

Significant positive correlations between EI-UI Severity Index scores and pad weight gain were observed across all three conditions ( $p < 0.05$ ), indicating moderate agreement between subjective and objective assessment methods regardless of device use (no device:  $\rho = 0.61$ ; tampon:  $\rho = 0.55$ ; pessary:  $\rho = 0.41$ ).

### ***3.3.5 Pelvic Floor Morphometry***

Running produced significant pre- to post-run changes in all three morphometric variables (all  $p < 0.001$ ; Table B3; Appendix B). In all conditions, LHA and LPL increased, while BNH decreased. There was no significant effect of intervention on the magnitude of these pre- to post-run changes for any morphometric variable (all  $p > 0.65$ ; Figure 8).



**Figure 8.** Changes in pelvic floor morphometric outcomes across intervention conditions. Changes in levator plate length (LPL), bladder neck height (BNH), and levator hiatus area (LHA) from before to after running, shown for the no-intervention, tampon, and pessary conditions ( $n = 26$ ). Grey points and lines represent individual participant observations. Dark red lines and error bars indicate estimated marginal means  $\pm$  95% confidence intervals derived from the linear mixed-effects models.

### 3.3.6 Participant Reported Satisfaction and Perceived Improvement

Satisfaction scores tended to be higher in the pessary condition than the tampon condition, although this difference was not statistically significant ( $p = 0.224$ ,  $r = 0.25$ ; Table B2; Appendix B). Perceived improvement followed a similar pattern, with participants tending to rate the pessary more favourably, though this was also not significant ( $p = 0.067$ ,  $r = 0.38$ ).

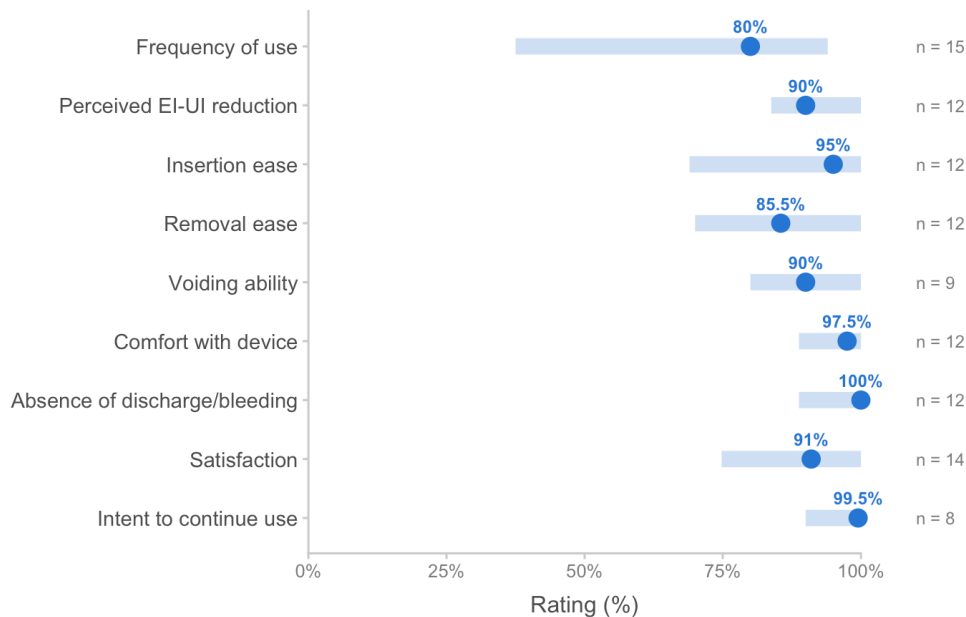
### 3.3.7 Predicted and Actual Device Use

Participants were significantly more likely to anticipate future use of the pessary (83%) than the tampon (50%; OR = 5.00,  $p = 0.008$ ; Table 4). Greater EI-UI Severity Index scores and

pad weight gain with the tampon were each associated with lower odds of predicting future tampon use (both  $p < 0.05$ ). No equivalent associations were observed for the pessary. Actual pessary use over the 4-week follow-up was significantly higher than actual tampon use (58% vs. 12%; OR = 10.45,  $p = 0.001$ ; Table B2; Appendix B).

### 3.3.8 User Experience with the Pessary

Twenty-six participants completed the 4-week Intervention Follow-Up Questionnaire, though response rates varied across individual items. Of these respondents, 15 (57.7%) reported using the pessary at least once during the follow-up, compared to three (11.5%) who used the tampon. Eight participants (30.8%) reported using no device, and none reported using both devices (see Table B4, Appendix B). Among the 15 participants who used the pessary, ratings across most domains were high with narrow IQRs as presented in Figure 9.



**Figure 9.** Pessary user experience outcomes at four-week follow-up.

User experience ratings among pessary adopters across clinical effectiveness, usability, tolerability, and acceptability domains assessed using visual analogue scales (0–100%). Points indicate medians; horizontal bars indicate interquartile ranges. Sample sizes vary by outcome ( $n = 8–15$ ) due to missing responses.

## 3.4 Discussion

### 3.4.1 *Summary of Findings*

This assessor-blind randomized crossover trial demonstrates that both a self-fitted Uresta® pessary and a regular menstrual tampon reduce EI-UI Severity Index during standardized treadmill running/brisk walking compared with no device. The pessary produced a greater reduction in EI-UI Severity Index scores and was the only device to significantly reduce pad weight gain relative to no device. While device satisfaction and perceived improvement tended to favour the pessary, this finding was not statistically significant. The pessary was associated with higher predicted and actual device use than the tampon at the four-week follow-up. Neither device altered the magnitude of exercise-induced pelvic floor morphometric changes, indicating that using these devices during an acute exercise bout does not add measurable pelvic floor tissue strain beyond that produced by running without a device.

### 3.4.2 *Clinical Implications of the Findings*

The primary finding supports intravaginal devices as immediately effective, self-administered strategies for active females who leak urine during running. Both devices produced meaningful reductions in the EI-UI Severity Index, with large effect sizes relative to no device (pessary:  $d = 1.6$ ; tampon:  $d = 0.89$ ), yet the pessary outperformed the tampon ( $d = 0.71$ ). This pattern is consistent with the proposed role of intravaginal pessary support in augmenting urethral compression during rises in intra-abdominal pressure (DeLancey, 1994; Komesu et al., 2008), though the mechanism by which either device reduces leakage during running was not directly assessed and cannot be established from the present data. Moreover, the degree to which device geometry, material stiffness, and vaginal positioning influence the magnitude of urethral support

remains unknown and warrants investigation through dynamic imaging studies and comparative device trials.

While the pessary appears to be the superior option on average, some individuals responded well to the tampon. However, these findings are limited to acute device use and cannot speak to long-term effectiveness, adherence, or adverse events. In particular, the impact of repeatedly using a “dry tampon” on the vaginal mucosa is unknown, and this approach is therefore not currently recommended.

Although only one adverse event occurred during the study, it highlights the importance of considering vaginal tissue health when recommending intravaginal continence devices. Peri- and post-menopausal females and others with symptoms of vaginal atrophy may require additional counselling regarding device use, and current pessary management guidelines recommend considering vaginal estrogen in women with vaginal atrophy to improve vaginal tissue health and reduce pessary-related complications (Harvey et al., 2021). Because the present study evaluated self-fitted pessaries, clear instructions regarding device selection, insertion, and circumstances warranting discontinuation (e.g., pain or vaginal bleeding) should accompany device use. Despite this isolated event, both devices were generally well tolerated during acute laboratory use, with high participant acceptance and greater real-world adoption of the pessary over the four-week follow-up.

The findings of this study are generalizable to recreational runners and brisk walkers with EI/UI during every single exercise bout and without pelvic organ prolapse. Results with intravaginal devices are only applicable to the Uresta® pessary and/or a regular Sportex® menstrual tampon. Results are consistent across all ages, parity, whether nulliparous or parous, and BMI.

### ***3.4.3 Effectiveness of Intravaginal Devices in Reducing Leakage***

Most prior research has used an exercise-based pad test to evaluate the effectiveness of a pessary or a tampon to mitigate urine leakage. The findings of this study align with and extend the evidence suggesting that intravaginal devices reduce urine leakage during exercise. Nygaard and Zinsmeister (1993) first reported reduced pad weight gain with a Hodge pessary compared to no device during a variety of non-standardized exercises in a small within-subject study ( $n = 9$ ). Nygaard (1995) subsequently demonstrated that both the Hodge pessary and a tampon significantly reduced pad weight gain during a 40-minute standardized aerobics session ( $n = 18$ ). Similarly, Gephart et al. (2018) reported reduced pad weight gain during CrossFit exercises with a pessary, a vaginal insert, and a tampon ( $n = 18$ ). The consensus across all studies is that relative to no intervention, the use of an intravaginal device improved urine leakage during exercise, confirmed by decreased pad weight gain relative to no intervention.

Unlike prior studies that reported reduced pad weight gain with tampon use (Gephart et al., 2018; Nygaard, 1995), the tampon did not significantly reduce pad weight gain in the present study, although the direction of effect was consistent with prior findings.

### ***3.4.4 Pelvic Floor Morphometry***

A single bout of treadmill running produced consistent pre- to post-run increases in LHA and LPL and decreases in BNH across all conditions, replicating prior findings of transient pelvic floor tissue strain during running (Bérubé & McLean, 2024). Neither device modified these morphometric changes, suggesting that acute use of an intravaginal device during running does not increase the magnitude of pelvic floor tissue strain. Whether repeated or prolonged use affects pelvic floor tissues over time remains unknown.

### ***3.4.5 Patient-Reported Outcomes and Device Adoption***

Beyond leakage reduction, real-world uptake is essential to evaluating the clinical utility of any conservative intervention. Satisfaction and perceived improvement ratings exceeded 65% for both devices, consistent with prior reports (Gephart et al., 2018). Predicted future pessary use (83%) exceeded predicted tampon use (50%), and this disparity was amplified in actual use assessed at the four-week follow-up (pessary: 58%; tampon: 12%). The gap between predicted and actual tampon use suggests that despite acute effectiveness in the laboratory, the tampon may be perceived as a less desirable and/or less effective option. Among pessary adopters, user experience ratings were consistently high across most domains though frequency of use varied. The rate of actual pessary use in the absence of any post-study instruction compares favourably with Farrell et al. (2007), who reported 90% continued Uresta® use at three months among women with SUI, and with Campbell et al. (2023), who found high satisfaction and adherence to pessary use among active women. However, discrepancies may suggest that acute effectiveness does not consistently translate to habitual use, and that factors beyond leakage, such as use burden, may influence whether a device is consistently adopted into exercise routines.

### ***3.4.6 Strengths and Limitations***

Key strengths include the randomized crossover design, the standardized treadmill protocol, bladder volume standardization, and the use of both objective and subjective leakage outcomes alongside measures of real-world device adoption. These features address methodological limitations seen in prior studies.

Despite its strengths, this study has limitations. The findings are restricted to a single treadmill-based running/brisk walking session, which may not capture the full range of leakage triggers experienced during real-world running. Indeed, two participants did not leak during the

baseline visit despite habitually reporting leakage on every run, illustrating the challenge of reproducing EI/UI under controlled conditions. The findings of this work are specific to the Uresta® pessary and may not be generalizable to other pessary designs. Moreover, it cannot be assumed that the Uresta® is the best pessary for all females with EI/UI. Outcomes may be improved with a fitted pessary, especially among those who experienced discomfort or a lack of EI/UI reduction with the Uresta® pessary.

The absence of a validated exercise-specific UI measure is a recognized limitation in this study and in the field. The EI/UI Severity Index is conceptually consistent with the Incontinence Severity Index and has been validated for the assessment of generalized SUI (Sandvik et al., 1993, 2006), but it has not been validated for the assessment of SUI during an exercise bout. Similarly, the pad test has been validated for generalized SUI (Krhut et al., 2014; Lose et al., 1986) but its validity during aerobic exercise is questionable due to contamination from sweat and vaginal fluids (Petter Rodrigues et al., 2025), despite being widely implemented in EI/UI research (Farrell et al., 2007; Gephart et al., 2018; Lovatsis et al., 2017; Nygaard, 1995; Nygaard & Zinsmeister, 1993). Since neither measure has been independently validated for use during exercise, we included both the EI/UI Severity Index and pad weight gain as complementary subjective and objective outcomes, respectively, to provide a more complete characterization of EI/UI. To our knowledge, these two measures have not previously been assessed concurrently in an interventional study of EI/UI.

EI/UI Severity Index scores and pad weight gain were significantly correlated across all three conditions, providing evidence of convergent validity between the two outcomes. However, this association was weaker when intravaginal devices were used, which may reflect a genuine

discrepancy between perceived and objective urine leakage with device use, or may reflect the confounding effects of perspiration and vaginal secretions on a pad when used during exercise.

The four-week follow-up provides useful insight into expected adoption rates but is considered exploratory given the limited sample.

### **3.5 Conclusions**

Both the Uresta® pessary and a regular menstrual tampon significantly reduced EI-UI Severity Index scores during treadmill running, with the pessary producing superior reductions in severity and higher rates of real-world adoption over four weeks. Neither device increased the magnitude of exercise-induced pelvic floor tissue strain. These findings support intravaginal support devices as acute, self-administered conservative options for active females seeking to self-manage EI-UI during running. Further, this study provides the foundational evidence needed to justify a longer-term randomized controlled trial examining the effectiveness of these interventions.

## **Chapter 4. Discussion**

### **4.1 Overview**

EI-UI is a prevalent and under-managed condition in physically active females, yet the evidence base for conservative interventions developed specifically for this population remains limited. This study is the first randomized crossover trial to compare a self-fitted incontinence pessary and a menstrual tampon against a no-device control in female recreational runners/brisk walkers during a standardized treadmill protocol with leakage severity and volume measurement, concurrent pelvic floor morphometry, as well as a four-week real-world follow-up. This chapter expands on the findings presented in Chapter 3, situating them within the broader EI-UI literature, examining the measurement and mechanistic dimensions of the results, and discussing their clinical implications and directions for future work.

### **4.2 Comparison with Prior Work**

Prior to the present study, evidence supporting intravaginal devices for the management of EI-UI was favourable but limited to three small studies (Gephart et al., 2018; Nygaard, 1995; Nygaard & Zinsmeister, 1993). Across these studies, pad weight gain was the sole outcome measure, exercise protocols and bladder volume were not standardized, and samples were small. The present study addresses each of these limitations while testing the effectiveness of the Uresta® self-fitted pessary.

The finding that both devices significantly reduced EI-UI severity relative to no device is broadly consistent with the earlier literature and extends it in several meaningful ways. Most notably, the use of participant-reported EI-UI severity as the primary outcome rather than pad weight gain alone captures the leakage experience from the participant's perspective, which is

arguably the most clinically relevant dimension of EI-UI management, since shame and embarrassment are critical barriers to exercise (Cheater & Castleden, 2000). Both devices produced large reductions in EI-UI Severity Index scores relative to no device (pessary:  $d = 1.6$ ; tampon:  $d = 0.89$ ), and the pessary was superior to the tampon ( $d = 0.71$ ) – this is a novel finding that earlier studies did not detect.

The pessary also significantly reduced pad weight gain relative to no device, consistent with Nygaard (1995) and Gephart et al. (2018). The tampon did not significantly reduce pad weight gain, though the direction of effect was consistent with prior findings. This dissociation between the tampon's effect on EI-UI severity and pad weight gain is most plausibly explained by the limited specificity of pad weight gain as a measure of urine loss during exercise, as sweat and vaginal secretions contribute to fluid accumulation in the pad (Petter Rodrigues et al., 2025). While a pyridium-based pad test demonstrates 100% sensitivity for detecting urine loss in women with SUI, its high false-positive rate in asymptomatic women limits its utility in this context (Wall et al., 1990). To date, no study has characterized intra-individual consistency of perineal sweat and vaginal secretions across repeated exercise sessions. Consequently, even with the crossover design and standardization of bladder volume before the run, it cannot be assumed that changes in pad weight gain across visits reflect changes in urine leakage alone. The detection of urine from other fluids poses its challenges.

#### **4.3 Interpretation of the Main Findings**

The moderate-to-strong correlation between EI-UI Severity Index scores and pad weight gain across all three conditions provides evidence of convergent validity, suggesting that these two measures capture related dimensions of leakage. This relationship weakened when intravaginal devices were used, which may reflect a genuine divergence in how subjective and objective

measures respond to intervention or the limitations of each measure. Either way, this pattern reinforces that relying on either measure alone would give an incomplete picture of device effectiveness and supports retaining both as complementary outcomes in future EI-UI intervention trials.

No EI-UI Severity Index threshold was identified to suggest any clear benefit from either device, suggesting that device response is not dependent on baseline symptom severity. This is a clinically important observation: benefit from intravaginal support does not appear to be confined to a particular severity profile, suggesting that these devices may be a reasonable option for any active female reporting EI-UI during running, regardless of symptom severity. The exact factors that determine benefit from devices have yet to be evaluated.

While this work did not aim to assess the mechanism by which intravaginal devices reduce EI-UI, the pessary's consistent advantage across leakage outcomes is plausibly explained by its interaction with the anterior vaginal wall. Drawing on DeLancey's hammock hypothesis (1994), the anterior vaginal wall and its supportive structures form a stable backboard against which the urethra can be compressed during rises in intra-abdominal pressure; an intravaginal device may reinforce this function by providing additional structural support against which the urethra is compressed. Direct urodynamic evidence for this mechanism comes from Komesu et al. (2008), who used dynamic magnetic resonance imaging to demonstrate that a pessary restored anatomical support of the urethra in women with SUI, evidenced by increased urethral resistance and elevation of the bladder neck, providing a mechanistic basis for a pessary's effect at rest. Whether this mechanism operates equivalently during repetitive high-impact loading, such as running, is unknown and cannot be addressed by the static pre- and post-run ultrasound imaging collected in this study. The difference in effectiveness between the pessary and tampon may reflect differences

in device geometry. The tampon's smaller volume and narrower shape may provide sufficient mechanical support in some individuals, but the pessary's greater volume and diameter may generate more consistent or complete urethral support across a broader range of anatomies. The degree to which the device geometry, material stiffness, vaginal fit, and placement interact to determine the magnitude of urethral support during running remains an important open question. Although difficult to execute, data capture during running, such as pelvic organ kinematics and urethral closure forces, and comparative trials examining different pessary designs are logical next steps toward identifying which device characteristics drive effectiveness.

#### **4.4 Pelvic Floor Morphometry: Exercise-Induced Strain**

A single 38-minute treadmill run produced significant and consistent pre- to post-run increases in LHA and LPL and decreases in BNH across all three conditions. These findings align with previous work by Bérubé and McLean (2024) demonstrating transient strain to the pelvic floor tissues during running. Critically, neither device influenced the magnitude of these morphometric changes compared with no device. The null intervention effect on pelvic floor morphometry is clinically reassuring as it demonstrates that the weight of an intravaginal device does not increase tissue strain during high-impact activity.

One participant was withdrawn from the study based on bleeding experienced while self-fitting the pessary. Vaginal dryness and atrophy are common among peri- and post-menopausal females (Cagnacci et al., 2016) and are a consideration when using intravaginal devices. Current clinical guidelines recommend considering vaginal estrogen in postmenopausal females with vaginal atrophy who use a pessary to improve vaginal tissue health and reduce pessary-related complications (Harvey et al., 2021). Consistent with these recommendations, Uresta® states that the device may be used alongside vaginal estrogen or hormone creams for users experiencing

vaginal dryness or atrophy and advises allowing adequate time for the medication to be absorbed before pessary insertion. Although only one adverse event occurred in the present study, these recommendations should be clearly communicated to potential users, particularly peri- and post-menopausal females or others with symptoms of vaginal atrophy. It is also possible that insertion of a dry tampon may be less well tolerated than insertion of a silicone pessary because the tampon can adhere to the vaginal epithelium, particularly in the presence of vaginal dryness. Future research should evaluate the tolerability and safety of different intravaginal continence devices alongside their efficacy, as these factors are likely to influence device acceptability and continued use.

This study only assessed the immediate pre- to post-run changes in pelvic floor morphometry following a single 38-minute running bout. Whether repeated or prolonged device use influences pelvic floor tissue properties over time remains unknown.

#### **4.5 Device Adoption and Real-World Relevance**

Beyond leakage reduction, patient-reported satisfaction, perceived improvement, and continued use are important indicators of whether an intervention is likely to be adopted in real-world exercise settings. In this study, participants rated satisfaction and perceived improvement above 65% with moderate effect sizes favouring the pessary (satisfaction:  $r = 0.25$ ; perceived improvement:  $r = 0.38$ ), which is consistent with Gephart et al. (2018), who reported high satisfaction with a ring pessary and a vaginal insert device during exercise. While the difference between the pessary and the tampon failed to reach statistical significance, the effect sizes were moderate, in favour of the pessary.

Predicted future use also favoured the pessary. Participants were more likely to report that they intended to use the pessary compared with the tampon, suggesting that the pessary may have

been perceived as a more acceptable or effective strategy outside of the laboratory. This aligns with survey findings from Brennand et al. (2018), who found that among 59 active females with SUI, 63.5% expressed interest in trying a pessary as a strategy to manage exercise-induced leakage, making it one of the most sought-after conservative options after pelvic physiotherapy. To the author's knowledge, comparable data on interest in tampons as a management strategy for EI/UI are not available, limiting direct comparison.

An important pattern emerged between predicted and actual device use over the four-week follow-up. Predicted use exceeded actual use for both interventions, but the gap was much larger for the tampon: half of participants predicted using the tampon after their laboratory visit, yet only 12% reported using a tampon over the following four weeks. For the pessary, predicted use (83%) translated more closely to actual use (58%).

These findings are clinically relevant because effectiveness in a controlled laboratory setting does not guarantee adoption. The greater follow-up use of the pessary suggests that participants viewed it as a more effective and/or suitable longer-term option. This interpretation is supported by Farrell et al. (2007), who reported 90% continued use of the Uresta® at three months in women with SUI, and Campbell et al. (2023), who similarly reported high satisfaction and adherence among active women.

Several explanations for the low tampon adoption are plausible. The tampon may have been perceived as insufficiently effective. Familiarity with the tampon as a menstrual product rather than a continence device may create a barrier to repurposing it in an exercise context. Some participants, especially postmenopausal women, may have found tampon insertion less comfortable due to vaginal dryness and atrophy. Qualitative assessment is necessary to identify

key factors that influence adherence, and as noted above, the safety and efficacy of using a tampon in this context requires further study.

Among pessary adopters, user experience ratings were consistently high across clinical effectiveness, usability, tolerability, and acceptability domains. However, frequency of use was variable, which may be explained by a variety of experiences rather than a single reason for reduced adoption. First, some participants may have discontinued use altogether due to discomfort with the pessary ( $n = 5$ ) or uncertainty with sizing ( $n = 3$ ). One participant described this directly: *“I tried several times (3) to use [the pessary] after the study and had problems, it didn't feel comfortable. Also, I could not empty my bladder.”* This account highlights that self-fitting, while convenient, may leave some users without the confidence or support needed for sustained use. Second, for other participants, low frequency of use did not necessarily indicate rejection of the device, but rather a selective adoption pattern in which the pessary was reserved for higher-risk contexts rather than used on every occasion. As one participant explained: *“I would use the pessary on long runs, over an hour. On short runs, I don't bother. There's just the bit of difficulty inserting and removing, so I don't feel it's worthwhile for my 30-minute runs”*. While this reflects a single experience, it raises the possibility that context-dependent use may be common among recreational runners and that the binary question “did you use it?” would fail to capture. Future studies should assess frequency, duration, and exercise type during which the device was used to better characterize real-world adoption. Finally, adoption was not solely a function of comfort or fit, but also of personal preference. When evaluating conservative solutions for EI/UI, willingness to use an intravaginal device at all should be assessed independently of clinical effectiveness, as some individuals may simply prefer not to use a supportive device. This was captured by one participant’s reflection: *“I see the value in it but don't like using devices if I can find another way.”*

Taken together, these comments suggest that pessary adoption is shaped by a range of individual and contextual factors, and that UI reduction alone cannot serve as the sole measure of device effectiveness in this population.

These findings, although exploratory, highlight that laboratory efficacy and real-world adoption are related but distinct dimensions of intervention success. Both devices were acutely effective and broadly acceptable, yet only the pessary translated into consistent use outside the laboratory. This pattern suggests that comfort, ease of use, and compatibility with an individual's exercise routine may be as influential to sustained use as leakage reduction itself. Moreover, a single laboratory visit is unlikely to capture the full picture of how individual's integrate devices into their routines over time. Future studies should move beyond binary outcomes and examine the contextual, behavioural, and anatomical factors that predict sustained adoption.

#### **4.6 Methodological Contributions and Limitations**

Several methodological features of this study represent meaningful advances over prior work in the EI-UI intervention literature and have implications for how future trials in this area should be designed.

The standardization of the exercise protocol, including individualized speed and gradient carried across all three visits, addresses a key limitation of prior work. Crucially, including a five-minute high-intensity challenge at the end of the exercise session was intended to maximize leakage provocation, acknowledging that EI-UI is more likely to occur at higher exercise intensities (Goldstick & Constantini, 2014). Despite these adaptations, two participants did not leak during the baseline despite reporting habitual leakage on every run, illustrating the inherent challenge of reproducing EI-UI under laboratory conditions. The findings are therefore most applicable to leakage occurring during a 30-minute steady-state treadmill run and may not

generalize to other exercise modalities or outdoor running contexts where terrain, speed changes, and directional loading differ substantially.

Pre-exercise bladder volume standardization using 3D transabdominal ultrasound is a methodological contribution absent from all prior EI-UI intervention studies. It is unclear whether bladder volume has an effect on subsequent leakage experienced during exercise (Lose et al., 1986; Petter Rodrigues et al., 2025). Given the uncertainty, standardization to a 100-200mL range at each visit was executed to strengthen the confidence that observed differences in leakage reflect device effects rather than variation in bladder fullness.

The absence of a validated exercise-specific leakage measure is a recognized limitation in the field and is reflected in our use of the EI-UI Severity Index. The index was developed from the validated Incontinence Severity Index (Sandvik et al., 1993, 2006) and was significantly different among all three intervention conditions, with a large effect size, which suggests that this measure is responsive to change. However, test-retest reliability, minimal detectable difference, and minimally clinically meaningful differences have not been established, and should be prioritized in future work before this index is recommended as a standard outcome measure.

Similarly, pad weight gain is not specific to urine loss when implemented during exercise. Its inclusion was justified by its use in all prior EI-UI intervention studies, enabling comparison with the existing literature, and it was interpreted throughout as a secondary, supportive outcome rather than a primary index of urine loss. Future studies may consider approaches to isolate urine from other perineal fluid sources.

Finally, the findings of this study are specific to the Uresta® pessary, which was selected for its self-fitting design, commercial availability, and prior evidence of effectiveness and adherence in women with SUI (Campbell et al., 2023; Farrell et al., 2007; Lovatsis et al., 2017).

Whether findings generalize to other pessary designs is unknown and should be tested. The four-week follow-up provides useful but exploratory insight into real-world device adoption and should be interpreted accordingly.

#### **4.7 Clinical Implications**

Current first-line management of general SUI, supervised PFMT, has not demonstrated equivalent efficacy in active females with EI/UI (Petter Rodrigues et al., 2025), and access to specialist pelvic health physiotherapy is limited in many settings. Self-fitted intravaginal devices offer an immediately accessible option that does not require clinical fitting, is commercially available, and can be implemented autonomously while awaiting or alongside other treatment. However, pessaries are not generally a “one size fits all approach” and pessary fittings performed by health care providers offer patients an opportunity to be prescribed a device that fits their anatomy best. Thus, despite the demonstrated efficacy of the self-fitted Uresta® pessary in this study, the findings are subject to user error in pessary fitting. Findings may be different when fitted pessaries are used. In any event, the findings of this study support including intravaginal devices in conservative management discussions for active females who experience EI/UI, particularly those seeking immediate symptom control to maintain exercise participation. The tampon may be a low-cost and familiar option, while the Uresta® pessary may offer better continence support and a greater likelihood of continued use. However, device effectiveness is variable among users.

Clinicians across disciplines, including pelvic health physiotherapy, urogynecology, sports medicine, and primary care, should be aware that both devices are acutely effective, but that the pessary is associated with greater leakage reduction and higher real-world adoption. Yet clinical recommendations should be understood in the light of the study’s scope: findings are specific to a 30-minute run, the Uresta® pessary, and recreationally active females. Long-term effectiveness

and adherence data are still needed before this device can be recommended as a sustained management strategy.

#### **4.8 Future Directions**

This study provides a foundation for several important lines of future investigation. Longer-term randomized controlled trials are needed to evaluate sustained effectiveness, adherence, and adverse events associated with both devices across habitual exercise routines and a broader range of activity types. Comparative trials examining different pessary designs including clinician-fitted devices would help identify which device characteristics drive effectiveness and whether the Uresta®'s self-fitting advantage comes at a cost to efficacy relative to more customized options.

Formal evaluation of the EI-UI Severity Index is a priority. The index requires test-retest reliability data before it should be recommended as a standard outcome in EI-UI trials. Extending its evaluation to other exercise modalities would also establish whether the measure generalizes beyond treadmill running.

Identifying predictors of device response, including anatomical, clinical and demographic variables, would improve the ability to match individuals to the most appropriate intervention and is a logical extension of the current findings. Finally, qualitative research exploring barriers and facilitators to device adoption in active women would complement the quantitative adoption data reported here and would support the development of implementation strategies to improve the translation of laboratory efficacy into habitual exercise behaviour.

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## Appendix A: Intervention Follow-Up Questionnaire

### Participant Information

1. Please enter your study ID provided in the email that was sent by the researcher (ex: P\_014)
2. Do you consent to participating in this study step, as described in the provided letter of information?

Yes

No

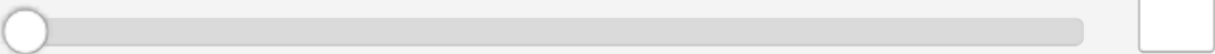
### Tampon and/or Pessary Usage

3. Have you used the tampon while running in the past 4 weeks?

Yes

No

4. If yes, how often have you used the tampon while running in the past 4 weeks? If no, please register 0 on the slider.

|                                                                                      |                                                                           |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| 0 - I did not use the tampon at all after participating in the study                 | 100 - I used the tampon during every run after participating in the study |
|  |                                                                           |

5. Have you used the pessary while running in the past 4 weeks?

Yes

No

6. If you did not use the pessary at all OR if you stopped using the pessary, please comment on:

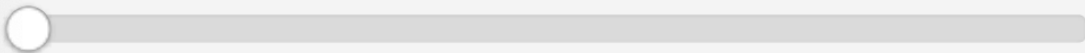
(A) For how many runs did you use the device before stopping?

(B) Why did you stop using the pessary?

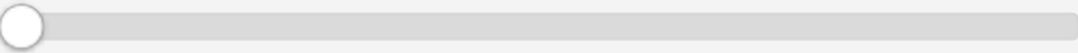
### Pessary Experience

*This questionnaire is designed to collect information regarding your experience with the pessary over the past 4 weeks. Please answer all questions using a scale ranging from 0 to 100. Simply click and slide the button to register your answers.*

7. Please indicate the frequency of pessary usage following your participation in the study. If you have not used the pessary at all since the study, please register 0 on the slider and simply skip the rest of the questions and submit.

|                                                                                      |                                                                                            |                      |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|----------------------|
| (0) I did not use the pessary at all after participating in the study                | (100) I have used the pessary every time I have exercised since participating in the study | <input type="text"/> |
|  |                                                                                            |                      |

8. Please indicate your ability to empty your bladder while using the pessary. If you haven't used the pessary while in the bathroom, please skip this question (the answer value box will be blank when skipped).

|                                                                                      |                                                                                  |                      |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------|
| (0) With the pessary in place, I am not able to empty my bladder at all              | (100) The pessary has no impact on my ability to empty my bladder when I want to | <input type="text"/> |
|  |                                                                                  |                      |

9. How would you rate the ease of inserting the pessary?

|                                                                |                                               |                      |
|----------------------------------------------------------------|-----------------------------------------------|----------------------|
| (0) The pessary is extremely difficult or impossible to insert | (100) The pessary is extremely easy to insert |                      |
| <input type="range"/>                                          |                                               | <input type="text"/> |

10. How would you rate the ease of removing the pessary?

|                                                                |                                               |                      |
|----------------------------------------------------------------|-----------------------------------------------|----------------------|
| (0) The pessary is extremely difficult or impossible to remove | (100) The pessary is extremely easy to remove |                      |
| <input type="range"/>                                          |                                               | <input type="text"/> |

11. How would you rate the level of comfort you experience while wearing the pessary?

|                                                                                         |                                                                                                 |                      |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|----------------------|
| (0) The pessary is extremely uncomfortable or painful the whole time it is inside of me | (100) The pessary is extremely comfortable once inserted. I cannot feel it when it is inside me |                      |
| <input type="range"/>                                                                   |                                                                                                 | <input type="text"/> |

12. On a scale from 0 to 100, what is your opinion about the pessary design?

|                                                                 |                                                                          |                      |
|-----------------------------------------------------------------|--------------------------------------------------------------------------|----------------------|
| (0) The design of the pessary is extremely unattractive or ugly | (100) I really like the look of the pessary. It is extremely attractive. |                      |
| <input type="range"/>                                           |                                                                          | <input type="text"/> |

13. How would you rate the extent to which the pessary causes vaginal discharge and/or bleeding?

(0) The pessary causes considerable vaginal discharge or bleeding

(100) The pessary has not caused any vaginal discharge or bleeding

☐☐

14. How would you rate the level of urine leakage you experience while exercising using the pessary?

(0) Using the pessary does not change how much I leak urine while exercising and/or might make it worse

(100) I do not leak any urine while exercising when I use the pessary

☐☐

15. How satisfied are you with the pessary's effectiveness in preventing urine leakage while running?

(0) I am completely unsatisfied with it

(100) I am extremely satisfied with the pessary

☐☐

16. Please indicate your intention to continue using the pessary during physical exercise.

(0) I do not intend to continue to use the pessary during exercise

(100) I fully intend to continue to use the pessary when I exercise

☐☐

17. Please rate your level of urine leakage outside of exercise, during activities of daily living (i.e. sneezing, coughing, laughing, lifting, etc)

(0) I do not leak urine  
other than when I am  
exercising

(100) I leak urine  
outside of exercise on a  
daily basis

☐☐

18. Please indicate your intention to continue using the pessary during daily activities beyond exercise (i.e. sneezing, coughing, laughing, lifting, etc).

(0) I do not intend to  
continue to use the  
pessary during daily  
activities beyond  
exercise

(100) I fully intend to  
continue to use the  
pessary during daily  
activities beyond  
exercise

☐☐

19. Any other comment

## Appendix B: Supplementary Tables

**Table B1**

*Summary of bladder volume measurements, EI-UI Severity Index, and pad weight gain outcomes for the no-intervention, tampon, and pessary conditions in female recreational runners with EI-UI.*

|                                             | n  | None                          | Tampon                        | Pessary                       | p                | Effect size       |
|---------------------------------------------|----|-------------------------------|-------------------------------|-------------------------------|------------------|-------------------|
| Pre-exercise bladder volume, mL, mean (SD)  | 30 | 156 (50)                      | 148 (34)                      | 152 (50)                      | 0.748            | $\eta^2p = 0.007$ |
| Post-exercise bladder volume, mL, mean (SD) | 30 | 196 (74)                      | 211 (72)                      | 210 (86)                      | 0.683            | $\eta^2p = 0.02$  |
| EI-UI severity, EMM (95% CI)                | 28 | 0.84 (0.58-1.10) <sup>a</sup> | 0.42 (0.24-0.60) <sup>b</sup> | 0.19 (0.07-0.31) <sup>c</sup> | <b>&lt;0.001</b> | $\eta^2p = 0.40$  |
| Pad weight gain, g, EMM (95% CI)            | 28 | 17.4 (10.2-29.4) <sup>a</sup> | 10.9 (6.4-18.4) <sup>ab</sup> | 7.4 (4.4-12.5) <sup>b</sup>   | <b>&lt;0.01</b>  | $\eta^2p = 0.19$  |

*Note.* CI, confidence interval; EI-UI, exercise-induced urinary incontinence; EMM, estimated marginal means; SD, standard deviation;  $\eta^2p$ , partial eta squared. Significant differences ( $\alpha \leq 0.05$ ) are indicated in bold. Significant within-subject between-condition differences ( $\alpha \leq 0.05$ ) are indicated with superscripts.

**Table B2**

*Satisfaction, perceived improvement, and predicted and actual device use outcomes across intervention conditions.*

|                              | n  | Tampon           | Pessary          | p               | Effect size |
|------------------------------|----|------------------|------------------|-----------------|-------------|
| Satisfaction, median % (IQR) | 28 | 67.5% (56.2)     | 82.5% (37.5)     | 0.224           | $r = 0.25$  |
| Improvement, median % (IQR)  | 28 | 65.0% (67.5)     | 80.0% (50.0)     | 0.067           | $r = 0.38$  |
| Predicted use, % [95% CI]    | 30 | 50% [32.8, 67.2] | 83% [65.7, 92.9] | <b>&lt;0.01</b> | OR = 5.00   |
| Actual use, % [95% CI]       | 26 | 12% [2.4, 30.2]  | 58% [36.9, 76.6] | <b>&lt;0.01</b> | OR = 10.45  |

*Note.* CI, confidence interval; IQR, interquartile range; OR, odds ratio; r, rank-biserial correlation coefficient. Significant differences ( $\alpha \leq 0.05$ ) are indicated in bold.

**Table B3**

*Pelvic floor morphometric outcomes including levator hiatus area, levator plate length, and bladder neck height before and after running with no intravaginal device, a tampon, and a pessary.*

|           | Before the run |     |        |     |         |     | After the run |     |        |     |         |     | Timepoint Effect |             | Intervention Effect |             | Timepoint x Intervention |             |
|-----------|----------------|-----|--------|-----|---------|-----|---------------|-----|--------|-----|---------|-----|------------------|-------------|---------------------|-------------|--------------------------|-------------|
|           | None           |     | Tampon |     | Pessary |     | None          |     | Tampon |     | Pessary |     |                  |             |                     |             |                          |             |
|           | Mean           | SD  | Mean   | SD  | Mean    | SD  | Mean          | SD  | Mean   | SD  | Mean    | SD  | <i>p</i>         | η² <i>p</i> | <i>p</i>            | η² <i>p</i> | <i>p</i>                 | η² <i>p</i> |
| LHA (cm²) | 18.4           | 4.5 | 18.6   | 4.7 | 18.5    | 4.5 | 20.4          | 5.2 | 20.7   | 5.4 | 20.3    | 5.9 | <0.001           | 0.310       | 0.659               | 0.007       | 0.911                    | 0.001       |
| BNH (mm)  | 15.6           | 5.0 | 15.3   | 3.9 | 15.6    | 4.7 | 14.3          | 4.8 | 13.8   | 4.3 | 13.8    | 5.7 | <0.001           | 0.121       | 0.669               | 0.006       | 0.837                    | 0.003       |
| LPL (mm)  | 54.6           | 6.5 | 55.8   | 7.0 | 55.7    | 5.7 | 58.1          | 7.3 | 58.6   | 7.8 | 58.5    | 7.3 | <0.001           | 0.209       | 0.354               | 0.016       | 0.881                    | 0.002       |

*Note.* BNH, bladder neck height; LHA, levator hiatus area; LPL, levator plate length; SD, standard deviation,  $\eta^2p$ , partial eta squared. Significant differences ( $\alpha \leq 0.05$ ) are indicated in bold.

**Table B4**

*User experience ratings among pessary adopters (n = 15) assessed via visual analogue scale (0-100%), where 0 represents the worst and 100 the best possible experience. Sample sizes vary by outcome (n = 8-15) due to missing responses.*

|                                       | n  | Median [IQR]        |
|---------------------------------------|----|---------------------|
| Frequency of pessary use              | 15 | 80.0 [37.5, 94.0]   |
| Perceived EI-UI reduction             | 12 | 90.0 [83.8, 100.0]  |
| Satisfaction                          | 14 | 91.0 [74.8, 100.0]  |
| Intent to continue use                | 8  | 99.5 [90.0, 100.0]  |
| Comfort with device                   | 12 | 97.5 [88.8, 100.0]  |
| Ease of insertion                     | 12 | 95.0 [69.0, 100.0]  |
| Ease of removal                       | 12 | 85.5 [70.0, 100.0]  |
| Absence of discharge/bleeding         | 12 | 100.0 [88.8, 100.0] |
| Voiding ability while wearing pessary | 9  | 90.0 [80.0, 100.0]  |

*Note.* IQR, interquartile range.