



Bladder leakage can be a **serious** challenge for women.

With *Leva*, it doesn't have to be.

*Leva*<sup>®</sup>  
PELVIC HEALTH  
SYSTEM

WHY NOT LEVA?

DID YOU KNOW

LEVA USER FEEDBACK

NEXT STEPS & WHAT TO EXPECT

PROVEN RESULTS

CARE PATHWAY & TREATMENT OPTIONS

WHAT IS INCONTINENCE AKA BLADDER AND/OR BOWEL LEAKAGE?

WHAT IS THE PELVIC FLOOR AND WHY SHOULD I CARE?

WHY LEVA?



## Why Leva?

The *Leva Pelvic Health System* is a **non-medication, non-surgical** first-line treatment for stress, mixed, and urgency urinary incontinence (UI) (including *overactive bladder*) and chronic fecal incontinence (FI).

*Leva* is **supervised, at-home, pelvic floor muscle training**.

*Leva* is a 12-week treatment that you can use in the privacy of your own home (or from anywhere) and **takes just 2.5 minutes, twice a day**.



[Watch](#) how *Leva* works

## The *Leva* Program has four key components

The flexible **Leva Device** is inserted vaginally (for both UI or FI treatment) and is equipped with **six motion sensors that communicate wirelessly** with an app on your smart phone.

The *Leva* device measures movement when you contract your pelvic floor muscles, **essentially acting as a mirror to your pelvic floor**.

Women are wowed by the at-home nature of the device, the visual cues to help them perform their pelvic floor exercises correctly, and the **in-app progress tracking**.

### 1. *Leva* Device

- 2.5 minutes
- 2x/ day
- While standing
- For 12 weeks

### 2. *Leva* App

### 4. *Leva* Patient Report

Your healthcare provider receives a **Leva Patient Report** with your adherence and symptom information, so they can monitor and adjust your treatment if necessary.

We want your healthcare provider involved in your treatment, which is why ***Leva* requires a prescription**.

### 3. *Leva* Women's Center

You are paired with a Coach from our **Leva Women's Center**.

Our Coaches help you stay accountable and motivated throughout your **12-week *Leva* course of therapy**.



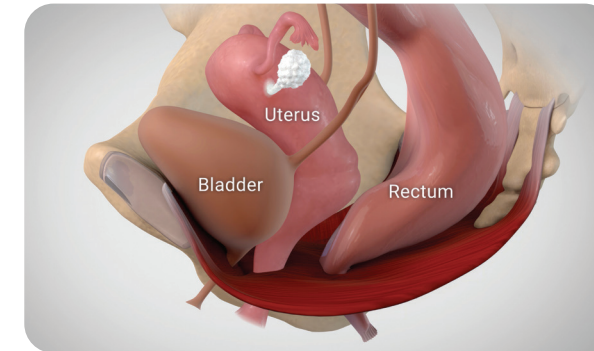
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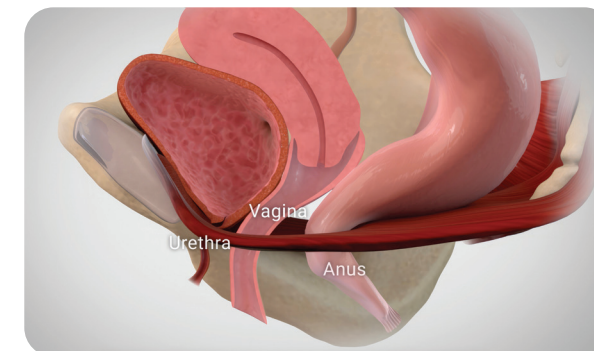
## What is the pelvic floor and why should I care?

The pelvic floor has more than a dozen interconnected muscles that form a hammock anchored at the pubic bone and work together to support the bladder, uterus, and rectum. These muscles play an important role in bladder and bowel control. They are always active, working to prevent leakage of urine or stool.



[See the medical animation](#)

A normal pelvic floor muscle contraction produces a combined lift and squeeze motion and closes the openings of the urethra, the vagina, and the anus. These muscles move up and down as they contract and relax to meet the demands of day-to-day activities.

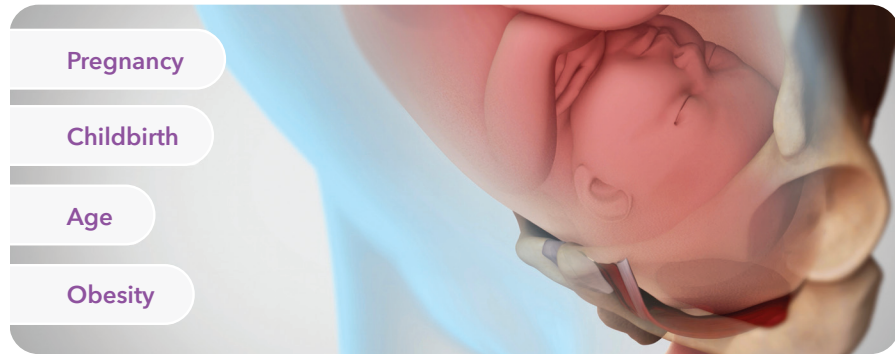


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# What is incontinence, aka bladder and/or bowel leakage?

The pelvic floor muscles may be injured or weakened as a result of pregnancy, childbirth, age, obesity, and other factors. Weak or damaged pelvic floor muscles can contribute to pelvic floor disorders, such as urinary incontinence (UI), overactive bladder, and fecal incontinence (FI).



## Types of Incontinence

### Stress Urinary Incontinence (SUI)

Do you leak when you laugh, cough, sneeze, jump, and/or exercise?

**You likely have SUI.**



[See the medical animation](#)

### Urgency Urinary Incontinence (UII)

*(including overactive bladder)*

Do you have a sudden urge to rush to the restroom but can't always make it?

Do you experience a frequent need to empty your bladder?

**You likely have UII.**



[See the medical animation](#)

### Mixed Urinary Incontinence (MUI)

Do you experience a combination of leaking with physical activity and a sense of urgency to rush to the restroom?

**You likely have MUI.**

### Fecal Incontinence (FI)

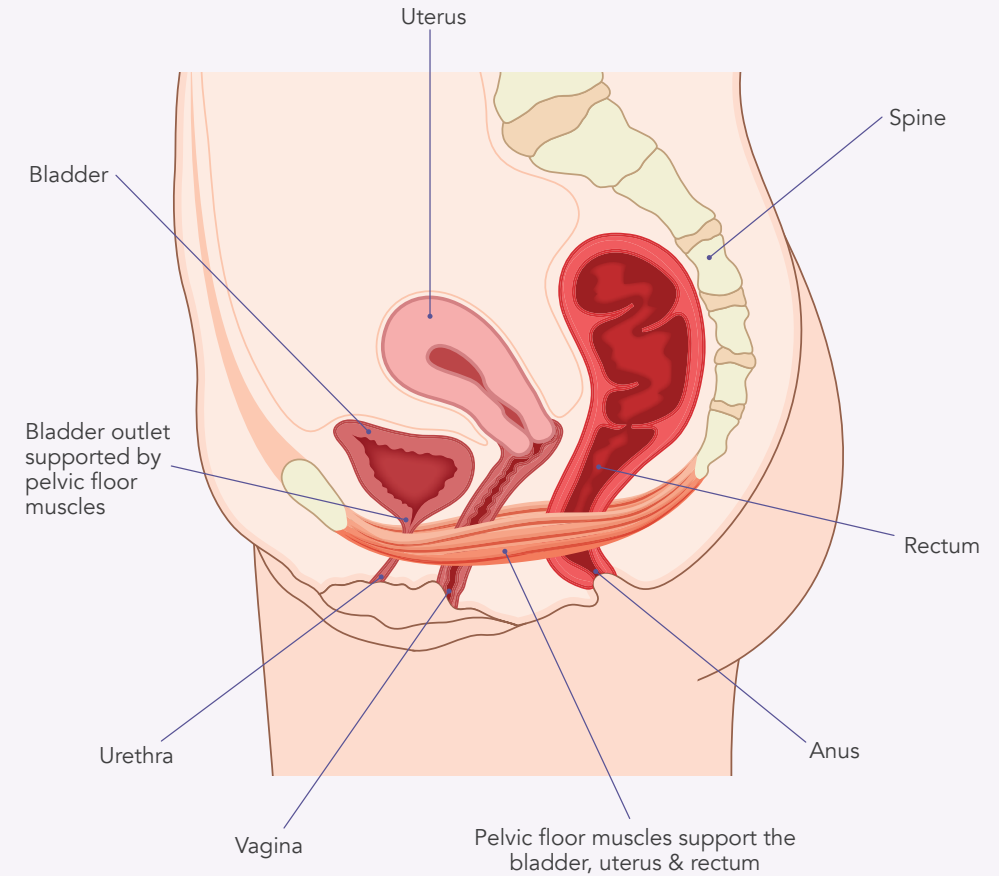
Some women who experience UI also experience bowel leakage or FI, which is the involuntary loss of solid or liquid stool (feces).

**While embarrassing and frustrating, you have options!**



[See the medical animation](#)

This diagram may be useful for you and your healthcare provider to discuss your pelvic floor symptoms



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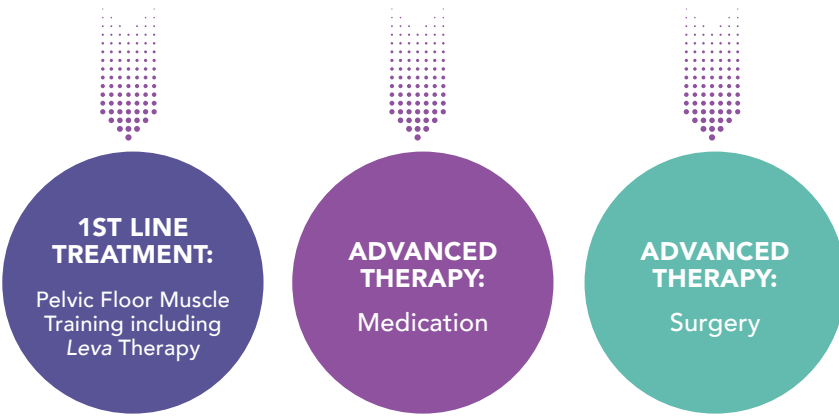


### Treatment options

Pelvic floor muscle training (PFMT), also known as Kegel exercises, is the recommended first step and gold standard in treating urinary incontinence because, when done correctly, it works.<sup>1</sup> Second- and third-line treatments include medication and surgical interventions, but medication may have side effects, and surgery can be invasive.

### 78M U.S. Women with UI<sup>2</sup> Female Urinary Incontinence Care Pathway<sup>1</sup>

LEAST invasive → MORE invasive



PFMT may be unsupervised, such as doing Kegels at home on your own, or supervised, such as with a physical therapist. However, there are limitations to both approaches that may make PFMT less effective. In-person physical therapy may be hard to get to or a challenge to get an immediate appointment due to long wait lists. Practicing on your own has its own challenges. Most women either don't know if they are doing the exercises correctly, don't do them enough or don't even do them at all.



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## Proven results

We are a company driven by data and relentlessly dedicated to women's health. To that end, we don't just **say** Leva works, we have data to **prove** Leva works.



### In a large clinical study of women with bladder leakage, most Leva users saw:

- UI symptom improvement **as early as four weeks** into treatment.
- An **80% reduction** in bladder leakage episodes.<sup>3</sup>



### In a follow-up to this clinical study, most Leva users saw:

- Improvement regardless of UI symptom severity.
- Continued UI symptom improvement **lasting two years** (after an 8-week treatment period).<sup>4</sup>



### A study of real-world Leva users found:

- **Leva** is effective for stress, mixed, and urgency urinary incontinence (including overactive bladder).
- **78%** of Leva users saw **significant UI symptom relief**.<sup>5</sup>



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## Next steps & what to expect

- ✔ **Ask your healthcare provider to send in a prescription** to the *Leva Women's Center*. This allows you to schedule a **free consultation** to check your insurance coverage.
  - A prescription for *Leva* **does not require you to purchase**, but it does expedite the process if you decide to move forward.
- ✔ Once our team receives your prescription, **you will receive a text message** from the *Leva Women's Center* (with a 617-area code). **The text will have a link** to schedule a time to chat with us on a live call.
- ✔ You can always call us directly at **1-855-FOR-LEVA** (367-5382) to get started immediately.
- ✔ We will check your insurance coverage to determine out-of-pocket costs and provide affordable payment options accordingly:
  - National and regional **insurance coverage**, plan dependent
  - HSA/FSA **eligibility**
  - Monthly **payment plan** options
  - A money-back **guarantee**, subject to eligibility



## Moving forward with *Leva*

- ✔ A coach will reach out with a welcome message **via text**.
- ✔ Your device will ship to your home in discreet packaging. You cannot pick it up from a pharmacy.
- ✔ Once you receive *Leva*, **download the *Leva* app**. The app will guide you in getting started.
- ✔ Once you've trained with *Leva* two days in a row, **you'll receive a text to schedule time with your dedicated Coach**. She'll support you throughout your 12-week therapy. Your coaching **call is 10-15 minutes and is encouraged!** Speaking with a Coach can help build confidence, provide personalized tips, and set you up for success (*however, it's not required*).
- ✔ Complete your therapy by **using *Leva* two times a day for 12 weeks!** Your provider will receive monthly reports, to monitor your therapy and progress.\*
- ✔ Once therapy is complete, **check back with your provider** to discuss your results.

\*Dependent on fax verification



**Get started today! Call 1-855-FOR-LEVA (367-5382)**



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## LEVA USER FEEDBACK<sup>10</sup>

“ I used to use pads when I went to the gym, but I always worried that I smelled bad. Now I don't leak anymore! This worked so much better and faster than I thought it would. *Leva* teaches you how to control your own body. It's like a personal trainer for muscles you can't see. **I wish I'd tried *Leva* sooner.** I had been leaking a little for years after having my kids, and thought it was unavoidable, so it's huge to not have to worry about it anymore. What if someone says something funny and I laugh? What if I sneeze? Now I don't need to think about things like that!

Leva User, Age 47 ”

“ **The encouragement from my provider and her certainty that *Leva* could help me was most compelling.** I would not have known about *Leva* otherwise. She was right; it helped me. The instructions are very clear, so it's easy to follow the plan. The daily tips are helpful. You can easily find 2-3 min twice a day to commit to *Leva*. I felt like I had a cheerleader rooting for me. It kept me motivated to continue. *Leva* is worth the time and effort to help you feel stronger. The program does work, and I am very happy I did it. I have more control over feelings of urgency and many less episodes of leaking.

Leva User, Age 63 ”

“ I tried Kegels prior to *Leva*, but it was hard to know how to do them correctly and frequently enough. *Leva* made it easy to do the right frequency and duration. I'm finding less frequency of urination and less leakage with sneezing and coughing. The most compelling part of *Leva* was being able to do it in the privacy of my home. It was much less hassle than finding and going to a PT provider. **My doctor recommended it, and I would tell her to continue to do so for other patients. It was worth the time and expense.**

Leva User, Age 38 ”

“ I saw improved strength as I progressed through the 12 weeks. Thank you for recommending this program. It has improved my situation. I just feel stronger and more in control. It has also helped manage my bowels. **The convenience of being able to do the exercises in the privacy of my own home and the ability to see my progress over the course of the program was wonderful.** I would highly recommend this program.

Leva User, Age 68 ”

“ *Leva* met my expectations. I no longer have to use pads for leaking. It has worked fantastic. I did not want surgery, but I wanted to have the ability to work out again without incontinence...and *Leva* helped with giving me that ability back. **I couldn't believe how well *Leva* worked to give me the confidence to go about my day without wearing a pad for unexpected leaks.** Extremely grateful this product worked!

Leva User, Age 40 ”

“ I think all women should use *Leva* after having children. It's an easy way to rebuild pelvic floor strength and easy enough to fit into a mom's daily routine. **I actually wish I started with *Leva* over PT.**

Leva User, Age 37 ”

“ My prescribing medical provider's recommendation persuaded me to take the leap and it's been well worth it. I'm much better educated than I expected, feel I have ongoing tools, and have seen great results. That progress was measurable, and the support was robust and proactive. I was feeling really anxious about my bladder leakage in regard to my long-term health. **I really appreciate that *Leva* addresses such an essential element of women's health that is so often neglected or swept under the rug.**

Leva User, Age 52 ”

“ The *Leva* System has helped me improve my incontinence. **Being someone who has suffered with incontinence, has done Kegels, had physical therapy and yet continued to suffer with incontinence, the *Leva* System – recommended by my urogynecologist – was instrumental in improving my goal.** I appreciated the measurements that *Leva* gives you. With every use I was motivated to hold for a longer time and lift a little higher.

Leva User, Age 65 ”

“ My symptoms have improved immensely! My incontinence issues were getting worse, and I had gone from using light pads to heavier incontinence pads. I was using the bathroom at least once an hour during the day and a few times at night. Since using *Leva*, I am now experiencing better control and less trips to the bathroom. **So I'm glad my doctor put me on this program. Such an embarrassing health issue and this was such an easy way to improve without meds.** So effective!

Leva User, Age 53 ”

“ *Leva* has met my goal 100%. Now I can control my laugh and my cough and not get wet. My Coach was the best. She helped me so much and kept pushing me to do this. **I want to take a moment to thank my doctor for recommending *Leva*. Keep recommending it! It's the best thing that was ever prescribed for me.** I was considering an operation for this problem and now I'm very happy I didn't and that I used *Leva* first.

Leva User, Age 48 ”



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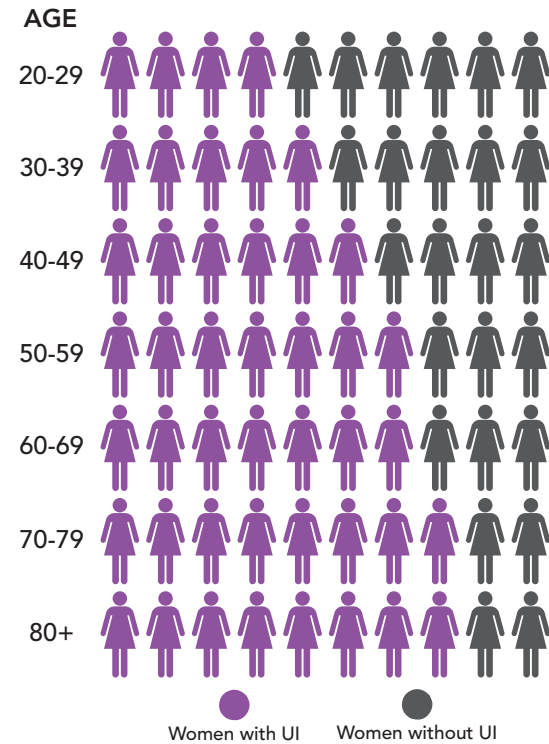


## DID YOU KNOW?

### Age is an independent risk factor for UI<sup>2</sup>

With each decade of life, more women experience incontinence. In fact, the adult diaper market is outpacing the baby diaper market!

While diapers and protective garments can be helpful to manage leaks, treating the problem can reduce or eliminate the need for these products altogether.



Women who experience bladder leakage often experience negative effects on their overall quality of life.

UI is associated with:



Reduced physical activity and exercise<sup>1</sup>, which can lead to weight gain



Mental health concerns, including anxiety, depression, and social isolation<sup>8</sup>



There is research to show UI may progress over time<sup>9</sup>

At younger ages, women often report their UI symptoms come and go. **But over time, UI symptoms may progress.** This means symptoms may return and they may be more severe (e.g. more frequent leaks).



Most women who use Leva are very consistent with their daily treatment

This is because it is **convenient, easy-to-use**, and may be completed at home or from **anywhere**.

Incontinence can be a serious challenge for women. With Leva, it doesn't have to be. You've waited long enough.

It's time to take control of your bladder leakage because you deserve it.

Pelvic floor muscle training (PFMT) is the recommended first step in treating bladder leakage<sup>1</sup> and is a key component of first-line care for bowel leakage<sup>11</sup>

It is important to try PFMT before moving to advanced treatments.

Most women will experience symptom improvement with PFMT and for those that do not, advanced interventions may include medications or surgery.

Some women worry that Leva may not work for them because of their age ("I'm too old") or weight ("I'm too heavy"). But there is good news!

Research shows that incontinence in older women and women who are overweight or obese can improve with pelvic floor muscle training.<sup>3,5</sup>



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## Are there reasons why *Leva* may NOT be appropriate for me?

If any of the following apply to you, it is recommended you discuss with your healthcare provider, as they may indicate that *Leva* is not right for you:

- If you are **pregnant, or if you think you may be pregnant**, unless authorized by your healthcare provider.
- If you are **less than 6-weeks postpartum**, unless authorized by your healthcare provider.
- If you are **unable to stand on your own** for at least five minutes a day.
- If you **do not own a smartphone** or have access to one during the time you use *Leva*.
- If your main pelvic health problem is **pelvic pain**.
- If you have **pain with inserting anything into the vagina** or are unable to insert anything into the vagina for other reasons.
- If you have a **vaginal bulge** that comes to or out of the vaginal opening.
- If you are **unwilling to perform daily exercises** for at least eight weeks to address your leakage symptoms.



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*Leva*<sup>®</sup> | PELVIC HEALTH SYSTEM

### Important Safety Information for *Leva* Pelvic Health System:

The *Leva* Pelvic Health System is intended for: **(1)** strengthening of pelvic floor muscles, **(2)** rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary incontinence (*including overactive bladder*) in women and **(3)** rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (*>3-month uncontrolled passage of feces*) in women. Treatment with the *Leva* System is by prescription and is not for everyone. Please talk to your prescriber to see if *Leva* System is right for you. Your prescriber should discuss all potential benefits and risks with you. Do not use *Leva* System while pregnant, or if you think you may be pregnant, unless authorized by your doctor.

For a complete summary of the risks and instructions for the *Leva* System, see its Instructions for Use available at [www.Levatherapy.com](http://www.Levatherapy.com).

### Disclaimer Regarding Patient Testimonials:

Testimonials are collected or recorded via surveys, emails and interviews and reflect real-life experiences from real patients. However, each individual's results will vary and included testimonials are not intended to represent or guarantee that any one patient will achieve the same or similar results. Please also note that some patients may be paid for their testimonials.

**Sources:** 1. McKinney JL, Keyser LE, Pulliam SJ, Ferzandi TR. Female Urinary Incontinence Evidence-Based Treatment Pathway: An Infographic for Shared Decision-Making. *J Womens Health (Larchmt)*. 2022;31(3):341-346. doi:10.1089/jwh.2021.0266. 2. Patel UJ, Godecker AL, Giles DL, Brown HW. Updated Prevalence of Urinary Incontinence in Women: 2015-2018 National Population-Based Survey Data. *Female Pelvic Med Reconstr Surg*. 2022;28(4):181-187. doi:10.1097/SPV.0000000000001127. 3. Weinstein MM, Dunivan G, Guaderrama NM, Richter HE. Digital Therapeutic Device for Urinary Incontinence: A Randomized Controlled Trial. *Obstet Gynecol*. 2022;139(4):606-615. doi:10.1097/AOG.0000000000004725. 4. Weinstein MM, Dunivan GC, Guaderrama NM, Richter HE. A Motion-based Device Urinary Incontinence Treatment: A Longitudinal Analysis at 18 and 24 Months. *Int Urogynecol J*. Published online January 22, 2024. doi:10.1007/s00192-023-05721-z. 5. Keyser LE, McKinney JL, Pulliam SJ, Weinstein MM. A digital health program for treatment of urinary incontinence: retrospective review of real-world user data. *Int Urogynecol J*. 2023;34(5):1083-1089. doi:10.1007/s00192-022-05321-3. 6. Erekson EA, Ciarleglio MM, Hanissian PD, Strohhahn K, Bynum JP, Fried TR. Functional disability and compromised mobility among older women with urinary incontinence. *Female Pelvic Med Reconstr Surg*. 2015;21(3):170-175. doi:10.1097/SPV.0000000000001136. 7. Corréa LCAC, Pirkle CM, Wu YY, Vafaei A, Curcio CL, Câmara SMAD. Urinary Incontinence Is Associated With Physical Performance Decline in Community-Dwelling Older Women: Results From the International Mobility in Aging Study. *J Aging Health*. 2019;31(10):1872-1891. doi:10.1177/0898264318799223. 8. Siddiqui NY, Wiseman JB, Cella D, et al. Mental Health, Sleep and Physical Function in Treatment Seeking Women with Urinary Incontinence. *J Urol*. 2018;200(4):848-855. doi:10.1016/j.juro.2018.04.076. 9. Li Q, Cheng Y, Shi H, Xue K, Zhou F. Advances in the natural history of urinary incontinence in adult females. *J Obstet Gynaecol*. 2023;43(1):2171774. doi:10.1080/01443615.2023.2171774. 10. Axena data on file. 11. Brown HW, Dyer KY, Rogers RG. Management of Fecal Incontinence. *Obstet Gynecol*. 2020;136(4):811-822. doi:10.1097/AOG.0000000000004054.

**It's not your mother's Kegels.  
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