

Appendix 1. Instructions for Using *leva* Pelvic Floor Muscle Training. (Appendix courtesy of Renovia Inc.)

You have agreed to participate in a clinical trial to evaluate treatment for urinary incontinence.

You have been assigned to a group using *leva* to perform pelvic floor muscle training. The instructions here will help you to perform the exercises correctly.

Use *leva* 3 times per day for 2 ½ minutes for each **Training** session.

If you have questions, call your study team at **888-646-7760**

Getting Started with *leva*

- Wash hands and empty bladder.
- Remove *leva* from its case.
- Wash the part of the *leva* that goes into the vagina with mild soap and water (do not immerse the handle).
- Open the *leva* app on the mobile device.
- Place the phone within reach and with the screen visible. Keep the *leva* case near the phone.


How to insert *leva*

- Hold the purple handle with your thumb on the oval. The *leva* logo and raised indicator line must face up to the ceiling.

- Insert *leva* into your vagina. Keep the handle outside the vagina.
- Pull up your underwear to hold *leva* in place.

**JUST 2 ½
MINUTES
5 CYCLES
THREE TIMES A
DAY**

Begin Your Training Exercises

- Tap the  on the Home screen of the *leva* app.

Follow the prompts:

- Lift your pelvic floor muscles up and in. Draw in towards your belly button. Hold as long as you can for up to 15 seconds. Don't hold your breath.
- The line on the screen moves to the left as you lift up and in.
- Relax the pelvic floor muscles during the 15-second rest.

Complete all 5 cycles

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- Your data will be recorded after all 5 cycles of Lifts and Rests have been completed.
- Remove **leva** by pulling gently down and out.
- Wash and dry **leva** and store in its case.

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Appendix 2.

Participant Instructions – Control Group

You have agreed to participate in a clinical trial to evaluate treatment for urinary incontinence (UI).

You have been assigned to a group performing Kegel exercises. The instructions here will help you to perform the exercises correctly.

Perform 10 Kegel exercises 3 times a day.

If you have questions, call your study team at **888-646-7760**

How to Perform Kegel Exercises

Like any other form of exercise, it is important to do pelvic floor muscle exercises (PFME) correctly and regularly.

Unfortunately, because pelvic muscles are hidden from view, it is hard to know if you are doing them correctly. To be sure that you are working the right muscles:

- Imagine you are going to pass gas and squeeze the muscles that would prevent that gas from

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How to Perform Kegels Pelvic Floor Muscle Exercises

escaping from your rectum.

Exercising the muscles around the rectum will also strengthen those around the vagina and under the bladder.

- Use a hand mirror to look at your vaginal opening and the perineum (the space between the vagina and rectum). You should see the perineum lift up when you contract your pelvic muscles.
- While lying or sitting, place one finger inside your vagina. Squeeze as if you were trying to stop urine from coming out. You should feel your finger lifted and squeezed if you are correctly contracting your pelvic muscles.
- No one should be able to tell you are doing PFME
- if you are visibly moving, you are not using the right muscles.
- *You should not be contracting the gluteus ("butt") or thigh muscles.*
- *Keep your stomach and back muscles relaxed as you work those pelvic muscles. And, do not squeeze your legs together or hold your breath while doing the exercises.*

Try this Routine

- 1. Start by pulling in and holding a pelvic muscle squeeze for 3 seconds then relax for an equal amount of time (3 seconds).*
- 2. Do this for 10 repetitions three times a day*
- 3. Try to hold for 1 second longer each week until you are holding for a 10 second squeeze.*
- 4. Remember to rest and breathe between contractions. Relaxing can be as important as squeezing*
- 5. At the beginning, do the exercises while lying down. As you get stronger; do the exercises while sitting or standing.*

**10 KEGELS
3 TIMES A DAY**

TIPS for Success. (Courtesy of Renovia, Inc.)

- Work as hard as you can to Lift. Exercise with **maximum** effort to get the best results.
- Make sure you have ‘keep me signed in’ checked on your *leva* app
- Complete all 5 exercise cycles to get credit for the session
- Keep the leva case near your phone during Training (less than 3 feet away, or at arm’s length)
- Track progress daily, weekly, monthly
- Contact your study team with any questions
- For technical assistance call 888-646-7760



*The **leva**® Pelvic Floor Trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urge incontinence in women.*

This product interacts with the user via smartphone technology.

***leva** Safety: Do not share your **leva**. **leva** is a single user medical product. Do not use **leva** in any other place in your body. Do not leave **leva** in your vagina overnight. If you experience odor, fever, vomiting, diarrhea, any signs of infections or any flu like systems, contact your healthcare provider immediately. If you experience redness or swelling near the insertion area, contact your healthcare provider, as you may have an allergic reaction to the silicone rubber.*

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Appendix 3. Responses to Individual Questions on Urogenital Distress Inventory (UDI-6) Questionnaire

UDI-6 Questions	Control			Intervention		
	Baseline n (%)	Week 4 n (%)	Week 8 n (%)	Baseline n (%)	Week 4 n (%)	Week 8 n (%)
Do you usually experience frequent urination?						
0-Not Present	40 (26%)	41 (27%)	52 (33%)	40 (28%)	54 (40%)	63 (44%)
1-Not at all	2 (1.3%)	2 (1.3%)	4 (2.6%)	0 (0%)	2 (1.5%)	3 (2.1%)
2-Somewhat	32 (21%)	42 (28%)	45 (29%)	30 (21%)	23 (17%)	38 (27%)
3-Moderately	35 (22%)	35 (23%)	28 (18%)	35 (24%)	33 (24%)	23 (16%)
4-Quite a bit	47 (30%)	32 (21%)	27 (17%)	38 (27%)	23 (17%)	16 (11%)
Do you usually experience urine leakage associated with a feeling of urgency?						
0-Not Present	36 (23%)	38 (25%)	41 (26%)	39 (27%)	45 (33%)	54 (38%)
1-Not at all	0 (0%)	0 (0%)	2 (1.3%)	1 (0.7%)	2 (1.5%)	0 (0%)
2-Somewhat	22 (14%)	36 (24%)	36 (23%)	20 (14%)	27 (20%)	34 (24%)
3-Moderately	20 (13%)	35 (23%)	34 (22%)	37 (26%)	26 (19%)	33 (23%)
4-Quite a bit	78 (50%)	43 (28%)	43 (28%)	46 (32%)	35 (26%)	22 (15%)
Do you usually experience urine leakage related to coughing, sneezing, or laughing?						
0-Not Present	0 (0%)	5 (3.3%)	5 (3.2%)	2 (1.4%)	8 (5.9%)	16 (11%)
1-Not at all	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	2 (1.4%)
2-Somewhat	11 (7.1%)	33 (22%)	48 (31%)	8 (5.6%)	38 (28%)	56 (39%)
3-Moderately	35 (22%)	51 (34%)	51 (33%)	37 (26%)	37 (27%)	33 (23%)
4-Quite a bit	110 (71%)	63 (41%)	51 (33%)	96 (67%)	52 (39%)	36 (25%)
Do you usually experience small amounts of urine leakage (drops)?						
0-Not Present	11 (7.1%)	21 (14%)	23 (15%)	13 (9.1%)	22 (16%)	32 (22%)

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1-Not at all	1 (0.6%)	1 (0.7%)	1 (0.6%)	0 (0%)	0 (0%)	5 (3.5%)
2-Somewhat	16 (10%)	36 (24%)	49 (31%)	18 (13%)	35 (26%)	52 (36%)
3-Moderately	62 (40%)	56 (37%)	47 (30%)	47 (33%)	38 (28%)	30 (21%)
4-Quite a bit	66 (42%)	38 (25%)	36 (23%)	65 (45%)	40 (30%)	24 (17%)
Do you usually experience difficulty emptying your bladder?						
0-Not Present	102 (65%)	115 (76%)	119 (76%)	99 (69%)	109 (81%)	112 (78%)
1-Not at all	1 (0.6%)	1 (0.7%)	2 (1.3%)	0 (0%)	0 (0%)	1 (0.7%)
2-Somewhat	18 (12%)	16 (11%)	13 (8.3%)	12 (8.4%)	9 (6.7%)	13 (9.1%)
3-Moderately	12 (7.7%)	8 (5.3%)	11 (7.1%)	16 (11%)	9 (6.7%)	6 (4.2%)
4-Quite a bit	23 (15%)	12 (7.9%)	11 (7.1%)	16 (11%)	8 (5.9%)	11 (7.7%)
Do you usually experience pain or discomfort in the lower abdomen or genital region?						
0-Not Present	135 (87%)	138 (91%)	145 (93%)	116 (81%)	112 (83%)	127 (89%)
1-Not at all	1 (0.6%)	1 (0.7%)	0 (0%)	1 (0.7%)	1 (0.7%)	0 (0%)
2-Somewhat	9 (5.8%)	8 (5.3%)	7 (4.5%)	10 (7.0%)	12 (8.9%)	12 (8.4%)
3-Moderately	7 (4.5%)	3 (2.0%)	3 (1.9%)	7 (4.9%)	5 (3.7%)	3 (2.1%)
4-Quite a bit	4 (2.6%)	2 (1.3%)	1 (0.6%)	9 (6.3%)	5 (3.7%)	1 (0.7%)

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