Original Research

Digital Therapeutic Device for Urinary Incontinence
A Randomized Controlled Trial

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OBJECTIVE: To evaluate whether pelvic floor muscle training using a motion-based digital intravaginal device is more effective than home pelvic floor muscle training for treatment of stress or stress-predominant mixed urinary incontinence (UI).

METHODS: In a remote, virtually executed 8-week prospective randomized controlled superiority trial, women with stress or stress-predominant mixed UI were randomized to pelvic floor muscle training using a motion-based digital therapeutic device or a home training program using written and narrated instructions. Primary outcomes were change in UDI-6 (Urogenital Distress Inventory, Short Form) score and stress urinary incontinence (SUI) episodes on a 3-day bladder diary. A sample size of 139 per group (n=278) was planned to meet the power analysis requirements for the UDI-6 score (n=278) and the bladder diary (n=78). Prespecified secondary outcomes included quality-of-life surveys and adherence reporting.

RESULTS: From September 2020 to March 2021, 5,353 participants were screened, and 363 were randomized: 182 in the intervention and 181 in the control group. There were no baseline clinicodemographic differences between groups. The mean change in UDI-6 score was significantly greater for the intervention group compared with the control group (18.8 vs 14.7, P=.01). The median (interquartile range) number of SUI episodes on the 3-day bladder diary was significantly reduced from 5 (3–8) and 5 (3–8) episodes to 1 (0–3) and 2 (1–4) (P=.005) in the intervention group compared with control group, respectively. A significantly greater number of participants in the intervention group than in the control group reported they were "much improved" or "very much improved" on the PGI-I (Patient Global Impression of Improvement) (63/143 [44.1% vs 45/156 [28.8%], odds ratio 1.94, 95% CI 1.21–3.15). There were no device-related severe adverse events.

CONCLUSION: In this all-remote, virtually conducted trial, pelvic floor muscle training guided by a motion-based digital therapeutic device resulted in significantly improved UI symptoms and reduction of UI episodes compared with a home training program.

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U rinary incontinence (UI) affects as many as 50% of women across their lifespans.[1] Prevalence

estimates rise with each decade of life, and symptom severity and related quality of life tend to worsen over time.[2–4] Pelvic floor muscle training represents first-line conservative treatment for UI, including stress urinary incontinence (SUI), urgency UI, and mixed UI subtypes. Though level I evidence supports the application of pelvic floor muscle training to improve and resolve UI symptoms,[5] uptake and adherence to training programs remain suboptimal, with multiple individual and institutional barriers to care.[6–8] These include limited patient knowledge about how to perform pelvic floor muscle training and limited access to care owing to a deficit of skilled professionals (ie, physical therapists, continence nurse specialists).[7,9]

In the absence of supervised care, women may embark on an unsupervised pelvic floor muscle training regimen, often with limited efficacy.[10] Digital health technologies have attempted to facilitate adherence to pelvic floor muscle training for this population, and early data suggest there is a role for mobile applications (apps) in the treatment of female UI.[11] Digital therapeutics represent a specialized niche within digital health as evidence-based, regulated, prescription products that incorporate digital systems, such as smartphone apps, to manage or treat a specific health condition.[12] Early feasibility studies using a motion-based digital therapeutic device to guide at-home pelvic floor muscle training provided limited efficacy data, because they were not adequately powered to show a difference between the device and home pelvic floor muscle training.[13,14] The device is composed of a small, flexible vaginal insert that takes the shape of the vagina when placed, and using accelerometers, reflects the motion of the vagina when pelvic floor muscles are contracted. Data are wirelessly communicated to the users' smartphone app, and adherence to the exercise program is transmitted for cloud-based storage (Fig. 1).

The current study is a larger, adequately powered, randomized controlled trial using this same device. The primary aim was to compare the efficacy of pelvic floor muscle training by using this digital therapeutic device with a home training program in reducing the severity of stress-predominant or stress-predominant mixed UI symptoms and incontinent episodes. Secondary aims were to assess health-related quality of life, adherence to pelvic floor muscle training, and other non-UI pelvic floor symptoms, as well as to examine safety.

METHODS

This was a prospective randomized controlled superiority trial evaluating the efficacy and safety
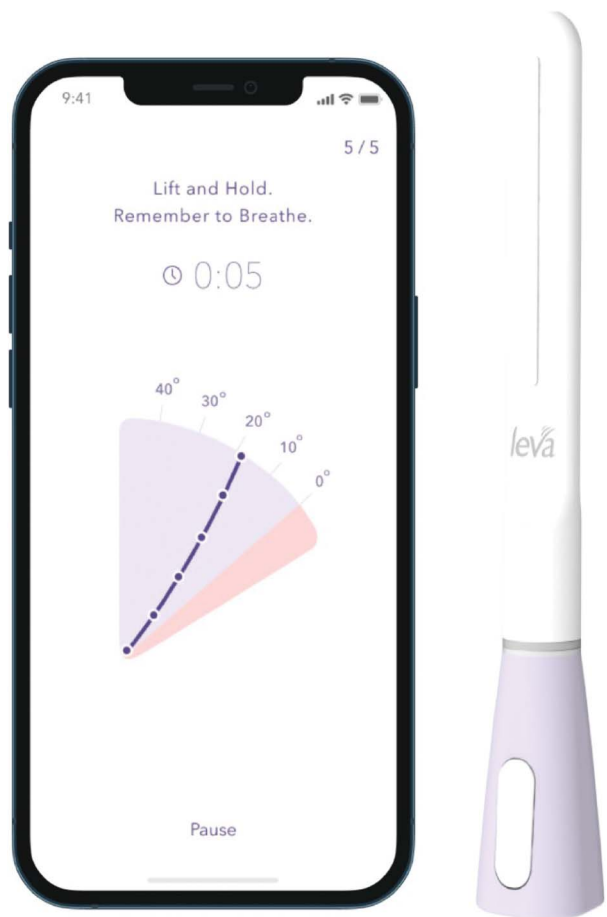
Fig. 1. Digital therapeutic device. Image courtesy of Renovia Inc.

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of a motion-based digital therapeutic device used to perform pelvic floor muscle training, compared with a standard home exercise program for the treatment of female SUI and stress-predominant mixed UI. The leva Pelvic Health System is indicated for the treatment of female SUI, urgency UI, mixed UI, and pelvic floor muscle weakness (U.S. Food and Drug Administration–cleared 510[k] K133990 and K180637). The device incorporates an intravaginal biofeedback component with a smartphone app. The intravaginal insert uses accelerometers to detect pelvic floor motion, and this motion-based biofeedback is visually depicted in the app. This is represented as a dial that shows correct and incorrect motion during pelvic floor muscle training. Data were cloud-captured and relayed to the prescribing health care professionals to enable remote monitoring of adherence using embedded validated surveys.

The study was conducted virtually in response to limitations on research imposed by the coronavirus disease 2019 (COVID-19) pandemic, in addition to literature supporting initiation of nonsurgical therapy after virtual visits in the absence of physical examination.[15] All screening and data collection were completed remotely. Women were recruited through advertising on social media outlets including Facebook, Instagram, and Twitter in the United States from October 2020 through March 2021. Ethics approval was obtained from Western Institutional Review Board (study no.1287912). The comprehensive study protocol (methods paper) has been published.[16]

Women at least 18 years of age with SUI or stress-dominant mixed UI symptoms for 3 months or longer were eligible. Before screening, participants provided informed consent by e-signature. Urinary incontinence type was determined by responses on the MESA (Medical, Epidemiologic and Social Aspects of Aging) questionnaire, where the MESA stress incontinence score was required to be greater than the MESA urgency incontinence score.[17] Before randomization, participants who met study criteria were prompted to download the study app (Claim-It!2020) and were required to supply demographic and medical history data, complete baseline questionnaires, and provide a 3-day bladder diary with a minimum of two stress incontinence episodes over the 3 days. Owing to the virtual nature of the study, these requirements served to minimize withdrawals and loss to follow-up. Race was included to determine whether our study population was representative of women with UI and was self-reported during the baseline assessment. Once completed, participants were randomized (1:1) to one of two study arms using computer-generated block randomization. Investigators were masked to group assignment. Participants were compensated $350 over the course of the study.

Participants in the intervention arm were mailed the device and written instructions (Appendix 1, available online at http://links.lww.com/AOG/C636) for use. After installing the device app, participants followed in-app instructions to set up the device and complete pelvic floor muscle training. The device was programmed to guide users through a two-and-a-half minute program of five 15-second contractions, followed by a 15-second relaxation period. Participants were asked to complete this training regimen three times per day.

Participants in the control arm were mailed written and video instructions (on a thumb drive) regarding performance of pelvic floor muscle training. These were adapted from the patient advocacy group affiliated with the American Urogynecologic Society (Voices of PFD)[18] and included an exercise frequency of three times per day with self-guided exercise progression from supine to standing positions as tolerated. The information provided to the control group is included in the supplemental materials (Appendix 2, available online at http://links.lww.com/AOG/C636).

All participants were asked to confirm receipt of their mailings within the data-collection app and were asked to schedule three phone calls. All participants were instructed to complete 8 weeks of daily training according to their group assignment. Eight weeks was chosen as the timing of the primary outcome based on prior research using the study device, as well as the authors' experience with the duration of supervised pelvic floor muscle training under the care of a physical therapist. Data were captured at baseline, 4 weeks, and 8 weeks. Participants in both arms scheduled three phone calls with clinical study staff to ensure they were comfortable with the education they received about the use of the device (intervention arm) or pelvic floor muscle training (control arm). These conversations were conducted with a script to ensure standardization of points addressed and answers to questions.

The two primary outcomes included change in UDI-6 (Urogenital Distress Inventory, Short Form) score from baseline to 8 weeks and change in number of SUI episodes on a 3-day bladder diary from baseline to 8 weeks. The UDI-6 is a validated questionnaire assessing the presence and degree of bother of UI symptoms and is scored 0–100 points.[19]

Secondary outcomes included the following validated measures: PGI-I (Patient Global Impression of Improvement); PGI-S (Patient Global Impression of Severity); PFIQ (Pelvic Floor Impact Questionnaire), highlighting the IIQ-7 (Incontinence Impact Questionnaire, short form); POPDI-6 (Pelvic Organ Prolapse Distress Inventory-6); CRADI-8 (Colorectal-Anal Distress Inventory-8); and PISQ-IR (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-revised).

Participants completed all questionnaires using the study app at baseline, 4 weeks, and 8 weeks. Self-reported adherence within each group was captured using a visual analog scale at 4 weeks and 8 weeks. Participants were asked to indicate what percentage of the time they completed pelvic floor muscle training, as directed (three times daily). In the intervention arm, device-reported adherence was recorded

automatically on each use of the device and reported as a cumulative percentage of adherence to a three-times-daily regimen at 4 weeks and at 8 weeks. Safety and adverse events data were captured throughout the duration of the trial.

Sample size calculation was performed using results from a pilot randomized trial that followed a similar protocol,[14] comparing baseline with 8-week results of the UDI-6 (subjective outcome measure) and SUI episodes on a bladder diary (objective outcome measure). The prior trial, though not adequately powered, demonstrated superior outcomes for the intervention device when compared with home pelvic floor muscle training alone; thus, a one-tailed t test was selected. The difference in scores for the UDI-6 was -13.7 (SD 18.7) in the treatment arm and -7.5 (SD 21.1) in the control arm, resulting in an effect size of 0.3. Power analysis was determined using this 0.3 effect size (alpha=0.05, power=0.8, using a one-tailed t test), with a calculated sample size of 278. Allowing for an attrition rate of 20% owing to the uncertainty introduced with a virtual trial format, 350 participants were targeted for randomization. Because we elected to use both a subjective and an objective primary outcome, we performed a power analysis for the bladder diary measure as well. The difference in scores for SUI episodes on a bladder diary in the same trial was 0.6 (SD 1.7) in the control arm and 1.9 (SD 2.2) in the intervention arm, with an effect size of 0.6. The sample size needed to adequately power this outcome from baseline to week 8 using alpha=0.05, and power of 0.8, resulted in a needed sample of 78 participants.

Participant demographics, medical history, and baseline UDI-6 scores and data from 3-day bladder diaries were collected. Mean scores were calculated for each measure, including the POPDI-6, CRADI-8, PISQ-IR, and PFIQ (with IIQ), for each group. Paired t tests or Wilcoxon rank-sum tests were applied to determine score differences in baseline and posttreatment scores within and between treatment groups, as appropriate. The χ^2 test was used to analyze the PGI-I and PGI-S measures.

Because the UDI-6 does not have an established minimum clinically important difference, UDI-6 scores were converted to UDI long form scores to determine whether a minimum clinically important difference of 11 points was met for each group.[20,21] The Wilcoxon signed-rank test was used to determine the 8-week treatment differences in median SUI episodes within and between treatment groups. Participant self-reported adherence was plotted against device-reported adherence for the intervention group at 8 weeks to assess the relationship between these two variables. $P<.05$ was considered statistically significant. R 1.4.113 software was used for statistical analyses.

A modified intention-to-treat analysis was applied for the primary outcome analysis, where participants with at least one data point reported at 8 weeks were included in the final analysis.

ROLE OF THE FUNDING SOURCE

RESULTS

A total of 5,353 women were consented and completed online screening; 363 participants were randomized. Data were available for analysis for 299 participants, with 143 in the intervention group and 156 in the control group. The CONSORT (Consolidated Standards of Reporting Trials) study flow diagram is illustrated in Figure 2. Participants' demographics and clinical characteristics are presented in Table 1. Overall, mean age of participants was 51.7 ± 13 years and mean body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) was 31.7 ± 7.4; racial and ethnic distribution is summarized in Table 1. There were no significant differences between groups in any characteristics at baseline. There were no significant baseline differences between those who were excluded from analysis and those who were included (data
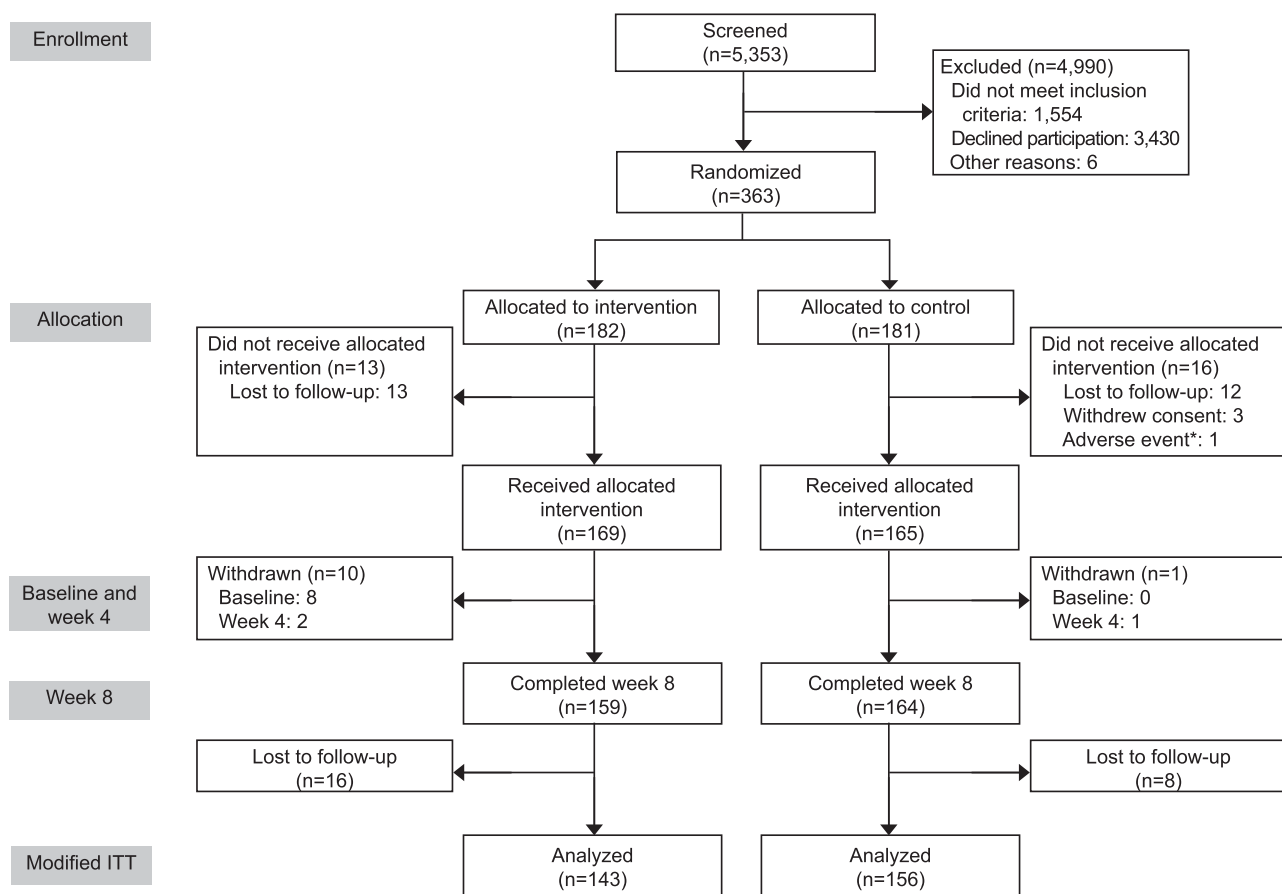
Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. ITT, intention-to-treat. *Coronavirus disease 2019 (COVID-19).

Weinstein. Digital Therapeutic for Urinary Incontinence. Obstet Gynecol 2022.

not shown). Additionally, there were no significant differences in the number of individuals who participated in the three scheduled phone calls between the intervention group (86/143, 60%) and the control group (107/156, 69%) (*P*=.13).

Results of the primary outcomes are noted in Tables 2 and 3. Both groups achieved improvement in UDI-6 scores over the treatment period with the intervention group reaching a significantly greater score improvement compared with the control group. The percentage difference between the mean change in UDI-6 scores was 34.5%. Responses to individual UDI-6 questions are presented in Appendix 3, available online at http://links.lww.com/AOG/C636. UDI-6 score was significantly improved in both groups from baseline to 4 weeks and from 4 weeks to 8 weeks. However, the intervention group reached significantly greater improvement than the control group at both timepoints (absolute mean change: baseline–4 weeks, 15.

3±13.3 vs 12.1±10.8, *P*=.026; 4–8 weeks, 13.2±11.2 vs 8.9±8.8, *P*<.001), with the overall absolute mean change between baseline and week 8 at 18.8 compared with 14.7 (*P*=.011) for the intervention and control groups, respectively. The intervention group met or exceeded the minimum clinically important difference of 11 points at both the 4- and 8-week postintervention timepoints; the control group met minimum clinically important difference at 4 weeks but not at 8 weeks. The 3-day bladder diary results showed that the median (interquartile range) number of SUI episodes at 8 weeks was significantly fewer in the intervention arm (1 [0–3]) than in the control arm (2 [1–4]) (z=−2.9, *P*=.005). More participants in the intervention group (59/143) than in the control group (37/139) (*P*=.036) reported a 50% or greater reduction in SUI episodes (odds ratio 1.7, 95% CI 1.03–2.81).

Overall, 36% (108/299) of participants reported they were "much better" or "very much better" on

Table 1. Participant Demographics and Baseline Characteristics

Characteristic	Control Group (n=156)	Intervention Group (n=143)	Total (N=299)
Age (y)	51.5±12.6	52.02±12.9	51.74±12.7
	50 (18–78)	53 (22–75)	52 (18–78)
Race			
Asian	8 (5.1)	3 (2.1)	11 (3.7)
Black	12 (7.7)	17 (11.9)	29 (9.7)
Middle Eastern, North African	0 (0.0)	1 (0.7)	1 (0.3)
Multi*	2 (1.3)	7 (4.9)	9 (3.0)
Pacific Islander, Native Hawaiian	0 (0)	0 (0)	0 (0)
Unknown	0 (0)	1 (0.7)	1 (0.3)
White	131 (84.0)	109 (76.2)	240 (80.3)
None of the above[†]	3 (1.9)	5 (3.5)	8 (2.7)
Ethnicity			
Hispanic, Latina	14 (9.0)	17 (11.9)	31 (10.4)
Not Hispanic, Latina	142 (91.0)	124 (86.7)	266 (89.0)
Declined to answer	0 (0.00)	2 (1.4)	2 (0.7)
BMI (kg/m²)	31.8±7.5	31.5±7.3	31.7±7.4
	31.3 (18.1–63.9)	30.9 (16.7–50.0)	31.0 (16.7–63.9)
No. of pregnancies			
0	22 (14.1)	15 (10.5)	37 (12.4)
1	23 (17.2)	19 (14.8)	42 (14.1)
2	44 (32.8)	34 (26.6)	78 (26.1)
3 or more	67 (43.0)	75 (52.5)	142 (47.5)
Mode of delivery			
Vaginal	76 (48.7)	79 (55.2)	155 (51.8)
Forceps or vacuum	32 (20.5)	28 (19.6)	60 (20.1)
Cesarean	19 (12.2)	18 (12.6)	37 (12.4)
Menopausal status[‡]			
Postmenopausal	83 (53.2)	79 (55.2)	162 (54.2)
Premenopausal	73 (46.8)	64 (44.8)	137 (45.8)
SF-20 score	67.0±18.3	70.3±17.5	68.5±18.0

BMI, body mass index; SF-20, Short Form Health Survey.
Data are mean±SD, median (range), or n (%).
* Participant self-identified two or more categories.
[†] Participant identified as "other."
[‡] If menopausal status was not specified, participants aged 55 years and older were assumed to be menopausal.

the PGI-I. A significantly greater number of participants in the intervention group than in the control group reported this improvement (63/143 [44.1%] vs 45/156 [28.8%], odds ratio 1.9, 95% CI 1.2–3.2). Each group achieved significant improvement in IIQ-7 scores over the 8-week period (absolute difference 18.4 [intervention] and 18.4 [control], P=.001), with no significant difference between groups (P=.99). At week 8, there was no difference in perception of disease severity (PGI-S) between groups (P=.51).

Additional secondary outcome measures are noted in Table 4. Both groups achieved significant improvement from baseline to 8 weeks on the CRADI-8, POPDI-6, PISQ-IR, and PFIQ, and there were no significant differences between groups on these measures (P=.65, .93, .96, and 0.14, respectively).

Self-reported adherence over 8 weeks was 84% in the intervention group and 89% in the control group; device-reported adherence for the intervention group was 69%. The differences between self- and device-reported adherence in the intervention group are presented in Figure 3. At week 8, 78.5% of participants (106/143) self-reported their adherence as higher than the device reported, and 21.5% agreed with or underreported when compared with the device. Participants in the lowest quartile of device-reported adherence had a greater divergence between device- and self-report (mean divergence 37.3% ±28.8) compared with those in the highest quartile of device-reported performance (mean divergence 8.8% ±6.6, P=.001, 95% CI 19.4–37.6).

There were no device-related serious adverse events reported. Five participants reported urinary

Table 2. Baseline and Week 8 Primary Subjective Outcome

| Group | UDI-6 Score | | Within-Group P* | Between-Groups P† |
	Baseline	Week 8		
Control	54.6±18.8	42.8±19.3	<.001	.01
Intervention	52.9±19.8	36.3±20.8	<.001	

UDI-6, Urogenital Distress Inventory, Short Form.
Data are mean±SD unless otherwise specified.
* Paired *t* test.
† *t* test.

tract infections: 1.7% in the control group (3/181) and 1.1% in the intervention group (2/182). Six participants reported vaginal irritation: 0.55% in the control group (1/181) and 2.7% in the intervention group (5/182). Of 363 participants, 11 had treatment interruptions due to COVID-19 illness.

DISCUSSION

In this robustly designed virtually conducted randomized controlled trial, pelvic floor muscle training guided by a motion-based digital therapeutic device yielded greater improvement of urinary symptom severity and degree of bother as measured by UDI-6 and by a 3-day bladder diary, compared with a home training program. In both groups, baseline UDI-6 scores were high (greater than 50), indicating severe incontinence symptoms and bother, with a score of 25 being associated with treatment seeking for UI.[22] Mean UDI-6 improvement reached statistical significance for both groups by 4 weeks, with the intervention arm significantly more improved than the control arm at both 4 and 8 weeks. Women in both groups saw clinical symptom improvement as measured by minimum clinically important difference on UDI change scores. The intervention group met or exceeded the minimum clinically important difference of 11 points at both the 4- and 8-week timepoints, whereas the control group met

the minimum clinically important difference at 4 weeks but not again at 8 weeks. Early and continued symptom improvement may enhance patient self-efficacy regarding pelvic floor muscle training and positively influence adherence to treatment over time.

A greater number of participants in the intervention group than the control group indicated that their symptoms were "much better" or "very much better" on the PGI-I. This is consistent with the greater symptom improvement identified on the UDI-6. Although both groups demonstrated significant improvement on the IIQ and PFIQ scales, there was no significant difference between them. This is a somewhat surprising finding given that the PGI-I was validated in part using correlations with incontinence-specific quality-of-life questionnaires.[23] It is possible that the value of these questionnaires during the COVID-19 pandemic may be limited, because many questions relate to activities that were affected by quarantine restrictions, such as attending movies or concerts, participating in social activities outside the home, travel, or going to the gym. A few publications have explored the effect of the COVID-19 pandemic restrictions on survey results for sexual health and UI,[24,25] but there is a paucity of data reporting UI-specific quality-of-life surveys within the pandemic.

Among those using the device, there was a discrepancy between self-reported adherence and

Table 3. Baseline and Week 8 Primary Objective Outcome

| Group | SUI Episodes (3-d Diary) | | Within-Group P* | Between-Groups P† |
	Baseline	Week 8		
Control	5 (3–8)	2 (1–4)	<.001	.005
Intervention	5 (3–8)	1 (0–3)	<.001	

SUI, stress urinary incontinence.
Data are median (interquartile range) unless otherwise specified.
* Wilcoxon signed-rank test.
† Wilcoxon rank-sum test.

Table 4. Baseline and Week 8 Secondary Outcomes

Outcome Measure	Baseline	Week 8	P*	Absolute Difference	P†
POPDI-6					
Control	15.2±16.9	8.9±12.7	<.001	8.2 (9.9)	.93
Intervention	15.4±17.6	10.4±15.0	<.001	8.3 (10.6)	
CRADI-8					
Control	22.1±20.1	16.8 (18.5)	<.001	10.8 (10.8)	.65
Intervention	19.8±20.1	17.0 (19.0)	.02	10.3 (11.3)	
PFIQ					
Control	59.1±51.4	36.17±41.7	<.001	29.9 (27.7)	.96
Intervention	58.2±51.8	32.1±34.2	<.001	30.0 (32.2)	
IIQ-7					
Control	40.6±26.8	25.6±22.9	<.001	18.4 (15.8)	.99
Intervention	38.4±25.7	22.2±19.2	<.001	18.4 (16.6)	
PISQ-IR					
Control	2.7±0.3	4.2±0.9	<.001	1.6 (1.0)	.14
Intervention	2.7±0.3	4.0±1.0	<.001	1.4 (1.0)	

POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; CRADI-8, Colorectal-Anal Distress Inventory-8; PFIQ, Pelvic Floor Impact Questionnaire; IIQ, Incontinence Impact Questionnaire; PISQ-IR, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised.
Data are mean±SD unless otherwise specified.
* Paired *t* test.
† *t* test.

device-reported adherence, such that most users over-estimated their adherence, and infrequent users over-estimated adherence by a greater amount than those who were more adherent. This finding underscores the challenges in self-reporting and renders the validity of self-reported adherence questionable. Device-reported adherence in the current study aligns with the 70% adherence reported in a study of physiotherapy-guided home pelvic floor muscle training.[26]

Strengths of this study include the large sample size, with power to detect clinically important differences and minimal loss to follow-up over the 8-week period. The virtual nature of the study was novel and permitted nationwide recruitment of community-dwelling participants despite the COVID-19 pandemic, including those outside the reach of major academic medical centers, where large trials often take place. The virtual study design also allowed for uninterrupted data collection during the COVID-19 pandemic. The large number of participants screened compared with participants eligible and randomized may be typical of virtually conducted studies,[27] although this is a successful virtually conducted study using social media recruitment among women with UI. A weakness of the study was the inability to conduct a physical examination before enrollment. For example, pelvic organ prolapse beyond the introitus was an exclusion criterion, and participants were asked about "seeing or feeling a bulge," a question

that has been used in other epidemiologic studies.[28] Baseline pelvic floor muscle strength assessment may have added value to a study of first-line UI treatment,
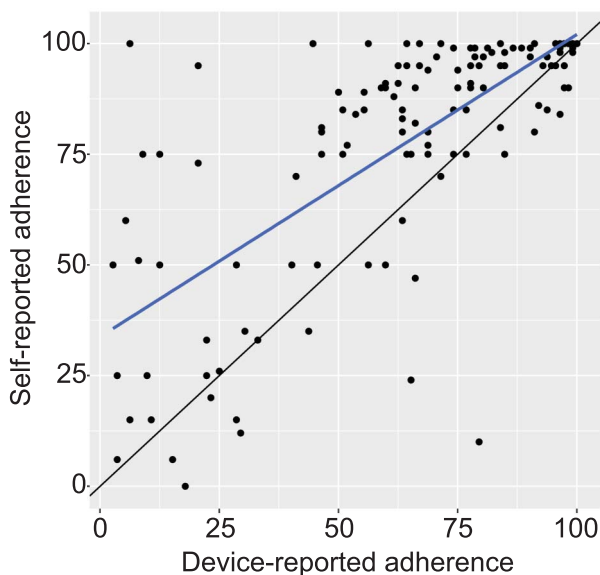

Fig. 3. Device- vs self-reported adherence (intervention group only). Adherence of each participant in the intervention group is plotted as percent of use based on perfect use of three times daily. The *black line* indicates ideal fit for assuming perfect match for self- vs device-reported adherence. The *blue line* is the trend line for the actual self- vs device-reported adherence.

Weinstein. Digital Therapeutic for Urinary Incontinence. Obstet Gynecol 2022.

although research and expert consensus supports digital health in the remote context, including initiation of pelvic floor muscle training in the absence of a physical examination.[15]

This study used a conservative version of the device available for use incorporating motion-based biofeedback and remote monitoring. Components, including audio–visual evidence-based education, remote coaching, and monthly patient progress reports to prescribing health care professionals, of the commercial version of the device were removed from the system used in the trial. Future work will investigate these additional components and potential added benefits to pelvic floor muscle training alone.

This study demonstrates efficacy and safety of a motion-based digital therapeutic device to guide pelvic floor muscle training for women with SUI and stress-dominant mixed UI, yielding superior results compared with a home program of written and verbal instructions. Additionally, the device enables remote monitoring of adherence to pelvic floor muscle training, which offers a new opportunity for obstetrician-gynecologists to monitor and engage with patients during first-line care. Longer-term follow-up is underway to better understand the durability of the treatment regimen and evaluate the need for maintenance exercises to maintain the benefits of therapy.

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Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Data are available upon request.*

What data in particular will be shared? *Deidentified data from the trial (core variables and outcomes) are available upon request.*

What other documents will be available? *Statistical analysis plan, protocols, and ethics approvals are all available upon request.*

When we data be available (start and end dates)? *Data will be available for 5 years from the submission of the manuscript.*

By what access criteria will data be shared (include whom, for what types of analyses, and by what mechanism)? *Deidentified data from the trial (core variables and outcomes) can be made available to investigators who provide a written request to the corresponding author, regarding systematic review and meta-analysis. Decisions regarding data sharing will be made in conjunction with the sponsor.*

PEER REVIEW HISTORY