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Original Research

Digital Therapeutic Device for Urinary Incontinence

A Longitudinal Analysis at 6 and 12 Months

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OBJECTIVE: To evaluate the long-term efficacy of an 8-week regimen of pelvic floor muscle training guided by a motion-based digital therapeutic device compared with a standard home program in the treatment of stress urinary incontinence (SUI) and stress-predominant mixed urinary incontinence (MUI).

METHODS: The primary virtual trial was conducted from October 2020 to March 2021; 363 women with SUI or stress-predominant MUI were randomized to complete pelvic floor muscle training using the device (intervention group) or a standard home pelvic floor muscle training program (control group) for 8 weeks. Primary outcomes included change in UDI-6 (Urogenital Distress Inventory, Short Form) score and SUI episodes on a 3-day bladder diary. The PGI-I (Patient Global Impression of Improvement) was also assessed, with "much better" and "very much better" responses considered as improvement. In this planned secondary analysis, symptom and adherence data were collected in follow-up at 6 and 12 months. A modified intention-to-treat analysis was performed using Student's *t* tests and χ^2 tests as appropriate.

RESULTS: Of 299 participants analyzed at 8 weeks, 286 (95.7%) returned 6- and 12-month data (151 in the control group, 135 in the intervention group). Mean age was 51.9±12.8 years, and mean body mass index (BMI) was 31.8±7.4; 84.6% of participants were parous, and 54.9% were postmenopausal. Mean change in UDI-6 score from baseline to 6 and 12 months was significantly greater in the intervention group than in the control group (20.2±20.9 vs 14.8±19.5, *P*=.03 and 22.7±23.3 vs 15.9±20.3, *P*=.01, respectively). Participants in the intervention group had more than twice the odds of reporting improvement on the PGI-I compared with participants in the control group (OR 2.45, 95% CI 1.49–4.00).

CONCLUSION: Pelvic floor muscle training guided by a motion-based digital therapeutic device yielded significantly greater urinary incontinence symptom improvement compared with a standard home pelvic floor muscle training program at 6 and 12 months, although continued improvement waned over time. This technology may facilitate pelvic floor muscle training access and adherence for women with SUI and stress-predominant MUI and represents an effective modality for scaling first-line care.

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Urinary incontinence (UI) affects more than 60% of adult women in the United States, with more than 28 million reporting moderate or severe symptoms.[1] First-line management for stress urinary incontinence (SUI), urgency urinary incontinence (UUI), and mixed urinary incontinence (MUI) subtypes includes pelvic floor muscle training.[2,3] Supervised pelvic floor muscle training optimizes treatment results and can lead to improvement or resolution of UI symptoms.[4] However, most women do not access skilled care, do not adhere to pelvic floor muscle training programs, or do not perform exercises correctly.[5–9]

Emerging digital health technologies have shown promise in aiding treatment for female UI and promoting adherence to pelvic floor muscle training programs.[10,11] Digital therapeutics represent a category of digital health that includes evidence-based, software-enabled products designed to prevent, treat, or manage a specific health condition.[12] Initial results from an 8-week randomized controlled trial of the efficacy of a motion-based digital therapeutic device to guide pelvic floor muscle training for the treatment of SUI and stress-dominant MUI demonstrated superiority over a standard home pelvic floor muscle training program.[11]

The primary objective of this planned secondary analysis was to evaluate the long-term efficacy of an 8-week regimen of pelvic floor muscle training guided by a motion-based digital therapeutic device compared with a standard home pelvic floor muscle training program in the treatment of SUI and MUI. Secondary objectives were to evaluate long-term health-related quality of life, adherence to pelvic floor muscle training, impression of improvement, and non-UI pelvic floor symptoms. We hypothesized that the improvement in UI symptoms achieved by participants during the initial 8-week active study period would remain superior in the intervention group at 6 and 12 months compared with baseline.

METHODS

This study reports 6- and 12-month planned follow-up from a prospective, randomized controlled trial to evaluate the safety and efficacy of a motion-based digital therapeutic device in the treatment of SUI and stress-dominant MUI when compared with a standard home pelvic floor muscle training program (clinical trial registration: NCT04508153; Western IRB No. 1287912).

The device (*leva* Pelvic Health System) combines an intravaginal component and associated smartphone application (app) to guide pelvic floor muscle training. Using accelerometers, the intravaginal component measures the motion produced during a pelvic floor muscle contraction. This motion is represented in the smartphone app, where users can visualize correct and incorrect motion during pelvic floor muscle training. The device enables remote monitoring of adherence, performance, and symptom information. It is indicated for the treatment of SUI, MUI, and mild-to-moderate UUI, including overactive bladder, pelvic floor muscle weakness, and chronic fecal incontinence (U.S. Food and Drug Administration–cleared 510[k] K133990, K180637 and K213913).

The original study protocol and 8-week results have been published previously.[11,13] Briefly, from October 2020 through March 2021, 363 women aged 18 years or older with SUI or stress-dominant MUI were recruited through social media platforms to participate in a remote, virtually conducted trial. Screening and data collection were completed remotely using a research app (ClaimIt!2020). Block randomization was used to assign participants 1:1 to one of two groups. The control group received standardized written and video instructions to perform self-guided pelvic floor muscle training three times daily in a regimen adapted from the patient advocacy group affiliated with the American Urogynecologic Society (Voices of PFD).[14] The intervention group received the device, which was programmed to guide users through a three-times-daily, 2.5-minute pelvic floor muscle training program of five 15-second contractions, alternating with a 15-second rest period, completed in the standing position. All participants were instructed to complete training three times daily for a period of 8 weeks, after which they were free to stop training, continue training if desired, pursue additional treatment options, or a combination of these. Primary outcomes of the primary trial included change in score on the UDI-6 (Urogenital Distress Inventory, Short Form), a validated measure of the presence and degree of bother of UI symptoms,[15] and the change in number of SUI episodes on a 3-day bladder diary. Secondary outcomes included the PGI-I (Patient Global Impression of Improvement), with *overall improvement* defined as "very much better" or "much better"; the PGI-S (Patient Global Impression of Severity); the PFIQ (Pelvic Floor Impact Questionnaire), which includes the IIQ-7 (Incontinence Impact Questionnaire, Short Form) subscale; the POPDI-6 (Pelvic Organ Prolapse Distress Inventory 6); the CRADI-8 (Colorectal Anal Distress Inventory-8); and the PISQ-IR (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised). Outcome surveys were completed at baseline, 4 weeks, and 8 weeks. Participants were compensated $100 for completion at each follow-up interval.

For the planned follow-up, all surveys were collected at 6 and 12 months. Bladder diary results were assessed during the primary study but were not collected at 6 and 12 months. Importantly, during the 8-week active study, participants in each group were asked to exercise three times a day; however, for the 6- and 12-month follow-up, study participants were not asked to continue their exercises with any specific regimen, though they could continue if they wished in an ad lib fashion. At 8 weeks, adherence to pelvic floor muscle training was assessed by self-report for both groups and was passively monitored by the device in the intervention group. Device-reported adherence was assessed at 6 and 12 months. Safety data were collected throughout the study.

Participant demographics and clinical characteristics were summarized for the 6- and 12-month follow-up presented in the current article. This included participant-reported race and ethnicity, collected to ensure that the study population was representative of women with UI. Mean scores on each survey were calculated. UDI-6 scores were also converted to UDI Long Form scores to determine whether each group met the established minimum clinically important difference (MCID) of 11 points.[16,17] A modified intention-to-treat analysis was applied; participants with at least one data point at 8 weeks were included in the analysis. For UDI-6, PFIQ, POPDI-6, CRADI-8, and PISQ-IR scores, paired *t* tests were performed to determine within-group differences and Student's *t* tests

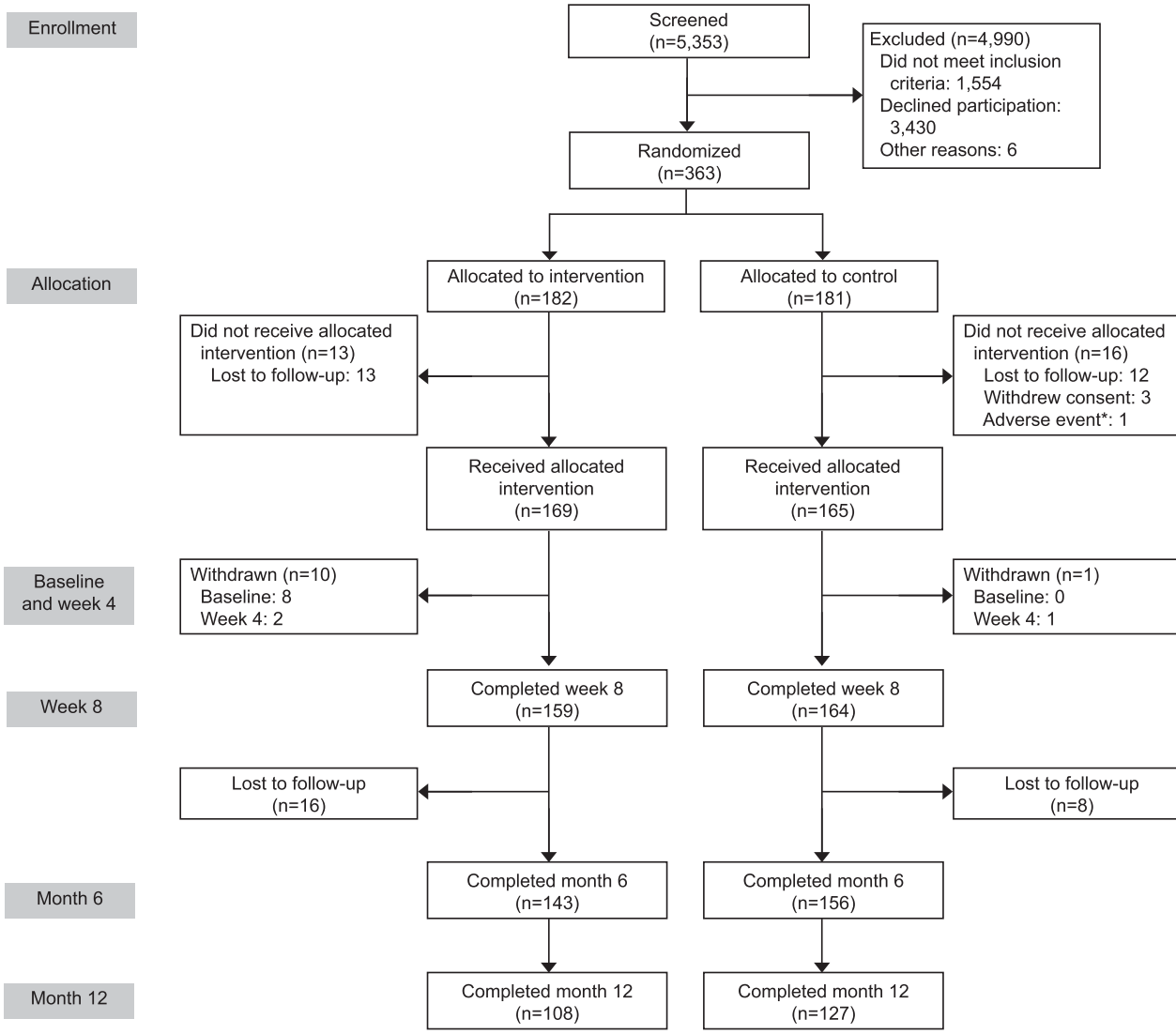

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) diagram. *Patient had coronavirus disease 2019 (COVID-19).
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were conducted to determine between-group differences at each timepoint. Chi-square tests were used to assess PGI-I and PGI-S outcomes, examining the proportion of participants who responded "very much better" or "much better" on the PGI-I and "moderate" or "severe" on the PGI-S. Nonresponders were assumed to have negative response on these measures. Statistical analyses were completed using R 1.4.113.

RESULTS

Of 299 participants analyzed at 8 weeks, 286 (95.7%) returned both 6- and 12-month data, 151 and 135 in the control and intervention groups, respectively. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram is presented in Figure 1. Table 1 presents demographic and clinical data for all participants at 6 and 12 months, because there was no loss to follow-up between those time points. Mean age was 51.9±12.8 years, and mean body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) was 31.8±7.4; 84.6% of participants were parous, and 54.9% were postmenopausal. There were no significant differences between groups at baseline and no significant differences between those who provided long-term data and those who did not (data not shown), or between those who did not provide data beyond baseline and those who completed the 12-week follow-up (Appendix 1, available online at http://links.lww.com/AOG/C972).

Mean change in UDI-6 score was significantly greater in the intervention group than in the control group at 8 weeks (previously published[11]), 6 months, and 12 months compared with baseline (P=.03, P=.01, Table 2, Fig. 2). Both groups met or exceeded the 11-point MCID from baseline to 12 months, with the intervention group reporting significantly greater improvement. From 8 weeks to 12 months, both groups reported statistically significant score improvements that did not differ significantly between groups. The difference between groups also did not reach MCID. The intervention group met the MCID from 8 weeks to 12 months, whereas the control group did not (Table 3).

Table 1. Participant Demographics and Clinical Characteristics at 6 and 12 Months

Demographic	Control (n=151)	Intervention (n=135)	Total (N=286)	*P*
Age (y)	51.6±12.7 50 (43–62)	52.2±13.0 53 (42–65)	51.9±12.8 52 (42–64)	.70
Race				
Asian	7 (4.6)	2 (1.5)	9 (3.2)	.18
Black	12 (8.0)	17 (12.6)	29 (10.1)	
White	127 (84.1)	105 (77.8)	232 (81.1)	
Middle Eastern/North African	0 (0.0)	1 (0.7)	1 (0.4)	
Multi	2 (1.3)	5 (3.7)	7 (2.5)	
Other*	3 (2.0)	4 (3.0)	7 (2.5)	
Unknown*	0 (0.0)	1 (0.7)	1 (0.4)	
Ethnicity				
Hispanic/Latina	13 (8.6)	14 (10.4)	27 (9.4)	.35
Not Hispanic/Latina	138 (91.4)	119 (88.2)	257 (89.9)	
Declined to answer	0 (0.0)	2 (1.5)	2 (0.7)	
BMI (kg/m^2)	31.9±7.5 31.5 (26.6–35.4)	31.6±7.3 30.9 (25.9–36.8)	31.8±7.4 31.1 (26.1–36.5)	.71
Parity	2 (1–4)	3 (2–3)	2 (1–4)	.70
Mode of delivery				
Vaginal	71 (47.0)	73 (54.1)	144 (50.4)	.55
Forceps or vacuum	33 (21.9)	29 (21.5)	62 (21.7)	
Cesarean	20 (13.3)	16 (11.9)	36 (12.6)	
Menopausal status†				
Postmenopausal	81 (53.6)	76 (56.3)	157 (54.9)	.65
Premenopausal	70 (46.4)	59 (43.7)	129 (45.1)	

BMI, body mass index.
Data are mean±SD, median (interquartile range), or n (%) unless otherwise specified.
* Other and Unknown were prespecified categories that participants could choose.
† If menopausal status was not specified, participants aged 55 years or older were assumed to be menopausal.

Table 2. UDI-6 (Urogenital Distress Inventory, Short Form) Score Change From Baseline to 8 Weeks, 6 Months, and 12 Months

	UDI-6 Score Change	Within-Group *P**	Between-Group *P*†	Mean Difference Between Groups (95% CI)
Baseline to 8 wk				
Control group	14.7±12.2‡	**.001**	**.01**	4.1 (1.0–7.2)
Intervention group	18.8±15.0‡	**.001**		
Baseline to 6 mo				
Control group	−14.8 (19.5)‡	**<.001**	**.03**	5.4 (0.7–10.1)
Intervention group	−20.2 (20.9)‡	**<.001**		
Baseline to 12 mo				
Control group	−15.9 (20.3)‡	**<.001**	**.01**	6.8 (1.7–11.9)
Intervention group	−22.7 (23.3)‡	**<.001**		

UDI-6, Urogenital Distress Inventory, Short Form.
Data are mean±SD unless otherwise specified.
Bold indicates statistical significance.
* Paired *t* test.
† Student's *t* test.
‡ Met minimum clinically important difference.

Assuming negative responses for participants who did not provide follow-up data at 6 and 12 months, the proportion of participants who reported "much better" or "very much better" on the PGI-I was significantly greater in the intervention group than in the control group at 6 months (43.4% vs 21.2%, respectively, *P*<.001, OR 2.85, 95% CI 1.73–4.78) and 12 months (44.1% vs 24.3%, respectively, *P*<.001, OR 2.45, 95% CI 1.49, 4.00). Participants in the intervention group had more than twice greater likelihood of improvement at 6 and 12 months.

Additional secondary outcomes are summarized in Table 4. Both groups experienced significant improvement in quality of life and non-UI pelvic health outcomes, and there was no significant difference between groups on these measures. Assuming that the participants who did not provide 6- and 12-month responses had severe disease, the proportion of participants who reported moderate or severe disease at 12 months on the PGI-S was 33.1% in the control group (50/151) and 22.2% in the intervention group (30/135), OR 1.73 (1.02–2.94).

For the intervention group, device-reported adherence was 69% at 8 weeks, 13% at 6 months, and 17% at 12 months. A sensitivity analysis was completed to determine whether participants who continued to use the device beyond 8 weeks achieved greater UDI-6 score improvements at 12 months compared with participants with low or no adherence. There was no

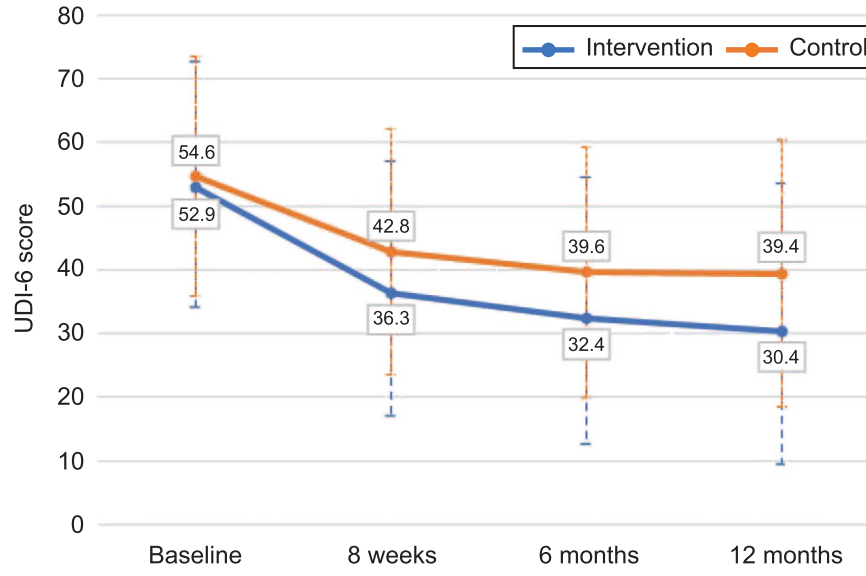

Fig. 2. Mean UDI-6 (Urogenital Distress Inventory, Short Form) scores with SDs. *Error bars* represent SDs.

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Table 3. Interval UDI-6 (Urogenital Distress Inventory, Short Form) Score Change After Completion of 8 Weeks of Therapy

	UDI-6 Score Change	Within-Group *P**	Between-Group *P*†	Mean Difference Between Groups (95% CI)
8 wk to 6 mo				
Control group	−2.8 (15.3)	**0.03**	0.57	1.2 (−2.7 to 5.1)
Intervention group	−4.0 (17.9)	**0.01**		
8 wk to 12 mo				
Control group	−3.71 (17.8)	**0.04**	0.29	2.6 (−2.0 to 7.1)
Intervention group	−6.3 (21.3)‡	**0.001**		
6 mo to 12 mo				
Control group	0.02 (16.6)	0.99	0.5	1.4 (−2.5 to 5.3)
Intervention group	−1.35 (16.5)	**0.04**		

UDI-6, Urogenital Distress Inventory, Short Form.
Data are mean±SD unless otherwise specified.
Bold indicates statistical significance.
* Paired *t* test
† Student's *t* test
‡ Met minimum clinically important difference.

significant effect of long-term use as reported by the device (*P*=.86).

No device-related serious adverse events were reported during the study period. At 12 months, 13 participants in the control group and four in the intervention group reported additional UI treatment, including pelvic floor physical therapy (3), medication (5), surgery (4), weight loss (1), laser (1), and continued pelvic floor muscle training (11). When these participants were excluded from the analysis, the differences between groups remained significant at 12 months.

DISCUSSION

Pelvic floor muscle training guided by a motion-based digital therapeutic device yielded significantly greater UI symptom improvement compared with a standard home pelvic floor muscle training program at 8 weeks, with results maintained at 6 and 12 months. Improvements decreased over time for both groups; however, the intervention group still met the MCID of symptom improvement during this timeframe. UDI-6 scores did not differ between the groups at either 6 or 12 months; neither did the differences

Table 4. Secondary Outcome Measures at Baseline and 12 Months

Outcome Measure	Baseline	12 mo	*P* for Difference Within Groups*	*P* for Difference Between Groups†
IIQ-7				
Control group	40.6±25.8	23.8±24.1	<.001	.54
Intervention group	38.43±25.73	22.2±19.18	<.001	
PFIQ				
Control group	59.1±51.4	38.1±50.3	<.001	.74
Intervention group	58.2±51.8	28.6±40.7	<.001	
POPDI-6				
Control group	15.2±16.9	10.6±14.9	<.001	.53
Intervention group	15.4±17.6	7.7±14.7	<.001	
CRADI-8				
Control group	22.1±20.1	14.2±17.8	<.001	.29
Intervention group	19.8±20.1	11.0±15.6	<.001	
PISQ-IR				
Control group	2.7±0.3	4.2±0.9	<.001	.46
Intervention group	2.8±0.3	4.1±1.0	<.001	

IIQ-7, Incontinence Impact Questionnaire, Short Form; PFIQ, Pelvic Floor Impact Questionnaire, POPDI-6, Pelvic Organ Prolapse Distress Inventory 6; CRADI-8, Colorectal Anal Distress Inventory-8; PISQ-IR, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised.
Data are mean±SD unless otherwise specified.
* Paired *t* test
† Student's *t* test

between groups meet the MCID. Participants in the intervention group were more than twice as likely to report symptom improvement on the PGI-I at the end of the study period.

Because the participants of our study were not given specific instructions to perform pelvic floor muscle training for the 6- and 12-month follow-up periods, we did not expect further improvement in UDI-6 scores in either group, but rather hypothesized that the groups would maintain the effect of the initial, intense 8-week pelvic floor muscle training period. Surprisingly, our results demonstrate that both groups showed statistically significant improvement from 8 weeks to 6 and 12 months within the groups. We acknowledge that these score differences did not demonstrate a difference in improvement between the groups and that UDI-6 scores did not reach the MCID between the groups. We postulate that one of the possible reasons that the intervention group reached a clinically meaningful improvement within the group may be related to neuromuscular re-education that was provided by use of the digital therapeutic device. More studies are needed to further understand the specific role of this type of digital therapeutic device on pelvic floor neuromuscular re-education.

Recent research highlights the utility of PASS (Patient Acceptable Symptom State) as a measure of treatment success that may be applied in tandem with the MCID for various outcome measures. Whereas the MCID represents the smallest change in score that corresponds to an individual's perception of improvement, PASS represents a validated measure of an individual's satisfaction with their current health state[18] and is defined as "the highest level of symptoms beyond which patients consider themselves 'well'."[19] In a recent report, Sanderson and colleagues[20] identified threshold scores on the UDI-6 associated with achievement of PASS for women receiving conservative management for UI. In their research, a score of 37.5 on the UDI-6 was associated with PASS. Though PASS was not examined a priori in the current study, mean UDI-6 scores for the intervention group fell below the reported PASS threshold (30.4), whereas those for the control group did not (39.4). This holds clinical relevance, because PASS attainment represents the point at which an individual may no longer seek treatment and considers her condition satisfactory.[19,20]

Research on long-term outcomes of pelvic floor muscle training for UI is limited. One study of women with concomitant osteoporosis and UI indicated a persistent positive effect at 1 year after a 12-week course of pelvic floor physical therapy compared with an education-only control group; effect size at 1 year was 0.34.[21] Our results add to this literature on long-term pelvic floor muscle training outcomes in the context of female UI. Moreover, the active control group in our study provides an effective comparator and strengthens conclusions in favor of pelvic floor muscle training guided by the digital therapeutic device. Another report highlighted favorable 2-year outcomes among women with SUI who used a mobile app to guide a 12-week pelvic floor muscle training program.[22] Of note, the majority of participants in that study did not continue regular pelvic floor muscle training after the 12-week intervention. Similarly, in our study, device-captured adherence declined substantially after the active intervention period (participants were not asked to continue in any specific fashion), but symptom improvement endured at 12 months. Sensitivity analysis demonstrated similar outcomes between those who continued to use the device from 8 weeks to 12 months and those who did not, suggesting that long-term adherence may have little effect on outcomes. It is plausible that the initial period of use of the motion-based digital therapeutic device provides adequate pelvic floor muscle rehabilitation to promote reflexive control or volitional activation during daily activities or both and that these functional gains persist after use of the device is discontinued.

Strengths of this study include the large, representative sample, adequate power, and minimal loss to follow-up at 12 months. Limitations include lack of physical examination and other objective measures of pelvic floor muscle performance at baseline and follow-up. Additionally, bladder diaries were not collected at 6 or 12 months to enable comparison of number of UI episodes reported during the active study period. Also, although we were able to collect information regarding continued use for participants in the intervention group due to reporting from the device, we were not able to collect parallel information for participants in the control group. Although this limited our ability to understand the presence or absence of continued pelvic floor muscle training in the control group, it is inherent in the design of the control group and typical for the use of home pelvic floor muscle training.

Use of this technology may facilitate remote access to pelvic floor muscle training for women with UI and represents an effective modality for scaling conservative first-line care above standard pelvic floor muscle training home programs. For women choosing first-line care at home for SUI or MUI, a motion-based digital therapeutic device may be considered to optimize durable treatment results.

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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 will 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)? *De-identified 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 study sponsor.*

PEER REVIEW HISTORY

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