Wearables for the Bladder: Stakeholder Perspectives on Moving Multiple Sclerosis Bladder Dysfunction Interventions Into the 21st Century

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ABSTRACT

BACKGROUND: Bladder dysfunction (BD) is common in people with multiple sclerosis (MS) and can reduce participation in daily life. Detecting BD early allows for effective prevention-focused treatments such as pelvic floor physical therapy. Pairing neurotechnology with patient-reported outcomes to remotely measure BD could significantly improve monitoring and treatment of BD. Therefore, we describe the process and findings of stakeholder engagement from a human-centered design process to assemble a wearables for the bladder (WeB) kit.

METHODS: Four people with MS with varying BD severity, and 5 MS clinical/research experts had 4 virtual meetings. Commercially available bladder tools were graded for ability to evaluate, monitor, or treat BD. The Health Information Technology Usability Evaluation Scale (utility, usability, feasibility) was used for evaluation. Scoring was performed individually and as a group.

RESULTS: Of the 11 devices, 5 obtained mean scores of greater than 6 of 10 for likability, usability, and device utility. The 2 highest scoring (9/10) devices were selected for the pilot. One device measures bladder urine levels, reporting the number/frequency of voids/leaks; the other guides pelvic floor exercises by pairing games on an app with biofeedback from intravaginal sensors. We uncovered critical differences in experts' and patients' appreciation of the tools, and the collaborative engagement led to substantial revisions of initial tool scores.

CONCLUSIONS: This process underscores the critical role of stakeholder engagement in the selection of digital tools, especially in sensitive domains like pelvic function. Ongoing clinical validation of the selected tools will yield a validated, user-friendly WeB kit that is able to fill gaps in our ability to evaluate BD treatments in people with MS, ultimately reducing the impact of BD on quality of life.

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Ambulatory disability is 1 of the most prominent and visible symptoms in multiple sclerosis (MS) and serves as the foundation for many rating scales, including the Expanded Disability Status Scale (EDSS)[1] and the Timed 25-Foot Walk.[2] However, other less visible symptoms, including bladder dysfunction (BD), significantly impact people with MS. BD typically emerges within a decade of diagnosis and progressively worsens over time, and is distinct from acute relapse-related BD.[3,4] BD may encompass symptoms such as both frequent and urgent urination, frequent nighttime urination (nocturia), and incomplete bladder emptying, which can also lead to significant urinary incontinence. It not only impacts primary functioning but also leads to secondary consequences, such as reduced physical activity, increased fatigue (presumably from interrupted sleep if nocturia is present), physical deconditioning, and reduced quality of life (QOL).[5-8] BD poses health and safety risks, including recurrent urinary tract infections, falls,[4,9] and significant health care costs, yet it remains largely underresearched.[10,11]

Barriers to the prompt detection of BD include a lack of time among clinicians, discomfort in managing BD if it was not emphasized during neurological training, and the level of detail in patient reporting. Patients often perceive BD as embarrassing, sensitive, or tied to aging, leading to the belief that nothing can be done to improve or maintain the symptoms. This can lead to a lack of communication regarding available BD treatment options.[12,13] Frequently, patients only bring up bladder issues with their clinician once symptoms have progressed to a point where invasive treatments like surgery are the only viable option.[4] Identifying BD early would allow for noninvasive, prevention-based treatments, such as pelvic floor physical therapy (PT),[14,15] to be effective.

The integration of neurotechnology and patient-reported outcomes (PROs) for remote monitoring would represent a substantial improvement in monitoring and treating BD. The current evaluation of BD severity relies on intrusive in-clinic assessments (eg, post-void residuals, urodynamic testing) and extended

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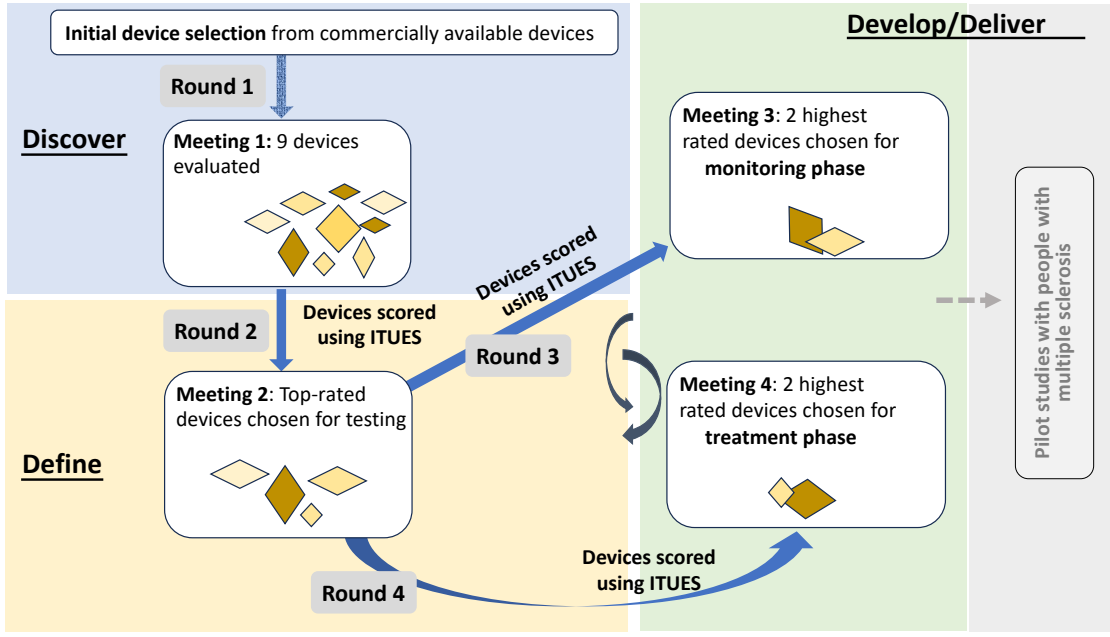
FIGURE 1. Summary of Study Design



ITUES, Health Information Technology Usability Scale.

Note: The various colored cubes represent the different bladder wearables that were evaluated and assessed.

The overall process of selecting devices for testing in the pilot studies for bladder dysfunction monitoring and treatment involved several stages, narrowing down the initial pool of potential devices (Discover Phase, Round 1, Meeting 1) in an iterative process (Define Phase into Develop Phase, Rounds 2-3 and 2-4, Meetings 2-4). The next phase is the pilot study, testing the devices against the traditional gold-standard metrics in people with multiple sclerosis. We will closely monitor participant feedback, as well as new devices of interest on the commercial market.

monitoring predominantly hinges on PROs. Although PROs are critical for documenting the patient experience, they may be less accurate due to recollection inconsistency and variations in deficit perception. To ensure successful adoption of novel technologies in clinical care and research, it is crucial to involve users, including clinicians and patients, in the development process and device selection. Therefore, our overall objective was to engage stakeholders in a human-centered design (HCD) process to develop a wearables for the bladder (WeB) kit with the goal of enhancing the evaluation, monitoring, and treatment of BD in people with MS. Subsequently, the WeB kit will be validated against gold-standard evaluation metrics, and its utility and effectiveness to improve the intensity, duration, and frequency of pelvic floor PT interventions will be tested in a clinical trial.

METHODS

Study Design

Frameworks

The study was based on the theories and stages of HCD, prioritizing the usability and requirements of a tool's intended users (in this case, patients and clinicians). The development process consisted of extensive stakeholder engagement and evaluation of tool usability utilizing the Health Information Technology Usability Evaluation Model (Health-ITUEM) and Scoring (Health ITUES).[16]

The HCD model is a problem-solving approach that places individual users at the core of the development process, creating solutions customized to their specific needs.[17] Although wearable technologies for bladder monitoring are commercially available, to our knowledge, they have not been tested individually or in combination in people with MS. To increase the likelihood that the devices chosen would be used and successful, each round of device selection and scoring used the Health-ITUEM and ITUES, including both subjective and objective outcomes. The subjective outcomes focused on satisfaction, specifically perceived ease of use and perceived usefulness of each device evaluated. In addition, variables associated with the potential WeB kit tools were considered, including their alignment with HCD principles and their capacity to engage patients.[18] These variables included usefulness, ease of use/learnability, effectiveness, and how much participants liked the device overall. The devices were tested by the stakeholders, both clinicians and patients, in their homes.

Iterative Design

Four virtual stakeholder meetings were held between April 2021 and May 2022. To accommodate COVID-19 restrictions and geographical barriers, meetings were conducted via the University of California San Francisco (USCF) Zoom video platform (**FIGURE 1**; **TABLE S1**).

Stakeholders

Clinician stakeholders were contacted either by email or in person and invited to participate. Patients who had previously

TABLE 1. Device Overview

Device name (FDA approval; commercially available[a])	Proposed commercial use	Proposed study use	Device use, frequency, and duration	Proposed mechanisms and benefits	Results of published trials or cost	Round(s)
Ieva Pelvic Health System[20] (Y;Y)	UI, mixed UI, stress UI, urge (OAB), PFMT	Monitoring (OAB) and/or treatment (PFMT)	1 to 2 days/week for 5 mins each time	Intravaginal accelerometer-based PFMT	Pilot trials are promising[21,b]	1
eCoin[22,23] (IT;N)	Remote neuromodulation; implantable PTNS	Urge UI, refractory OAB	-	Subcutaneous implantable device, stimulating tibial nerve fibers causing inhibition of the micturition pathway in SC and pelvic/pudendal nerve to inhibit OAB	Pilot trial resulted in reduction in leaks; trial ongoing, 3 month intervention, 9 month follow-up	1
BlueWind RENOVA[22] (IT;N)					Reduction in leaks; increase in void volume	
Uromonitor (P;N)	Catheter-free wireless cystometry	Monitoring of UI (OAB)	Device, app, 12-month subscription	Intravesical pressure sensor for remote bladder monitoring	Preliminary results promising	1
PeriCoach (Y;Y, but not in US)[c]	UI, stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 5 min for 8 weeks	Uses 3 visual biofeedback sensors for real-time remote results via app	$299 (device, app, 12m subscription)	1
Elvie (P;Y)[c]	UI, mixed UI, stress UI, PFMT	Treatment (TR-assisted PFMT)	5 min/day for 3 days/week	Kegel exercises, app with 1 internal and 1 external sensor	$199	1
Carin Pro (P;Y)[c]	Stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 10 mins, for 8 weeks	Sensor to track leaks, leakproof underwear, app for daily PFMT	$332.16 (app only, $33.43)	1, 2
Innovo (Y;Y)	Stress UI, PFMT	Treatment (TR-assisted PFMT)	Once daily for 30 min; 5 days/week for 4 to 12 weeks	NMES to perform 180 Kegels via wearable shorts with 8 sensors	$499	1, 2
DFree (P;Y)[c]	Urgency UI (OAB); notify user when to void	Monitoring (OAB, IE) and/or treatment (urge UI)	None specified; use as needed	Uses ultrasound to sense how much urine is in the bladder; real-time objective measure uploaded onto app	$100/month or $399	1, 2, 3, 4
Perifit (Y;Y)[c]	UI, mixed UI, stress UI, prolapse, sexual pain, PFMT	Treatment (TR-assisted PFMT)	Once weekly or 5 min/day for 30 min total/week	Kegel exercises, app, and video game using internal sensors for biofeedback	$139	1, 2, 3, 4

app, application; FDA, Food and Drug Administration; IE, incomplete emptying; IT, in trials; N, no; NMES, neuromuscular electrical stimulation; OAB, overactive bladder; P, pending at the time of the study; PFMT, pelvic floor muscle training; PTNS, posterior tibial nerve stimulation; SC, spinal cord; TR, telerehabilitation; UI, urinary incontinence; Y, yes.

Note: Devices for men: kGoal added the Boost external training device. Carin now offers an option for men, WiL, with a sensor and underwear to track leaks. Both appeared online after the stakeholder meetings were completed.

[a]As of date of study, March 2021.

[b]Also being tested for fecal incontinence (ClinicalTrials.gov NCT04027335). In the last 10 years, since neuromodulation (sacral nerve stimulation and percutaneous tibial nerve stimulation) was approved by the FDA, no progress has been made in this space. BlueWind RENOVA and eCoin are the only modified devices in neuromodulation recently developed (< 5 years), which may grow the field.

[c]Requires an application downloaded onto a smartphone device.

granted research participation consent, or who had known BD, were invited via secure email communication. The UCSF institutional review board (IRB #21-33653) approved all study activities and informed consent was obtained from all participants. No compensation was provided for participation.

The clinicians were a neuro-urologist (AMS), an MS neurologist (RB), a pelvic floor physical therapist (LM), an MS remote monitoring expert and physical therapist (VJB), and an international women's health expert (Doreen McClurg, PhD). The patients were 3 women and 1 man with MS who had varying degrees of BD (all with documented bladder-related issues in their electronic medical records). They had different levels of technical literacy and were aged between 36 and 68 years.

RESULTS

Round 1. Discovery Phase

TABLE 1 summarizes the initial devices selected for evaluation and assessment in Round 1, encompassing their respective inclusion/exclusion during stages of the evaluation process. A summary of the devices evaluated in each round, culminating in the selection of the devices for the pilot studies, is presented in **FIGURE S1**.

Initial Device Scoring

On a 10-point scale, the DFree, Perifit, and Innovo devices scored a 7 or above, were available in the United States for purchase at the time of the study, and were chosen for testing by stakeholders (full details in **TABLE S2**). The Carin Pro was not in stock at the time of the study. Notably, although the Uromonitor, eCoin, and BlueWind RENOVA (since renamed Revi) were thought to be promising, they were still under investigation and not available for commercial use at the time of the study.

The main qualitative feedback from the stakeholders regarding each device from Round 1, including the anticipated benefits, disadvantages, and key features for users (patients and clinicians) is summarized in **TABLE S3.**

Round 2. Define Phase

Stakeholder Feedback on At-Home Trials

Overall, the devices were worn by the 5 clinicians and 4 patients for an average of 2 days at home.

DFree: Four patients and 3 clinicians liked the device and rated it as useful for "visualizing the changes in bladder fullness over time" (7.4/10). More than 50% found it useful for helping to focus on other activities rather than planning restroom breaks, preventing accidents, and managing BD in general (**TABLE S4**).

Notably, the DFree was updated during the stakeholder evaluation process from an ultrasound device with an external wire connecting it to a clip-on Bluetooth device (that was hard to conceal) to a smaller, more discreet device. Participants had the opportunity to retest the newer model and this increased the overall score from 6.8 to 9.0 of 10.

Perifit: A smaller group of stakeholders (4 individuals) assessed the tool in person, as opposed to the 8 who evaluated the DFree device. Several individuals opted not to use it because it is an intravaginal device, citing personal preferences, while the male stakeholder was unable to test it. The Perifit scored high on ease of use and treatment utility. The higher average score for "helping to focus attention on activities of daily living, rather than managing BD" was derived from the discussions, indicating that the score was influenced by the perceived potential gains that the Perifit could offer if included in a treatment program.

Innovo: The device received a likability score of 0 from the stakeholders. A particular concern was about electric shocks near genitalia. Overall, it received a low recommendation score for use in the WeB kit.

Round 3 Define Phase and Round 4 Develop Phase

During stakeholder meetings, it became evident that clinicians and patients had substantial differences in their perceptions of the tools. For instance, clinicians substantially revised initially low usability scores for the DFree in response to patient recognition of the tool's potential benefits. One striking example was the enthusiasm among patients for the potential advantages of using these devices to monitor urine volume, in contrast to the conventional practice of adhering to fixed voiding schedules every 3 hours (timed voiding). This shift in perspective was primarily motivated by the potential to enhance personal freedom and mobility, especially outside of the home. Similarly, the gaming feature of the Perifit Kegel exerciser, initially perceived by clinicians as potentially juvenile, proved to be visually effective and highly engaging when tested by patients.

It's worth noting that, at this point in the study, we had to limit inclusion to female participants due to the specific mechanics of certain devices included in our kit. However, our commitment to inclusivity remains strong, and exploration of devices suitable for male participants to expand the reach and impact of our WeB kit is ongoing.

Choosing Devices for Monitoring BD

For the pilot WeB kit, the DFree and the Perifit were chosen for remote symptom monitoring. For the DFree, experts suggested validation against in-clinic post-void residual testing and conventional measures (ie, 3-day bladder diary) of bladder function. Stakeholders proposed comparing scores on a Perifit game that evaluates muscle strength with Manual Muscle Testing scores. This idea was shelved for future studies as additional funding would be needed for the single-user devices.

Choosing Devices for Treating BD

The DFree and Perifit were also both chosen as tools to include in the pelvic floor physical therapy (PFPT) pilot WeB kit, as each device offers unique potential benefits and recommended usage strategies. The Perifit scored as the most useful WeB device to augment the intensity, duration, and frequency treatment of PFPT objectives. The short, predefined games, the real-time feedback (closed loop), and the prescription suitability were highlighted as benefits by the clinician stakeholders. The patient stakeholders also rated the device as potentially useful to maintain exercise programs between PFPT sessions, citing potential benefits to improving adherence to the overall PFPT home exercise program.

The DFree was also chosen as a potential adjunct to PFPT training. Stakeholders proposed that participants could use the devices to monitor and suppress urges when experiencing strong sensations of urgency, helping to correlate these sensations with visualized (biofeedback) bladder volume. Additionally, stakeholders highlighted the opportunity for bladder training with guidance from pelvic floor physical therapists, suggesting that participants set a specific threshold volume for voiding, which could adapt as they receive training, akin to the principles of timed voiding in standard care, but with greater autonomy and personalization.

Monitoring and Treatment PROs

To assess any interactions or associations with MS symptom-specific questionnaires, PROs were selected as a group (from list of the most commonly used questionaries encompassing BD and other MS symptoms from the literature), combining urology and pelvic floor PT expertise. These are detailed in **TABLE S5**.

Future Planning

Anonymous credentials would be assigned to all devices in the WeB kit, and weekly (or biweekly) reports would be available for the therapist and research team to review. This would enable a prompt and closed-loop adjustment of the home program intervention and detection of adherence in an objective manner. Stakeholders recommended 3 to 5 days of DFree use a month for the monitoring phase (3 months), and as much as possible, with a set minimum threshold (1-3 days a week), for the intervention pilot phase. It was noted by all stakeholders that duration and frequency should be PFPT recommended after the initial evaluation visit. Patient stakeholders recommended training videos, not just written instructions, on the use, maintenance, and protocol for each WeB device.

DISCUSSION

Our pilot study findings underscore the critical importance of inclusive stakeholder engagement in choosing devices to monitor and potentially treat bladder dysfunction, a domain that is particularly sensitive, personal, and understudied.[11] The insights gained from clinicians and patients shaped the selection of devices that not only met users' preferences but also had the potential for widespread adoption. Without this invaluable input, our approach and outcomes might have been entirely different.

The difference in the perceptions of clinicians and patients regarding device utility was significant in this study. For instance, a device considered least useful by experts received high patient ratings, emphasizing the importance of including patient perspectives in device development for personal domains like pelvic function and BD. Moreover, there was a divergence in views regarding the optimal timing and duration of device usage. This reflects the challenge of balancing data acquisition with patient burden. Ultimately, we agreed on a suitable monitoring duration of 5 days per month for the DFree in this pilot study. The meetings also revealed a debate on device usage frequency throughout the study, highlighting the need for ongoing collaboration between health care professionals and patients to align monitoring and treatment protocols with patient preferences.

Progressing through the pilot study and beyond, it is vital that feedback from patients continues to shape our research. The ongoing input is valuable for collaborating with device manufacturers to enhance the suitability of BD devices for individuals with neurological disorders. Remote monitoring of functional domains in people with MS is a burgeoning field, with a multitude of research papers regarding validation and cross-sectional outcomes (in particular, for physical activity and walking in MS). However, it is essential to continue the process of transitioning WeB devices from their primary role as monitoring tools to their integration into rehabilitation interventions. In the case of BD, incorporating devices with traditional PFPT approaches signifies a move toward not only more objective, continuous, and remote monitoring but also actively treating individuals with BD.

The study had several limitations. It is important to acknowledge that larger-scale studies involving more diverse stakeholder cohorts are needed to further explore and substantiate these initial findings. Such studies will provide a more comprehensive understanding of the potential benefits and limitations of these devices in a broader context and contribute to the ongoing improvement of BD management strategies for individuals with MS. This version of the WeB kit proved to be exclusively for women. Additional research efforts are required to cater to the diverse needs of all sexes and genders in the comprehensive evaluation, monitoring, and management of BD in the context of MS.

CONCLUSIONS

After development, the WeB kit will be validated against gold-standard evaluation metrics, and its utility and effectiveness to enhance PFPT outcomes will be tested in a clinical trial. To our knowledge, there are no trials using commercially available, at-home bladder wearables in people with MS, underscoring the innovative potential of the WeB kit to complement existing treatments such as medications, PFPT, and surgical or Botox (onabotulinumtoxinA) procedures. If the results of the pilot studies are clinically meaningful, the WeB kit may emerge as a promising solution to address critical gaps in our ability to measure and manage BD in people with MS. By potentially reducing the adverse impact of BD on QOL, these devices could significantly improve the overall well-being of individuals with MS.

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FIGURE S1. Device Selection by Round

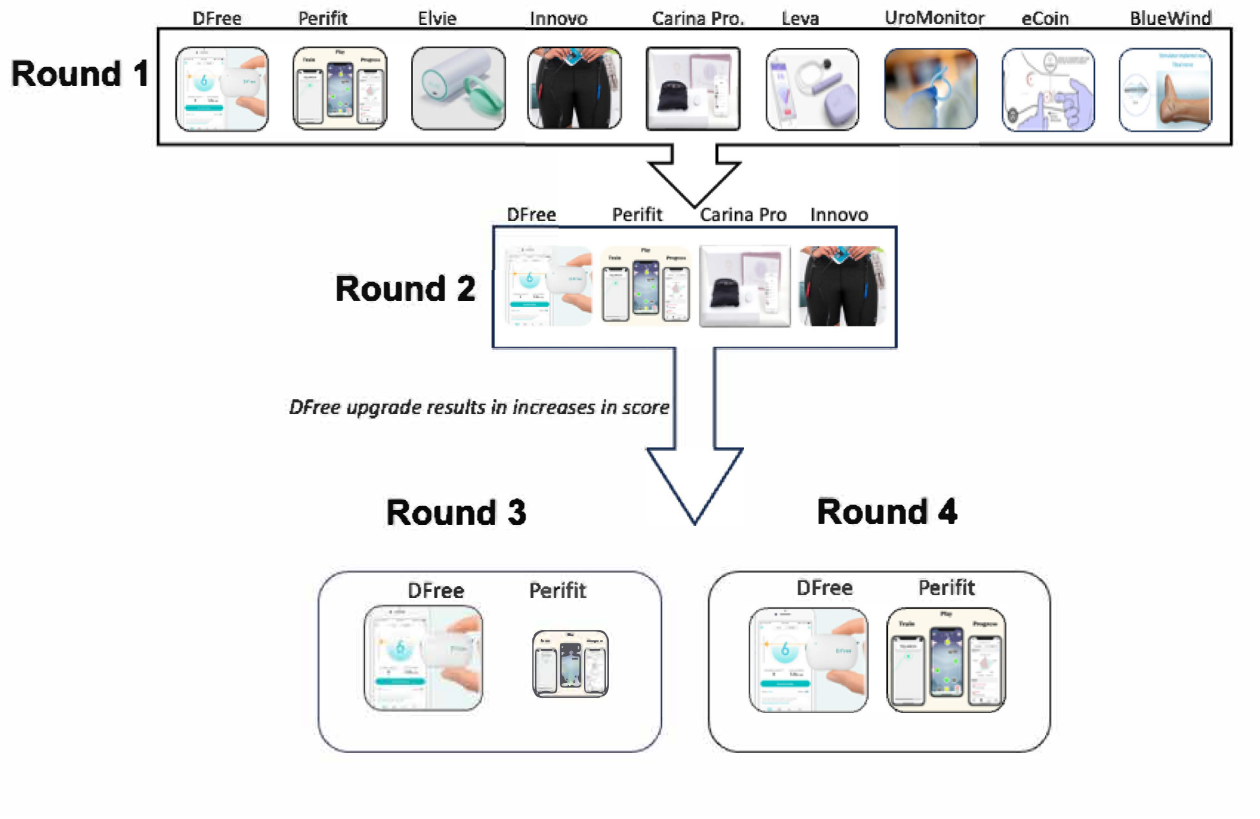

TABLE S1. Human-Centered Design Iterations: Selecting WeB Wearables Toolkit

Group	Objectives
Stakeholder advisory group ↓	**Meeting 1:** Study kickoff. **Goals:** Refine project goals, inform patient and clinician engagement protocols. **Meeting 2:** Review of initial assessment of devices and device scoring. **Goals and activities:** Stakeholder group discussion of safety, utility, and usability in people with MS across a spectrum of disability. Subset of group (clinician and patients) volunteer for device trial at home. **Meeting 3:** Final observational device scoring. **Goals:** Review, discuss, and perform final selection of devices for in-home BD evaluation and monitoring pilot study. **Meeting 4:** Final interventional study scoring and planning. **Goals:** Review, discuss, and perform final selection of devices for in-home BD treatment (combined PFPT and WeB) pilot.
Discovery session ↓	**Process:** The devices in Table S2 were presented to the stakeholders and links to device websites were provided for initial assessment. **Goal:** To identify devices that would be useful to, effective for, or liked by people with MS and BD. **Outcomes:** Scoring from a secure online platform (REDCap) was used to collect the initial assessment and feedback from the individual stakeholders.[19] The survey included questions derived from the Health-ITUES as well as recommendations for the device to be used in future pilot studies for monitoring or treatment (or potentially both) of urinary incontinence caused by BD.
Define/refine session ↓	**Process:** Devices that were available for purchase in the United States at the time of the study and were deemed safe by the study experts were sent to a subgroup of stakeholders for review and evaluation. **Outcomes:** Feedback was collected using Health-ITUES–derived questions including clinical validity of the data, safety, clinical actionability, cost, and barriers to adherence. Both patients and clinicians were asked to prioritize the devices by scoring their perceived usefulness.
Final tool scoring ↓	**Process:** Results from the review and evaluation of devices used at home, with specific focus on using these as evaluation/monitoring tools, were presented. Discrepancies between scoring of devices were discussed by the group, and the study's principal investigators resolved any differences. **Selecting final devices for the intervention pilot study:** The outcomes from the last review and evaluation of devices, with specific focus on using these as a complimentary intervention tool for PFPT to improve the intensity, duration, and frequency of treatments, were presented. Discrepancies between scoring of devices were discussed by the group, and the study's principal investigators resolved any differences. **Outcomes:** The highest scoring devices were chosen for testing in both pilot studies.
Future clinical trial	Stakeholders also discussed aspects of study design, including the ideal frequency of WeB kit remote monitoring or at-home treatment use within a preidentified range that was selected based on prior literature.

BD, bladder dysfunction; ITUES, Information Technology Usability Evaluation; MS, multiple sclerosis; PFPT, pelvic floor physical therapy; REDCap, Research Electronic Data Capture; WeB, wearables for bladder dysfunction.

TABLE S2. Round 1 Scoring From REDCap Survey Results

After Meeting 1	Initial likability: Do you like this tool?	Initial usefulness: Do you think this will be a useful tool for people with MS?	Do you think this tool could be used at home to gain information between in-person clinic visits?
DFree	9.1	8.6	9.0
PeriCoach[a]	5.0	5.2	6.2
Perifit	7.9	6.9	7.9
Ieva Pelvic Digital Health System	4.6	5.0	5.0
Carin Pro	5.0	5.8	5.8
Innovo	5.6	6.6	7.3
Transcutaneous Tibial Nerve Stimulation	6.5	7.5	2.4
Squeezy App	4.4	5.7	5.7
Uromonitor	2.9	3.0	3.0
eCoin[b]	4.3	7.0	5.1
BlueWind RENOVA[b]	3.9	7.3	4.5

app, application; MS, multiple sclerosis; REDCap, Research Electronic Data Capture.

Note: Scoring was on a Likert scale of 1 to 10.

[a]This device was not in stock at the time of the study.

[b]Implantable PTNS.

TABLE S3. Qualitative Feedback After Meeting 1

	What are main advantages of this tool?	What are main disadvantages of this tool?	Potential concerns	Key features	
				Patient	Clinician
DFree[a]	• External cuing • Easy to use • For men and women • Ability to get at-home PVR	• Is it practical to have on every day? • Too expensive if paid out of pocket • "Having to position device just above pelvic bone and attach to monitor in pocket; still unsure how this will work, but I am hopeful."[b]	• Placement of sensor: comfort of sticking devices to skin	• Plan voids • For men and women	• Remote PVR; could be bladder diary alternative (ie, number of voids per day)
PeriCoach[c]	• Potential for treatment, not just symptom management • Easy to use	• Confusion about how device works • Intravaginal placement seems invasive	• Only for women	• Plan voids • For men and women	• Plan voids • For men and women
PeriCoach[c]	• Potential for treatment not just symptom management • External cuing	• Confusion about how device works	• Only for women	• Visual and haptic biofeedback makes PFM learning and training easier	• Objective measure of PFM strength and ability to relax PFM • Adjunct to TR
Ieva Pelvic Digital Health System	• Potential for treatment not just symptom management	• Intravaginal seems invasive • Confusion about how device works	• Only available via order through doctor	• Visual (video game) app and biofeedback for PFMT	• Objective analysis of PFM (eg, strength, endurance)
Carin Pro	• Wearable technology, no implant	• Confusion about how device works	• Unclear if men can use	• PFMT from home; can store, share, visualize data on the app	• Static and dynamic profile of PFM
Innovo	• Wearable technology, no implant • Easy to use	• Is it practical to have on every day? • Significant time needed for potential benefit • Too expensive if paid out of pocket	• Unclear if men can use	• PFMT from home; can store, share, visualize data on the app • Objective measure of leaks • Leakproof so may improve confidence	• Number of leaks per 24 hours; alternative to bladder diary
Transcutaneous Tibial Nerve Stimulation	• Potential for treatment not just symptom management • Wearable technology, no implant	• Person needs to remember to use regularly • Concern about stimulation comfort • Significant time needed for potential benefit		• Ability to passively perform NMES at home	• Unclear if this is just passive NMES
Squeezy App	• Helpful to have external cuing • Easy to use	• Significant time needed for potential benefit	• Unclear if users are actually doing PFM	• Can continue benefits of PTNS from home • For men and women	
Uromonitor	• Device is implanted so no daily management required	• Surgery required			• Verified pelvic floor health education

TABLE S3. Qualitative Feedback After Meeting 1

eCoin	• Device is implanted so no daily management required • Potential for treatment not just symptom management • Insurance should cover	• Surgery required	• Intravesical pressure sensor for remote bladder monitoring	• Monitoring of UI (OAB) • PTNS
BlueWind RENOVA	• Device is implanted so no daily management required	• Surgery required		• PTNS

NMES, neuromuscular electrical stimulation; OAB, overactive bladder; PFM, pelvic floor muscle; PFMT, pelvic floor muscle training; PTNS, percutaneous tibial nerve stimulation; PVR, post-void residual; TR, telerehabilitation; UI, urinary incontinence.
[a]Device chosen for WeB pilot studies.
[b]This was before the newer model was released.
[c]Not in stock at the time of the study.

TABLE S4. Round 2 Scoring From REDCap Survey Results

Device	DFree	Perifit	Innovo
Day of testing/using the device (average days)	1.3	2.0	2.5
Did you like using the device? (% yes)	50	100	0
The device is useful for visualizing the changes in my bladder fullness over time.[a]	7.4	6.0	2.0
The device increases my ability to focus on other activities (not restroom planning) during my day.[a]	5.4	7.5	2.0
Using the device every day is practical.[a]	5.7	8.0	4.0
Using the device for parts of the day is easier than using it all day.[a]	8.0	8.5	4.5
The device is useful for preventing accidents.[a]	7.7	7.5	4.0
I am satisfied with the device as a tool to manage my UI.[a]	5.3	8.5	3.0
I am comfortable with my ability to use the device.[a]	6.6	8.5	4.0
Learning to operate the device was easy for me.[a]	7.7	8.5	4.5
It was easy for me to become skilled at using the device.[a]	6.9	9.0	4.0
I find the device easy to use.[a]	6.0	10.0	3.0
I can always remember how to wear and use the device.[a]	7.4	10.0	4.0
How likely are you to recommend the device to another person with MS?[a]	9.0	8.8	4.0

MS, multiple sclerosis; REDCap, Research Electronic Data Capture; UI, urinary incontinence.
Note: Stakeholders were provided with Table 1, and questions were completed through a secure REDCap survey. The questions were completed separately for each device tested. DFree was upgraded during this phase and scores substantially increased with newer model.
[a]Rated on a Likert scale from 0 (very much disagree) to 10 (very much agree).

TABLE S5. Patient-Reported Outcomes for WeB Pilot Studies

Domain	Questionnaire/measuring tool	Specific use	Stakeholder guidance (M or T)
Patient-reported outcomes			
Independent variable: bladder/bowel function	Overactive Bladder Symptom Score	NOAB severity	Yes (M and T) Block-recruitment. Baseline, end of study
	Bladder Control Scal	BD in previous 4 weeks	Yes (M and T) Baseline, end of study
	Urinary Distress Inventory-6	BD impact on QOL	No (M) Yes (T) baseline, end of study, 3m
	Actionable Bladder Symptom Screening Tool Short Form	Screening for patients in need of bladder referral	No Too many similar PROs; no added value
	Neurogenic Bladder Symptom Score Short Form	Evaluating neurogenic bladder symptoms	No (M) Yes (T) end of study
	Bladder Diary	Number of leaks, liquid intake, number of voids	Yes (M) baseline (T) if indicated by PFPT
	Bowel Control Scale	Bowel dysfunction in previous 4 weeks; could be a confounder	Yes (M) week 4 (T) baseline, end of study
Dependent assessment measures			
Quality of life	Multiple Sclerosis Quality of Life	MS-specific QOL assessment	Yes (T) Baseline, end of study, 3m
	Overactive Bladder Symptom and Health-Related Quality of Life Short Form	Symptom-specific health-related QOL	Yes (M) Week 4
Symptoms			
Fatigue	Modified Fatigue Index Scale	Mental and physical fatigue impact on everyday life	Yes (M) week 4 (T) end of study, 3m
Pain	Pain Effects Scale	Pain	No To reduce patient burden as not as relevant to BD
Depression	Center for Epidemiological Studies-Depression	Depression	Yes (M) baseline (T) baseline, end of study, 3m
Sexual function	MS Intimacy and Sexuality Questionnaire-15	Sexual satisfaction	Yes (M) baseline (T) baseline, end of study, 3m
Sleep	Pittsburgh Sleep Quality Index	Subjective sleep quality	No To reduce patient burden of too many PROs, but would be useful for people with nocturia
Ambulatory activity and safety			
Subjective walking	12-item MS Walking Scale	MS effect on walking over previous 4 weeks	No To reduce patient burden of too many PROs

TABLE S5. Patient-Reported Outcomes for WeB Pilot Studies

Falling	"Have you fallen in the last week?" If yes: Hopkins Fall Grading Scale	Falls and near falls	Yes (M and T) Weekly
Outdoor activities	Godin Leisure-Time Exercise Questionnaire	Subjective usual physical activity	No To reduce patient burden of too many PROs
Daily life participation			
Social engagement	Oxford Participation and Activities Questionnaire short form	Evaluates routine activities, emotional well-being, social engagement	Yes (M) week 4 (T) end of study, 3m
Social networks	Social network assessment tool	Quantitative social network assessment	No Too long and onerous for the patient
Work participation	Impact on Participation and Autonomy	Evaluate impact of disability via workdays missed due to symptoms	No To reduce patient burden of too many PROs
Patient biosensor data and device feedback			
Physical activity	Fitbit Ultra[19,20]	Objective physical activity levels via step count (daily and per minute)	Yes (M and T) Passive data monitoring is continuous
Sleep	Fitbit Ultra	Objective sleep duration and quality via length of time asleep, time in REM sleep; exploratory	Yes (M and T) Passive data monitoring is continuous
Health-ITUES	Health Information Technology Usability Evaluation Scale	Evaluate usability of information technology tools	Yes (M and T) End of study
Clinic-based measures			
Disability	Expanded Disability Status Scale (EDSS) with functional scores or Patient-Reported EDSS	Neurological impairment in MS	Yes (M) baseline (T) baseline, 3m
Walking	Timed 25-Foot Walk[21]	Walking speed	Yes (M and T) Baseline
Mobility	Timed Up and Go[22]	Functional mobility and balance	Yes (M and T) Baseline
PVR	Post Void Residual	Residual urine in bladder after voiding	Yes (M and T) Baseline
MMT	Manual Muscle Test	Strength, endurance, relaxation of PFM	Yes (T) Baseline, end of study

BD, bladder dysfunction; M, monitoring pilot study; m, month of follow-up; MS, multiple sclerosis; NOAB, neurogenic overactive bladder; PFM, pelvic floor muscle; PFPT, pelvic floor physical therapy; QOL, quality of life; REM, rapid eye movement; T, treatment pilot study; WeB, wearables for the bladder.