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Pilot Trial of a Technology Assisted Treatment for Trichotillomania

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Abstract
The present study examined the usability, acceptability, feasibility, and preliminary efficacy of a prototype wrist-worn motion detection device and accompanying mobile app, developed by HabitAware®, as a system for delivering self-administered Habit Reversal Training (HRT). As an exploratory aim, the effect of the device and HRT app combination was compared to a reminder bracelet. The pilot trial included 15 adults with trichotillomania who interacted with the device and app system (n = 10) or reminder bracelet (n = 5) for 4 weeks. Participants in the device and app condition reported high usability, acceptability, and perceived efficacy of the system. The device and HRT app combination reduced hair pulling severity. Individuals in the reminder bracelet condition also showed a significant improvement in hair pulling. A future efficacy study with a larger sample size, longer timeframe, and improved gesture detection algorithm is warranted.

1. Introduction
Trichotillomania (hair pulling) involves the recurrent pulling of one’s hair, which leads to noticeable hair loss (American Psychiatric Association, 2013). Individuals with hair pulling report significant distress from the behavior, which can result in psychological, social, and academic impairment, along with disruptions in occupational functioning (Diefenbach et al., 2005; Woods et al., 2006).

Habit Reversal Training (HRT) is an effective treatment for hair pulling (Azrin et al., 1980; Mouton & Stanley, 1996; Rapp et al., 1998a). In a meta-analysis, Bloch et al. (2007) found HRT yielded greater treatment effects on pulling than pharmacotherapy. Unfortunately, HRT is not universally effective (Rapp et al., 1998b), results in high relapse rates (Keijsers et al., 2006), is not widely available, and can be costly (Franklin et al., 2011; Woods et al., 2006). Due to these limitations, methods for improving HRT have been explored.

HRT focuses on increasing patients’ awareness of hair pulling and disrupting a chain of habitual responding (Azrin et al., 1980). HRT starts with awareness training, during which the client learns to recognize instances of hair pulling as it occurs, as well as when it is about to occur. After clients learn to be aware of their pulling, they are taught to engage in competing responses, which clients use to disrupt the habitual chain of behaviors that culminate in pulling. Awareness training has been found to be key in the success of HRT (e.g., Miltenberger et al., 1985; Woods et al., 1996), but because pulling often occurs in isolation, transferring awareness skills learned in therapy to settings outside of treatment can be challenging.

Given the importance of awareness, one could posit that electronic devices used to increase awareness of pulling could either reduce the behavior directly or enhance the efficacy of HRT. Indeed, several studies have employed electronic awareness enhancement devices (AEDs) to treat repetitive behaviors; either as stand-alone treatments (Ellingson et al., 2000; Himle et al., 2008; Stricker et al., 2001, 2003) or as adjunct treatments to HRT (Himle et al., 2018; Rapp et al., 1998a). However, in these early studies focusing on hair pulling and finger sucking, false positive alerts were common, and participants complained about the wearability of the AEDs. Furthermore, firm conclusions about the benefits of AEDs could not be drawn due to small sample sizes, lack of control conditions, and AED performance issues.

In addition to increasing awareness, the use of digital technology to effectively administer the remaining components of HRT may make treatment more accessible. Indeed, other forms of digital treatment have
been created to expand access. Mouton-Odum et al. (2006) designed an Internet-based, self-help treatment program called StopPulling.com that used evidence-based cognitive behavioral approaches, such as HRT, to treat hair pulling. Users demonstrated significant decreases in pulling after using the online program. Further, Flessner et al. (2007) tested a similar Internet-based, self-help approach called StopPicking.com that also led to decreases in skin picking. Thus, the creation of a digital approach to teaching HRT that interfaces with an AED could mitigate concerns related to treatment accessibility and cost.

1.1. Study overview
Previous studies suggest that AEDs can help reduce repetitive behaviors. Unfortunately, these AEDs had some limitations including poor detection accuracy and concerns regarding device wearability. The current study used a newly designed wrist-worn device and accompanying app, developed by HabitAware®, to increase participant awareness of hair pulling. Further, compared to past studies, the wearability of the device was improved as participants only needed to wear a small, discreet device on their wrist, similar to a modern fitness tracker. Finally, the current study added an app that interfaced with the device and taught participants to implement the two main components of HRT, awareness and competing response training.

The primary aim of this pilot study was to determine the usability, acceptability, and feasibility of this real-time awareness device and HRT app system. Another aim was to examine if the device and app system have the potential to decrease hair pulling severity. Finally, as an exploratory aim, the device and app system was compared to a “Reminder Bracelet” condition, which involved wearing an inert version of the same device (with no accompanying app) that was programmed to vibrate at random times throughout the day as a “reminder to not pull.” This between-group comparison was included to yield pilot data needed to establish parameters for a possible efficacy study.

2. Method
2.1. Participants
Participants (see Table 1) were fifteen women between 19 and 70 years old who had been diagnosed with hair pulling. They were recruited through online hair pulling support groups across the United States, the TLC Foundation for Body Focused Repetitive Behaviors, and posts on social media pages run by HabitAware®. Inclusion criteria included (a) English fluency, (b) ≥18 years of age, (c) meeting Diagnostic and Statistical Manual of Mental Disorder-5 (DSM-5) diagnostic criteria for hair pulling, (d) not on psychotropic medication for hair pulling symptoms or on same dose for at least the past 6 weeks, and (e) possession of an iPhone 6s or newer, and (f) score above the normative mean (M = 25.7; Flessner et al., 2008) on the automatic subscale of the Milwaukee Inventory for Subtypes of Trichotillomania-Adult Version (MIST-A). This criterion was included because theoretically, HRT is believed to help most with automatic hair pulling. Exclusion criteria included (a) current psychotherapy for pulling, (b) presence of other psychiatric conditions requiring more immediate care, or (c) previous use of a behavior awareness device to reduce hair pulling. The study was reviewed and approved by the Institutional Review Board at Marquette University and supported by a grant from the National Institutes of Health (NIH; R43MH114773). The clinicaltrials.gov ID for the study was NCT04241120. All participants were compensated for their time.
Variables | Relative Percentage \((n/N)\) | Overall \((N = 15)\) | Device/App \((N = 10)\) | Reminder Bracelet \((N = 5)\)
---|---|---|---|---
Gender | | | | |
Male | 0.0 (0/15) | 0.0 (0/10) | 0.0 (0/5) |
Female | 100.0 (15/15) | 100.0 (10/10) | 100.0 (5/5) |
Race | | | | |
White | 86.7 (13/15) | 80.0 (8/10) | 100.0 (5/5) |
Biracial | 13.3 (2/15) | 20.0 (2/10) | 0.0 (0/5) |
Current Medication for Trichotillomania | 13.3 (2/15) | 10.0 (1/10) | 20.0 (1/5) |
Any Current Medication | 60.0 (9/15) | 80.0 (8/10) | 20.0 (1/5) |
Any Comorbid Diagnoses | 40.0 (6/15) | 40.0 (4/10) | 40.0 (2/5) |
Age \(M (SD)\) | 36.7 (13.7) | 39.5 (15.5) | 31.2 (7.6) |

2.2. Measures

Trichotillomania Diagnostic Interview – Revised (TDI-R). The TDI-R (Rothbaum and Ninan, 1994) is a clinician-rated, semi-structured interview to establish a hair pulling diagnosis according to DSM-V criteria.

Massachusetts General Hospital – Hairpulling Scale (MGH-HS).
The MGH-HS (Keuthen et al., 1995) is a 7-item self-report measure designed to assess hair pulling severity by examining the urge to hair pull, actual hair pulling, and consequences of hair pulling. Total scores range from 0 to 28, with higher scores reflecting greater symptom severity. The instrument has shown good internal consistency and test-retest reliability, and acceptable convergent and divergent validity (Diefenbach et al., 2005; Keuthen et al., 1995).

National Institute of Mental Health - Trichotillomania Severity Scale (NIMH-TSS).
The NIMH-TSS (Swedo et al., 1989) is a clinician-rated scale that assesses pulling severity in the past week on a scale from 0 to 25, with higher scores reflecting greater severity. The NIMH-TSS has demonstrated sensitivity to changes in symptom severity, adequate internal consistency, and excellent inter-rater agreement but shows poor correspondence with self-reported hair pulling severity (Diefenbach et al., 2005).

Milwaukee Inventory of Subtypes of Trichotillomania – Adult version (MIST-A).
The MIST-A (Flessner et al., 2008) assesses focused and automatic hair pulling in adults with hair pulling. The 15-item self-report instrument includes a ten-item focused subscale and a five-item automatic pulling subscale. The average score from clinical populations on the focused scale is 45.3 \((SD = 16.2)\), while the average score on the automatic scale is 25.7 \((SD = 9.04)\). Both scales have shown acceptable internal consistency and good construct and discriminant validity (Flessner et al., 2008).
Mini-International Neuropsychiatric Interview (MINI) for Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).

The MINI (Sheehan et al., 1998, 2014) is a clinician-rated semi-structured diagnostic interview that assesses status on a variety of psychiatric disorders. Studies suggest that the MINI demonstrates good reliability and validity in clinical samples (Sheehan et al., 1998).

Self-Report Questionnaire.

This 21-question survey asked questions about the usability, acceptability, feasibility, and perceived efficacy of the device and app. The questions were rated on a scale of 1 (strongly disagree) to 5 (strongly agree). The questionnaire included two open-ended questions that asked how many days per week the participant wore the device and on the days the participant wore the device, how many hours it was worn.

2.3. Device

The device was a wrist-worn electronic bracelet developed by HabitAware® and equipped with a motion sensor, Bluetooth® transceiver, haptic motor, battery, microprocessor, and screen. The device was programmed to record a specific behavior when in a “training mode” enabled by the companion smartphone app. After the device was trained to recognize a specific behavior, a “detection mode” was engaged. During “detection mode,” the detection algorithm continuously compared the live data generated from the motion sensor to the recorded data and determined if the behavior was similar. If so, the device vibrated in real-time to alert the participant that they were performing the pulling behavior the device had been trained to detect.

2.4. Procedures

Potential participants completed a phone screening with an independent evaluator (IE) to determine preliminary study eligibility (Fig. 1). Those deemed likely eligible provided consent and were invited to complete a baseline evaluation via video conference, during which the IE administered the MINI, TDI, and NIMH-TSS. The participants also completed the MGH-HS and MIST-A online. Eligible participants were randomly assigned (via block randomization with a 2:1 ratio) to one of the following two conditions: 1) prototype wrist-worn motion detection device and accompanying app (n = 10; Fig. 2) or 2) reminder bracelet (n = 5). Unequal sample sizes were obtained due to the exploratory nature of the comparison, and because the primary focus of the pilot trial was to test the usability, acceptability, and feasibility of device and app, rather than compare the device and app combination to the reminder bracelet. All participants were informed they would receive either a wrist-worn device and accompanying phone app or a stand-alone wrist-worn device. They were told that the two devices would be compared to assist researchers with the continued product development. The IE was masked to treatment assignment.
Fig. 1. Flow of participants through the pilot trial.

After randomization, participants were exposed to either the device and app or the reminder bracelet for 4 weeks. A short, four-week intervention period was chosen because past studies that evaluated AEDs led to near-zero levels of hair pulling (Rapp et al., 1998b) and finger sucking (Ellingson et al., 2000; Stricker et al., 2001, 2003) almost immediately. At midpoint (2 weeks) and post (4 weeks), participants were reevaluated via videoconference by the IE. At each visit, the IE administered the NIMH-TSS to the participants via a video call. Participants were instructed not to discuss their treatment assignment with the IE. After completing the video call, participants were sent a link to a Qualtrics survey that included the MGH-HS, MIST-A, and a self-report questionnaire. The IE did not have access to the Qualtrics survey until the study was completed.

2.5. Device + app condition
During the 4-week trial, participants wore the device and interacted with the app. The first module of the app provided participants with psychoeducation about hair pulling and HRT (Fig. 3). The second module addressed awareness training, during which participants were instructed to choose one hair pulling site that would be called their “danger zone.” They created a detailed description of their hair
pulling in the danger zone. Next, participants wore the device for three days, during which they were told to notice the real-time reminders (i.e., vibration) that could occur when they pulled from their danger zone.

![Fig. 3. Psychoeducation module of the app.](image)

After wearing the device for three days, the app informed the participants that they could “test” their awareness. During the awareness testing phase, the device would still detect the trained behavior, but the vibration was delayed by approximately 7 s. During the delay, the participants could “beat” the device by pushing a button on the device before it vibrated. Pushing the button before the device vibrated was used to demonstrate awareness of the hair pulling. Upon demonstrating 80% awareness for any three of the previous five days, participants received competing response training (CRT) via the app.

Using written explanations and video demonstrations, patients were taught to do a competing response when they noticed they were pulling or about to pull their hair. For their competing response, participants were instructed to gently make a fist with their primary hair pulling hand, hold it against their chest, and discreetly wiggle the device back and forth with their other hand for approximately 3 s. This allowed the device to automatically record when the competing response was being performed. Participants were then instructed to keep holding their fist against their chest until the urge to pull passed. The device was able to detect competing response use and calculate how often competing responses were done versus how often they pulled their hair. If participants used their competing response for 80% of their pulling episodes from their trained danger zone for any three of the previous five days, they were sent daily pop-up motivational support messages such as “believe you can, and you will” and “breathe and take this one day at a time” via the mobile app.

2.6. Reminder bracelet condition

Participants in the reminder bracelet group received a bracelet that was physically identical to the prototype awareness device in the device and app condition. However, there was no accompanying app and no motion detection ability. Rather than vibrating when hair pulling was detected, the reminder bracelet was pre-programmed to vibrate twelve times per hour at random intervals. This was based on past internal observational data of the average number of times those with hair pulling pulled per hour during the development of the motion recognition algorithm of the device. Participants were told the device would vibrate randomly several times per hour as a reminder not to hair pull. The device was to be worn during all waking hours for four weeks.
3. Results

All fifteen participants completed the 4-week trial (Table 2, Table 3). In the device and app condition, five of ten participants completed awareness training by demonstrating 80% awareness of their hair pulling in three out of five consecutive days; the other five participants did not meet this criterion and stayed in the awareness training phase. Of the five participants who completed awareness training, two completed CRT by using their competing response for 80% of their hair pulls for three of five consecutive days (Fig. 1). The remaining three participants persisted in the CRT phase until the end of the trial.

Table 2. National institute of mental health - trichotillomania severity scale (NIMH-TSS) scores.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Baseline</th>
<th>Mid</th>
<th>Post</th>
<th>Change Score from Baseline to Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device and App</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant 1</td>
<td>11</td>
<td>4</td>
<td>2</td>
<td>−9</td>
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<tr>
<td>Participant 2</td>
<td>19</td>
<td>18</td>
<td>13</td>
<td>−6</td>
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<tr>
<td>Participant 3</td>
<td>19</td>
<td>8</td>
<td>9</td>
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<td>Participant 4</td>
<td>20</td>
<td>10</td>
<td>15</td>
<td>−5</td>
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<td>Participant 5</td>
<td>14</td>
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<td>8</td>
<td>−6</td>
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<td>Participant 7</td>
<td>17</td>
<td>8</td>
<td>12</td>
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<td>Participant 8</td>
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<td>11</td>
<td>10</td>
<td>−7</td>
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<td>Participant 9</td>
<td>14</td>
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<td>−6</td>
</tr>
<tr>
<td>Participant 10</td>
<td>13</td>
<td>12</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Mean (SD)</td>
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<td>9.90 (3.60)</td>
<td>10.00 (3.65)</td>
<td>−5.60</td>
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<td></td>
<td></td>
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<tr>
<td>Participant 11</td>
<td>18</td>
<td>18</td>
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<td>−13</td>
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<tr>
<td>Participant 12</td>
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<td>−3</td>
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<td>Participant 13</td>
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<td>Participant 14</td>
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<td>13</td>
<td>−6</td>
</tr>
<tr>
<td>Participant 15</td>
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<td>0</td>
<td>−17</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>17.20 (2.49)</td>
<td>10.00 (6.52)</td>
<td>8.60 (6.11)</td>
<td>−8.60</td>
</tr>
</tbody>
</table>

Note. a) Participant completed both awareness and competing response training. b) Participant did not complete awareness or competing response training. c) Participant only completed awareness training.

Table 3. Massachusetts general hospital – hairpulling scale (MGH-HS) scores.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Baseline</th>
<th>Mid</th>
<th>Post</th>
<th>Change Score from Baseline to Post</th>
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</thead>
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<td></td>
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<td>−1</td>
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<td>Participant 7</td>
<td>12</td>
<td>10</td>
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<td>−3</td>
</tr>
<tr>
<td>Participant 8</td>
<td>21</td>
<td>15</td>
<td>13</td>
<td>−8</td>
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<tr>
<td>Participant 9&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>8</td>
<td>5</td>
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<td>Mean (SD)</td>
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<td>11.70 (3.80)</td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Participant 11</td>
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<td>9</td>
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<td>-16</td>
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<td>Participant 12</td>
<td>20</td>
<td>17</td>
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<td>-2</td>
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<td>Participant 13</td>
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<td>6</td>
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<td>19</td>
<td>0</td>
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<tr>
<td>Participant 15</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>-14</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>18.20 (4.87)</td>
<td>12.60 (8.26)</td>
<td>13.00 (8.40)</td>
<td>-5.2</td>
</tr>
</tbody>
</table>

Note. a) Participant completed both awareness and competing response training. b) Participant did not complete awareness or competing response training. c) Participant only completed awareness training.

3.1. Self-report ratings of the device + app condition
Participants in the device and app condition completed a 21-question survey about the usability, acceptability, feasibility, and perceived efficacy of the device and app. They rated the questions on a scale of 1 (strongly disagree) to 5 (strongly agree).

**Usability.**
Both the device and app, respectively, were rated as easy to use $(M = 4.00, SD = 0.94; M = 4.10, SD = 0.32)$. Participants felt the device and app interfaced well together $(M = 4.00, SD = 0.67)$ and that they would use the device and app system $(M = 4.50, SD = 1.27)$. During the 4-week trial, those in the device and app condition reported wearing the device an average of 6.35 days per week, with nine out of ten participants wearing the device more than 4 days per week. Participants reported wearing the device $M = 12.8$ h per day.

**Acceptability.**
Both the device and app, respectively, were rated as interesting/engaging $(M = 4.40, SD = 0.70; M = 4.20, SD = 0.79)$, a valuable tool for managing hair pulling $(M = 4.40, SD = 1.08; M = 4.00, SD = 1.05)$, and of high quality $(M = 4.00, SD = 0.82; M = 4.00, SD = 0.47)$. Participants also said they would recommend the device and app system to others $(M = 4.40, SD = 1.27)$.

**Feasibility.**
Participants reported that the device generally did a good job of recognizing their pulling $(M = 3.80, SD = 0.79)$, but also felt the device would vibrate when they had not pulled from their danger zone (i.e., there were false positives; $M = 2.50$, $SD = 1.08$). Participants suggested the device was accurate in recognizing their competing responses $(M = 4.00, SD = 0.71)$. Finally, after the 4-week trial, participants completed an interview to assess treatment adherence of competing responses. Participants were asked to perform the competing response and indicate when and how long to engage in it. Of the ten participants, five started CRT during the trial. Although only two of the five participants finished the training, four of the five were able to demonstrate how to perform a competing response with 80% accuracy.
Perceived Efficacy.
Participants felt the device and app system was effective at increasing their awareness of hair pulling ($M = 4.40$, $SD = 0.84$) and effective at reducing the behavior ($M = 4.30$, $SD = 0.95$).

3.2. Impact on hair pulling severity
Wilcoxon signed-rank tests were conducted on pre-post NIMH-TSS and MGH-HS total scores for participants in the device and app condition. There was a statistically significant decrease in NIMH-TSS total scores from baseline ($M = 15.60$, $SD = 3.65$), $Z = -2.68$, $p < .01$, $r = -0.60$. Further, there was a statistically significant decrease in MGH-HS total scores from baseline ($M = 16.00$, $SD = 3.43$) to post-assessment ($M = 11.70$, $SD = 3.80$), $Z = -2.81$, $p < .01$, $r = -0.63$.

Recognizing that not all participants proceeded to the CRT element of the app, Wilcoxon signed-rank tests were conducted on pre-post NIMH-TSS and MGH-HS total scores for the five participants who completed awareness training and began CRT. For these individuals, there was a statistically significant decrease in NIMH-TSS total scores from baseline ($M = 15.60$, $SD = 3.13$) to post-assessment ($M = 8.20$, $SD = 3.77$), $Z = -2.02$, $p < .05$, $r = -0.64$. There was also a statistically significant decrease in MGH-HS total scores from baseline ($M = 15.80$, $SD = 4.32$) to post-assessment ($M = 9.40$, $SD = 3.21$), $Z = -2.03$, $p < .05$, $r = -0.64$.

3.3. Preliminary comparison between device/app system and reminder bracelet
A 2 (group) by 3 (time) mixed analysis of variance (ANOVA) was performed to determine whether there were significantly greater decreases in NIMH-TSS total scores from baseline to post-treatment among participants who were given the device and app relative to the reminder bracelet (Table 2). Effect sizes were estimated using partial eta squared. For the NIMH-TSS total scores, a significant main effect was found for time, $F (1, 13) = 20.22$, $p < .01$, partial $\eta^2 = 0.61$. The main effect comparing the device and app to the reminder bracelet ($F (1, 13) = 0.003$, $p = .96$, partial $\eta^2 = <0.01$) and the interaction between group and time ($F (1, 13) = 0.74$, $p = .49$, partial $\eta^2 = 0.06$) were not significant. Further, a 2 (group) by 3 (time) mixed ANOVA was performed on the MGH-HS total scores (Table 3). Again, a significant main effect was found for time, $F (1, 13) = 7.48$, $p < .01$, partial $\eta^2 = 0.37$, but neither the main effect of group ($F (1, 13) = 0.32$, $p = .58$, partial $\eta^2 = 0.02$) nor the interaction between group and time ($F (1, 13) = 0.23$, $p = .80$, partial $\eta^2 = 0.02$) were significant.

4. Discussion
The current study tested the initial impact of a newly developed wrist-worn device and accompanying app designed to increase participants’ awareness of hair pulling and train them to deliver self-administered HRT. The study had two primary and one exploratory aim. First, it examined the usability, acceptability, and feasibility of the prototype wrist-worn motion detection device and accompanying app as a system for delivering self-administered HRT. Second, the study examined if the device and app system have the potential to decrease hair pulling severity. Finally, as an exploratory aim, the effect of the device and app combination was compared to a reminder bracelet condition.

Participants in the device and app condition reported high usability, acceptability, feasibility, and perceived efficacy of the device and app system. The use of a small, discreet wrist-worn device, rather than the wrist and neck units used in past studies, mitigated concerns related to device wearability.
Participants wore the device for an average of 12.8 h per day, and durability issues noted in past AED studies were not reported. In support of feasibility, participants reported that the device was generally accurate in recognizing when they pulled from their danger zone and performed their competing response; however, false positives still appeared to be an issue. Furthermore, preliminary results on the perceived and clinician reported effects of the device and app combination on reducing pulling were positive. The device and app combination appear to have potential to reduce hair pulling severity.

Another purpose of the study was to explore the relative effects of the active device and app vs a reminder bracelet control condition. Results of this comparison showed that both groups demonstrated significant reductions in hair pulling, with no significant differences between the conditions. There are numerous explanations for the failure to find differences between these two conditions. First, participant responses on the self-report questionnaire suggested that those in the device and app condition experienced false positives, which could have masked the difference between the device/app and reminder bracelet conditions. The true and false positive detection rate of the prototype device can be greatly influenced by the algorithm, user-adjusted settings, and how similar the trained behavior is to the actual behavior. An improved behavior training and detection algorithm may lead to more obvious differences between the device/app and reminder bracelet conditions. Second, this was only a 4-week pilot trial in which most participants in the device and app condition did not complete all the components of HRT. With a longer trial, and more time to progress through the HRT modules, the efficacy of the device and app combination could have been enhanced. Third, one of the five participants in the reminder bracelet condition demonstrated a complete reduction in hair pulling, and this outlier may have influenced the findings. After the efficacy of the device and app combination is confirmed in larger outcome trials, it will be important to understand the mechanism by which the device produces its effect. Results from the current study suggest that any device that increases attention on the pulling may be beneficial, thus supporting attention/awareness enhancement as a mechanism worth exploring.

4.1. Limitations
The current study had several limitations. First, the study had a small sample; however, its aim was to yield pilot data to establish parameters for a possible, future efficacy study with a much larger sample size. Second, the duration of the study was only four weeks, with no follow-up period. The short duration of the study may have impacted participant progression through HRT, as only 2/10 participants in the device/app condition completed the full HRT protocol. This feature limited study conclusions and provides support for a future study that utilizes at least an 8-week trial with a follow-up period. Third, the reliability of the device was also an issue as users reported experiencing false positives. Nevertheless, participants still indicated that the device and app system was effective at increasing awareness of and reducing hair pulling. Finally, although none of the participants were receiving psychotherapy for hair pulling during the trial, it is unknown whether any of the participants had prior HRT treatment. Participants with prior HRT treatment may have progressed through the HRT protocol faster.

4.2. Implications
The current pilot trial suggests that the HabitAware® wrist-worn device and accompanying app system has the potential to be an effective tool for reducing hair pulling. Participants reported that the device and app system was a valuable tool for managing hair pulling that they would recommend to others.
Further, individuals in the reminder bracelet condition showed significant improvements in hair pulling, which suggests that random reminders not to pull may also be an effective strategy. Overall, the results indicate that a future efficacy study with a larger sample size, longer timeframe, and improved gesture detection algorithm that can quantitatively measure false positives is warranted as the device and app system could be an effective self-administered treatment for hair pulling. Future studies could also investigate whether the wrist-worn device is useful when used without accompanying HRT or as an adjunct to clinical treatment.

CRediT authorship contribution statement

**Jordan T. Stiede:** Project administration, Writing – original draft, Formal analysis, Data curation. **Douglas W. Woods:** Writing – original draft, Conceptualization, Methodology, Supervision. **Aneela K. Idnani:** Conceptualization, Writing – review & editing. **John Pritchard:** Resources, Software, Writing – review & editing. **Kirk Klobe:** Resources, Software, Writing – review & editing. **Sameer Kumar:** Project administration, Funding acquisition, Conceptualization, Writing – review & editing.

Declaration of competing interest

Dr. Woods receives royalties from the Oxford University Press. Also, Mr. Kumar, Ms. Idnani, Dr. Pritchard, and Mr. Klobe are employed by and own equity in HabitAware. The other author has declared no conflicts.

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References


