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Awareness Enhancing and Monitoring Device plus Habit Reversal in the Treatment of Trichotillomania: An Open Feasibility Trial

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Abstract

Habit Reversal Therapy (HRT) is helpful for many persons suffering from trichotillomania. However successful habit reversal therapy requires awareness of hair pulling behaviors. Available methods to monitor hair pulling behaviors are less than ideal, particularly when sufferers are unaware of their pulling-related behaviors. This open feasibility trial included 20 persons with trichotillomania who were treated with nine weeks of HRT with experienced clinicians following a well-established HRT protocol. HRT was augmented with an electronic Awareness Enhancing and Monitoring Device (AEMD) designed to alert users of hand to head contact and to monitor the frequency of pulling-related behaviors. The AEMD included a neck unit and two wrist units, each equipped with vibrating alert functions. The results of the open trial revealed significant improvements in trichotillomania symptoms as measured by clinician and self-report rating scales. Most participants met study criteria for HRT completion and treatment effects were large. Participants reported that the AEMD, when operational, was effective in alerting participants to TTM-related behaviors. The monitoring function of the AEMD did not operate as designed. Subjective feedback focused on the AEMD concept was positive but AEMD reliability problems and complaints about the wearability the units were common. Recommendations for AEMD design modifications were included.

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Keywords

Trichotillomania; Habit Reversal Therapy; Device; Awareness; Measurement

The DSM-V (American Psychiatric Association, 2013) defines trichotillomania (TTM) as recurrent hair pulling resulting in hair loss. Diagnostic criteria indicate that affected individuals must repeatedly attempt to decrease or stop pulling and that pulling must also result in significant distress or functional impairment. The lifetime prevalence of TTM in the U.S. is unknown; however, studies suggest prevalence rates for hair-pulling range from 1.0% to 13.3% (Duke, Bodzin, Tavares, Geffken, & Storch, 2009; Rothbaum, Shaw, Morris, & Ninan, 1993; Stanley, Borden, Mouton, & Breckenridge, 1995; Woods, Miltenberger, & Flach, 1996). Hair pulling in TTM is episodic and usually begins with examining a pulling site for a suitable hair, handling and extracting the hair, followed by examining, touching, and/or consuming the hair (Gaffney, 1995). Common hair pulling sites include the scalp, eyelashes, eyebrows, or pubic regions (Christenson, Mackenzie, & Mitchell, 1991) and most persons with TTM pull from more than one site (Christenson & Crow, 1995; Diefenbach, Mouton-Odum, & Stanley, 2002). The majority of hair pulling occurs in isolation, especially when engaged in sedentary activities (Schlosser, Black, Blum, & Goldstein, 1994). In addition to situational triggers, emotions including boredom, anger, tension, anxiety, and feelings of indifference are also associated with hair pulling (Stanley et al., 1995). TTM has a significant impact on quality of life including interference with work, school, home management tasks, social life, and close relationships for both adults (Woods, Flessner, et al., 2006) and youth (Lewin et al., 2009).

Two subtypes of hair pulling have been observed among persons with TTM - focused and automatic pulling (Christenson & Crow, 1995; Flessner, Woods, Franklin, Keuthen, & Piacentini, 2009). Focused pulling involves purposeful hair pulling commonly performed in response to disturbing thoughts or increased anxiety. Persons engaged in focused pulling often report high levels of tension prior to pulling followed by a sense of relief after pulling (Christenson & Crow, 1995). The automatic subtype refers to pulling that occurs outside of the person's awareness. A psychometric study of the Milwaukee-Dimensions of Trichotillomania Survey, an instrument designed to measure levels of focused and automatic pulling, revealed two robust, weakly correlated subscales that provide clear support for these two pulling typologies (Flessner et al., 2006). Literature suggests that most TTM sufferers report that the majority of their pulling is automatic (44% predominately automatic, 25% predominately focused, and 31% mixed; Lochner, Seedat, & Stein, 2010).

The most widely tested psychosocial treatment for TTM is Habit Reversal Therapy (HRT). HRT involves several components including training in producing behaviors incompatible with pulling when pulling or pulling urges occur (competing response), identification and elimination of pulling precursor behaviors (e.g., avoiding touching face/head), altering activities in or avoiding pulling-prone situations, increasing awareness of pulling-related behaviors, self-monitoring and positive self-care of pulling sites (Azrin, Nunn, & Frantz, 1980). A meta-analysis confirms the efficacy of HRT and also found significantly greater effect sizes for HRT relative to medication treatment for TTM (Bloch et al., 2007). Also,

studies indicate that a combination of Acceptance and Commitment Therapy (ACT) and HRT is a useful intervention for TTM (Crosby, Dehlin, Mitchell, & Twohig, 2012; Flessner, Busch, Heideman, & Woods, 2008; Woods, Wetterneck, & Flessner, 2006). Acceptance and commitment strategies in part seek to address the tendency of TTM sufferers to avoid unpleasant and aversive thoughts, bodily sensations, emotions (experiential avoidance) by encouraging acceptance of these thoughts and emotions (Norberg, Wetterneck, Woods, & Conelea, 2007). Other HRT-augmenting approaches also address unpleasant emotions and behavior associated with TTM and include mindfulness (Heeren, Busana, Coussemont, & Philippot, 2015) and Dialectical Behavior Therapy (Keuthen et al., 2011; Keuthen et al., 2012).

Overall, HRT and augmented HRT are helpful for many persons with TTM. However, between 30 to 40% of patients in most studies do not experience clinically significant improvement after acute treatment and maintenance of gains may be problematic (Keijsers et al., 2006). Considering both medications and psychological treatment, approximately 60% to 70% of treatment-seeking patients have been found to be wholly or partially refractory over time (Cohen, Stein, Simmeon, & Spadaccina, 1995; Lerner, Franklin, Meadows, Hembree, & Foa, 1998). There is a clear need for innovative new approaches to improve treatment outcomes for TTM patients.

One opportunity to improve HRT is to intervene to help patients become more aware of their pulling. Stanley and Mouton (Stanley & Mouton, 1996) note that a significant problem in habit reversal training occurs when patients are unable to accept the model of learning that HRT is based upon. This model posits that pulling often occurs in specific habit prone situations, that pulling begins with a series of precursor behaviors (e.g., manipulating hair), and that negative and positive reinforcements maintain the behavior. Acceptance of this model requires awareness of TTM behaviors. Awareness of pulling is particularly important given that competing response practice, perhaps the most efficacious element of HRT (Stanley & Mouton, 1996), requires the individual to be aware of actual and near pulling episodes. Awareness enhancement is also critical for persons with TTM who pull during sleep (Murphy, Redenius, O'Neill, & Zalleck, 2007). In response to the need to improve awareness, several low-tech strategies including wearing heavy bracelets, perfume, gloves, etc. have been used to enhance TTM awareness (Boughn & Jaarsma Holdom, 2002; Rapp, Miltenberger, & Long, 1998). Rapp et al. (Rapp et al., 1998) reported promising results with an electronic awareness enhancement device (two modified hearing aids) used with a 36 year-old cognitively impaired woman with TTM. The device produced a feedback sound when a hearing aid on the wrist and a second on the shirt collar came in close proximity (Rapp et al., 1998). In this study, HRT did not reduce pulling until the awareness enhancing device was in place. With the device, pulling was nearly eliminated yet pulling returned to prior levels when the device was withdrawn.

Beyond awareness enhancement, evidence from Rapp et al. (1998) suggests additional opportunities to enhance HRT outcomes. The loud tone used in this study likely served as a punisher for pulling. An audio and/or tactile alert upon coming in contact with areas associated with pulling can be experienced as aversive and may contribute to a reduction in TTM behaviors in its own right. Therefore, pairing ethically appropriate and socially

acceptable aversive stimuli with TTM behaviors presents a second opportunity to enhance HRT.

A third opportunity to improve HRT involves reinforcement of competing responses. When an aversive stimulus is terminated by a behavior, the behavior is likely to be repeated (negative reinforcement). If persons with TTM experience relief from an aversive stimulus (e.g., a tone or vibrating alert) by moving the hand away from a pulling site, this behavior will likely occur more frequently.

Lastly, a fourth opportunity for improving the assessment and treatment of TTM concerns the monitoring of TTM behaviors. Self-monitoring is an important component of HRT for TTM in that it: helps to bring pulling into awareness (Rothbaum & Ninan, 1994); provides useful information regarding the time, duration, and activity/location associated with pulling; and is a vital source of TTM outcome data for clinical and research purposes. Although accurate monitoring is critical for both clinical and research purposes, adherence to common TTM self-monitoring strategies such as collecting hairs and/or completing written logs is often difficult (Miltenberger, Long, Rapp, Lumley, & Elliot, 1998). Underscoring the overall value of accurate monitoring of TTM behaviors, Stanley and Mouton (Stanley & Mouton, 1996) note the need for creative approaches to improving self-monitoring and suggest the use of an audiotape recorder or computer program. Researchers posit that the ideal measurement strategy should include a reliable method to catalog both the frequency and duration of pulling symptoms (Stanley, Breckenridge, Snyder, & Novy, 1999).

The current paper reports on an initial open trial of a device designed to address several of the opportunities to improve behavioral therapy outlined above. The Awareness Enhancing and Monitoring Device (AEMD) was designed with two primary functions: (1) a vibrating TTM behavior awareness function which is activated via two wrist units when persons with TTM place their hands in a location associated with pulling, and (2) a TTM monitoring function. The AEMD is designed to be used in conjunction with best-practice TTM intervention methods like HRT. This study follows our previously published research reporting on a positive laboratory-based experiment with an awareness enhancing device (a wired vibrating pager) that was remotely activated by an investigator when observing TTM-related behavior performed by patients through a one way mirror (Himle, Perlman, & Lokers, 2008). The current report utilizes an AEMD device that was designed to increase awareness of and to monitor TTM-related behavior *automatically* during the course of usual activities in the community. The aims of this project are to examine HRT outcomes using the AEMD in an open trial and to examine the feasibility and acceptability of the AEMD concept based on participant report of experiences using the device.

Method

Participants

Participants were 4 men and 17 women aged 19–53 ($M = 31.67$, $SD = 9.37$) who met diagnostic criteria for TTM and other study-related inclusion criteria. Participants were recruited through the usual clinical flow of TTM patients seeking treatment at the University

of Michigan Anxiety Disorders Program (ADP) and through an advertising initiative. ADP is a clinic designed to serve adults with a range of disorders including trichotillomania.

All participants must have experienced active hair pulling over the month prior to enrollment, had noticeable hair loss, and experienced significant distress related to TTM. Only potential participants who primarily pulled from the head area were included since the AEMD used in this study was designed only for those who pull from the head. Participants taking medications were included and no attempt was made to modify the use of their medication throughout the trial. Participants with either current HRT or a past history of at least 5 sessions of HRT were excluded given that the purpose of this trial was not to evaluate the utility of the AEMD for treatment-resistant TTM. Participants were asked to restrict all psychotherapy for TTM during the active phase of the study and throughout the follow-up period. Medication use was not restricted during the follow-up period.

Exclusion criteria were the presence of any of the following: the inability to read/write English, current substance use diagnosis, chronic neurological disorder (other than chronic tics), mental retardation, schizophrenia and other psychotic disorders, bipolar I disorder, or prominent suicidal/homicidal ideation with imminent risk.

Assessment and Measures

Participants were assessed at baseline, at the end of the 9-session treatment, and at 12-weeks post-treatment.

Clinical Diagnoses—The primary diagnostic measure was the Structured Clinical Interview (SCID) for DSM-IV Axis-I Disorders – Patient Edition (First, Spitzer, Gibbon, & Williams, 1995). The SCID does not include questions about TTM. Hence, the SCID was supplemented with the Trichotillomania Diagnostic Interview (Rothbaum & Ninan, 1994) modified to fit DSM-IV criteria for TTM. Although no psychometric information is available regarding this diagnostic instrument, it allows for careful review of the DSM-5 diagnostic criteria and is modeled after the SCID.

Demographics—Demographic information including gender, date of birth, race/ethnicity, educational level, family characteristics, and other relevant variables were collected at baseline.

Measures of TTM symptoms—The AEMD was designed to provide baseline and treatment frequencies of hand-to-head contact. The AEMD was also designed for patient self-characterization of hand to head alerts as an actual hair extraction, near pulling or benign touching behavior (e.g., adjusting one's glasses).

The NIMH Trichotillomania Severity Scale (TSS) and the NIMH Trichotillomania Impairment Scale (TIS; Swedo et al., 1989) were also used to respectively measure the severity and associated functional impairment related to TTM. This clinician-rated instrument yields a severity score that measures average time spent pulling, time spent pulling on the previous day, resistance to pulling urges, distress associated with pulling, and interference related to TTM. Each item on this portion of the TTS yields a score from 0 – 5

with 5 indicating the highest severity, resulting in a total of 25 possible points. Impairment is measured using a single item score from 0 (no impairment) to 10 (severe impairment). Psychometric data for the TSS are limited (Stanley et al., 1999) but inter-rater reliability has ranged from 0.78 – 0.92 (Diefenbach, Tolin, Crocetto, Maltby, & Hannan, 2005; Swedo et al., 1989). Given sensitivities related to the reporting of hair-pulling to others, a self-report inventory, the Massachusetts General Hospital Hair pulling Scale (MGHHPs; Keuthen, O’Sullivan, & Ricciardi, 1995) was also used to assess TTM symptoms. The MGHHS has acceptable test-retest reliability and convergent and divergent validity (O’Sullivan, Keuthen, & Hayday, 1995). In order to gather preliminary information about the utility of the AEMD among TTM subtypes, focused versus automatic pulling was measured using the Milwaukee Inventory for Subtypes of Trichotillomania – Adult Version (MIST-A; Flessner, Woods, Franklin, Cashin, & Keuthen, 2008).

Measures of Other Symptoms in Participants—Co-occurring depressive symptoms were assessed using the Beck Depression Inventory (BDI; Beck, Steer, & Carbin, 1988). The BDI has well-established reliability and validity (Beck, Steer, et al., 1988). Anxiety was assessed using the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988). The BAI, which measures severity of anxiety symptoms, is a widely-used scale with well-established reliability and validity (Fydrich, Dowdall, & Chambless, 1992).

Measures of treatment expectancy and satisfaction—Treatment expectations were measured using the Expectancy Rating (Borkovec & Nau, 1972). This is a five item self-report instrument designed to assess patient expectations regarding change with treatment. The Expectancy Rating has high internal consistency and high test-retest reliability (Devilly & Borkovec, 2000). Treatment satisfaction was rated using the Treatment Impressions Rating Scale, a Likert-based self-report instrument created for this study.

Participant interviews—Brief interviews were conducted with participants at the end of HRT. Participants responded to a series of brief questions asking for feedback on the design and function of the AEMD and to comment on usefulness of the device during treatment with HRT. Formal qualitative analyses were not conducted given that participant responses were typically limited to a few phrases and participants were not probed to provide detailed responses.

Device

The AEMD includes a family of three elements built using “off-the-shelf” components (see Figures 1 and 2). The AEMD is designed to be used throughout all waking hours. The first of the three elements, worn around the neck and under the shirt, broadcasts ultrasonic signals around the head forming a “cone” of non-audible sound around the head. The other two devices are a pair of vibrating wrist receivers that include sound receivers and accelerometers that combine with microprocessors to send vibrating alerts when users draw their hand near their face/head for at least 3 seconds. When the alarm is activated, users cancel the vibration by pressing one of three buttons on the activated wrist unit indicating a pull, near-pull or a benign touch. The device also has a power button and a temporary time-

out feature that disables the vibrating alert to accommodate typical hand-to-face/head behaviors such as eating and tooth brushing without activating the vibrating alert.

The AEMD is primarily designed to bring TTM-related behavior into awareness. Additionally, pressing a button to terminate the vibrating alert on an activated wrist unit serves as competing response activity given that pressing a button on a unit is incompatible with pulling. The goal of the vibrating alert is to interrupt potential pulling behaviors quite early in the behavior chain, often before hair extraction occurs, which is important given clinical impressions that urges usually increase after initial extraction. The device used in this study was only suitable for pulling from the face/head region.

The device was also designed to monitor TTM behaviors. The AEMD was designed to record the date and time of each vibrating activation. The wrist units could be connected via USB to a personal computer. A computer program then quantified the data and produced graphic displays of actual or near pulling behaviors, benign touches, unclassified TTM behaviors, and temporary time out events.

Intervention and Research Design

This open trial incorporated the AEMD throughout a full course of professionally-led HRT. Four clinicians with extensive training and experience in delivering in HRT from the University of Michigan Anxiety Disorders Program provided 9-session habit reversal therapy to TTM patients according to a published treatment manual (Rothbaum & Ninan, 1999). Weekly supervision took place throughout the trial. The AEMD was introduced at the end of session one and remained in use throughout the 9-session intervention trial. The median duration of treatment was 13 weeks. The AEMD's alert features were disabled for the first two weeks of treatment in an attempt to obtain baseline measures of TTM-related behaviors before the core HRT strategies were put in place at the end of session 3. The full functions of the AEMD (alert and monitoring) were activated after session three.

Two doctoral level treatment adherence and competence evaluators, with considerable experience in HRT from the Anxiety Disorders Program, rated 2 randomly selected sessions from 19 of 20 participants for HRT adherence and competence using a HRT-adherence and competency rating scale. Recordings were not available for one participant. Fidelity ratings were derived from a scale designed for the present study which yielded ratings between 1 (ineffective) and 5 (extremely effective) on a range of HRT domains and an average overall score for each session.

Analyses focused on detecting significant change on the two core measures of trichotillomania symptoms as well as core measures of comorbid depression and anxiety. To determine overall patterns of change, we used longitudinal mixed effects regression, which allowed for appropriate accommodation of small variations among participants in the timing of post-treatment and follow-up assessments. Planned contrasts were used to test average change from pre- to post-treatment and from pre-treatment to follow-up; effect sizes (Cohen's *d*) were computed for each contrast by dividing mean change by the baseline standard deviation for each measure. Exploratory analyses examined possible differential

effects by trichotillomania subtype. In addition, descriptive statistics were computed for measures of treatment expectation and satisfaction.

Statistical Methods Related to Participant Attrition—Participants who failed to complete at least 5 HRT sessions were coded as non-completers. All participants who attended at least one treatment session were included in analyses (intent-to-treat analyses). Of the 21 participants, two did not complete interviews at post-treatment or follow-up, and one did not complete the follow-up; further examination revealed that the two participants who completed neither the post nor follow-up interviews had significantly lower baseline scores on the automatic pulling dimension of the MIST ($M = 10.50$ vs 27.92 , $t(18.9) = 9.0$, $p < .001$). Accounting for the influence of this variable, missingness appeared to be at random (MAR), and expectation maximization (EM; Enders, 2010) was used to retain all 21 participants in the ITT analyses.

Statistical Power Analysis—The sample of 21 participants provided 80% power for a minimum detectable change of $d = .76$ on the self-report measures, assuming 2-tailed $p < .05$.

Results

Outcome Analysis

As can be seen in Table 1, there were significant declines on both measures of trichotillomania symptoms and severity. Both linear and quadratic change parameters were significant, indicating declining scores overall but also a leveling off between post-treatment and 3-month follow-up. Within-subject contrasts showed that post-treatment scores were significantly lower than baseline, with standardized effect sizes 1.21 SD lower than baseline for the NIMH TSS and 1.64 for the MGHHS. Despite leveling off after the post assessment, follow-up scores remained significantly lower than baseline with standardized effect sizes 0.90 SD lower for the NIMH TSS and 1.26 for the MGHHS. Follow-up scores were not significantly different from post-treatment scores on either trichotillomania scale. Measures of co-occurring depression and anxiety showed no significant change. Seventy-nine percent of participants met study criteria as treatment completers (attending at least 5 of 9 HRT sessions).

To explore whether treatment effects might differ by trichotillomania subtype, the Milwaukee Inventory for Subtypes of Trichotillomania was used to differentiate individuals who primarily engaged in focused vs. automatic hair-pulling. Mean baseline scores on the two dimensions of this measure were 30.98 ($SD = 14.82$) for focused pulling (9 items) and 26.36 ($SD = 9.37$) for automatic pulling (5 items). The proportion of maximum scaling approach (Little, 2013) was used to compute comparable scores across the two dimensions, and individuals were categorized according to their higher score. Using this approach, 16 participants were categorized as predominantly automatic and 5 as focused. It should be noted, however, that in half the cases, proportional scores on the two dimensions were within .20, suggesting substantial overlap between subtypes. No treatment outcome differences were observed between the two subtypes, likely due to very limited power afforded by the small sample.

Treatment expectation, satisfaction and intervention fidelity

At baseline, participants were positive in their expectation of the treatment, with all scoring at 2 or above on the Treatment Expectancy Questionnaire, indicating at least “some” confidence that the treatment would be successful, and half scoring at 3 or above, indicating “very much” confidence ($M = 3.06$, $SD = 0.54$). Satisfaction with the treatment was positive, with 13 of 19 who completed the post-treatment interview reporting that they were “much improved” or “very much improved”; only one participant reported seeing “no change.” Over half reported that they were “very likely” or “extremely likely” to recommend the treatment to others. However, 12 of 19 reported that it was “somewhat difficult” or “very difficult” to stick to the treatment program. Interviews revealed that the feasibility of using this AEMD regularly during the course of HRT was mixed. While some participants were able to use the AEMD on a near daily basis, several participants reported that the AEMD malfunctioned at times during the trial and that the unit was somewhat bulky and cumbersome, particularly when wearing light clothing. HRT treatment fidelity ratings (34 sessions rated) yielded an average overall rating of 4.75 ($SD = 0.31$), which is above our within-protocol threshold of 4.

Discussion

This open trial of HRT coupled with the use of an awareness enhancing device found similar effect sizes and retention rates to those typically found in outcome studies of HRT without such a device (Bloch et al., 2007). Specifically, the pre- to post-treatment effect sizes on the two main TTM outcome measures (NIMH TSS: $d = -1.21$; and MGHHS: $d = -1.64$) were quite similar to average pre- to post-treatment effect sizes found in a published meta-analyses of HRT compared attention control for TTM ($d = -1.14$ on primary outcome measure used; Bloch et al., 2007). There were no significant differences in outcomes for those who primarily experienced automatic pulling versus those who primarily experienced focused pulling. Firm conclusions about the potential benefits of this electronic device cannot be drawn based upon the lack of a control condition, the limited sample size, and AEMD performance problems (see below) in this trial.

Brief interviews with participants revealed that the AEMD’s awareness enhancement feature was generally valued by participants. The AEMD used in this trial, when in good working order, was reasonably accurate in discerning true from false alarms. However, users did report that they experienced some false alarms where the device indicated that the user’s hands were in the pulling zone when they were not (false positive) and some experiences when the device failed to alert when their hands were near or on the face or head (false negative). One situation that was problematic with respect to false alarms was when participants used the device while driving. Some driving styles, particularly when participants held the steering wheel at the 10:00 and 2:00 positions, yielded high false alarm rates. Users also indicated problems with false alarms when they used a hand-over-hand approach when making turns. These problems suggest that it may be best to have a button that disables the alert feature for extended periods when the user is driving.

The most challenging issue with the alert feature was overall device reliability throughout the nine-week treatment period. Budget issues necessitated the use of off-the-shelf

components in the prototype units used in the open trial. The units used in the trial were hand built. The combination of bulky components and hand assembly contributed to problems with the AEMD's durability. Given that the AEMD was intended to be used throughout all waking hours, the units were dropped on the floor, stepped on, put in purses and backpacks and otherwise handled in a rough fashion. Our experience over time suggested that these typical use patterns took a toll on the fine wires that were used in the neck units. The most common reason for a device breakdown were broken wires in the neck piece likely resulting in the wires bending back and forth while in use. Future device iterations would likely benefit from the use of stronger wires and soldering methods and perhaps a more rigid neckpiece design that would keep wires in a fixed position.

Beyond device breakdown, the second most common reason for not using the AEMD was the difficulty concealing the neck unit under certain clothing. This was particularly notable for women wearing light tops with thin straps in the summer months. Our expectation was that women and men would wear clothing that was compatible with device concealment throughout the active treatment period. We found that many of our female participants simply did not have enough collared shirts and other garments to sustain a reasonably varied wardrobe during the warm months of the year. Some respondents reported the opposite problem in colder months. Although the neckpiece has a strength of signal adjustment to accommodate tops of various density and thickness, adjusting the ultrasonic signal produced by the neck unit to fit very thick clothing proved to be quite difficult. Ideally, a future AEMD could be designed that does not require a neck unit such that concealment and clothing density difficulties would not hinder its use.

The AEMD's automated monitoring feature did not function well during the trial. Data analysis conducted at the end of the trial revealed problems with the automated classification of device activations. Many device activations captured by the monitoring system did not include a marker indicating that the user classified the event as a pull, near pull or benign touch. It was not clear whether the users simply did not press a button to indicate the nature of the event or if the AEMD's did not accurately archive the data. Impressions from brief post-treatment interviews with participants suggested that the limited classification data was at least in part due to problems with button function, confusion about the purpose of each button, participants finding the classification system too cumbersome to use regularly, and/or concerns about privacy associated with classifying an event around others. Our experience suggests that future classification systems include one easy-to-operate button indicating whether the alert was associated with a TTM behavior.

In addition to problems with the event classification system, examination of individual participant's device activation data often revealed unexpected missing data and patterns of activation (e.g., long strings of activation separated by only a few seconds) that did not match participant reports. Close examination of the automated device activation data yielded significant concerns about the overall reliability of the AEMD's event monitoring capability so the investigative team decided not to report the automated device activation data.

The substantial monitoring and occasional awareness alert problems notwithstanding, users generally approved of the concept of a device that assisted them with both TTM awareness

and monitoring. Satisfaction ratings indicated that most participants rated high levels of satisfaction with the concept. The size, difficulty concealing the device, the need to charge the device daily, and the complex classification system were consistently cited as opportunities for improvement. Future iterations of the AEMD would benefit from the use of more compact, low power use components and increased durability. These improvements would likely involve the use of very small components designed specifically for the AEMD. Initial engineering and assembly costs associated with the development of a very small, lightweight and durable AEMD would likely be substantial and would require investment capital beyond what is typically available in a research grant.

Finally, the utility of the AEMD will not be firmly established until it is subjected to a randomized, controlled trial of HRT with and without the AEMD. It would be particularly helpful if all participants in the trial used an unobtrusive, lightweight AEMD for TTM behavior monitoring with only half of the participants using the device with the alert functions activated. It would also be important to subject the new devices to rough handling before deploying them into the field. A final question worthy of study is to investigate whether the AEMD is useful when used without accompanying HRT. All of these studies await the development of a more compact, user friendly AEMD that overcomes the reliability and usability problems discovered in this trial.

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Highlights

- An open trial of habit reversal therapy augmented with device for trichotillomania
- Significant improvement in trichotillomania symptoms
- Positive subjective impression of device concept
- Reliability and wearability challenges

Figure 1.
Drawing of AEMD components on model.

Figure 2.
AEMD wrist and neck units.

Change on Self-report and Clinical Measures: Longitudinal Mixed Effects Regression and Planned Contrasts

Table 1

	Observed Means (<i>SD</i>)			Time Parameters (<i>se</i>)		Within-subject Contrasts			
	Pre treatment	Post treatment	3-mo. Follow-up	Linear	Quadratic	Pre-Post		Pre-Follow-up	
						Mean change (95% CI)	<i>d</i>	Mean change (95% CI)	<i>d</i>
NIMH TSS	13.00 (4.04)	8.13 (3.62)	9.35 (4.23)	-2.24*** (0.57)	0.27** (0.09)	-4.90*** (-7.15; -2.59)	-1.21	-3.65** (-5.62; -1.68)	-0.90
MGHHS	15.96 (3.90)	9.57 (4.96)	11.00 (5.73)	-3.35*** (0.62)	0.43*** (0.10)	-6.39*** (-8.81; -3.97)	-1.64	-4.96*** (-7.28; -2.65)	-1.26
BDI	6.48 (7.20)	5.90 (6.60)	10.29 (9.04)	-0.14 1.09	0.13 0.17	-0.57 (-4.02; 2.89)	-0.08	3.81 (-0.35; 7.97)	0.53
BAI	6.10 (6.47)	5.76 (5.97)	6.31 (6.03)	-0.01 0.54	0.02 0.09	-0.33 (-2.44; 1.77)	-0.05	0.21 (-1.91; 2.34)	0.03

Note. *N* = 21. NIMH TSS = NIMH Trichotillomania Symptom Severity Scale. MGHHS = Massachusetts General Hair Pulling Scale. BDI = Beck Depression Inventory. BAI = Beck Anxiety Scale.

*
p < .05.

**
p < .01.

p < .001.