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Title: Feasibility Study for Treating Trichotillomania With Wearable Device and App System

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STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

STUDY PROTOCOL

Potential participants completed a phone screening with an independent evaluator (IE) to determine preliminary study eligibility (Figure 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; Figure 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.

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., 1998) and finger sucking (Ellingson et al., 2000; Stricker et al., 2001; Stricker et al., 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.

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 (Figure 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.

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 seven seconds. 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 three seconds. 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.

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.

STATISTICAL ANALYSIS PLAN

For the usability, acceptability, feasibility, and perceived efficacy, participants completed a 21-question survey and rate each of the areas on a scale of 1 (strongly disagree) to 5 (strongly agree). Mean scores were compiled and examined. To examine the impact of the device and app on hair pulling severity, Wilcoxon signed-rank tests were conducted on pre-post NIMH-TSS and MGH-HS total scores. To examine the preliminary comparison between the device/app system and reminder bracelet, a 2 (group) by 3 (time) mixed analysis of variance (ANOVA) was conducted to determine whether there were significantly greater decreases in the NIMH-TSS and MGH-HS total scores from baseline to post-treatment among participants who were given the device and app relative to the reminder bracelet.