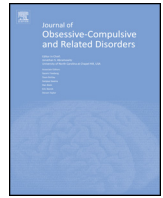




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Behavior therapy for pediatric trichotillomania: Rationale and methods for a randomized controlled trial



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ABSTRACT

There is a dearth of knowledge on trichotillomania in youth, which is particularly problematic given that trichotillomania typically develops in childhood or early adolescence. Early identification and treatment may prevent adult morbidity and impairment. This paper presents the rationale, design, and methods of a randomized controlled trial (RCT) that will investigate the efficacy of behavior therapy (BT) vs. supportive counseling (SC) for youth (ages 10–17) with trichotillomania (TTM). This study seeks to replicate and extend findings from a smaller RCT which compared BT to a minimal attention control condition and indicated an advantage for BT. Participants will be randomized to BT or SC. After eight weeks of treatment, participants in the BT condition will enter an eight week maintenance phase and participants in the SC condition will be offered BT. The primary aim is to examine the effect of treatment on TTM symptom reduction at post-treatment. Secondary aims include evaluation of the maintenance of BT gains through a naturalistic follow-up phase, predictors of acute and long-term response to BT (including psychiatric comorbidity, initial severity, family psychopathology, and pulling subtype), and the efficacy of BT for patients who initially receive SC, and to benchmark those outcomes against those achieved by patients who are initially randomized to BT. Given how little research has been devoted to pediatric TTM and its treatment, this study represents an essential step in identifying and implementing efficacious treatments for youth with TTM.

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1. Introduction

Trichotillomania (hair pulling disorder; TTM) is a disorder characterized by pulling out one's own hair, resulting in noticeable hair loss (Diagnostic and Statistics Manual of Mental Disorders, 5th Edition; DSM-5; APA, 2013). Although large epidemiological studies have yet to be conducted, TTM has been estimated to affect 0.6–3.5% of late adolescents and adults, with higher prevalence in women and girls (Christenson & Pyle, 1991; Woods et al., 2006a). The rates among children are unknown (Tolin, Franklin, Diefenbach, Anderson, & Meunier, 2007) but the disorder typically develops in late childhood or early adolescence (e.g., Christenson, Mackenzie, & Mitchell et al., 1991b). The adult literature suggests that TTM is a chronic condition often associated with significant psychiatric comorbidity and functional impairment (e.g., Woods et al., 2006a), and that behavioral treatments offer significant benefit (see Chamberlain & Heyman, 2007). An online poll of

children with TTM and their parents indicated that despite moderate interference in social and academic functioning from TTM, only 65% of the sample reported receiving treatment specifically for the disorder (Franklin et al., 2008). Furthermore, out of those that did receive treatment, only 17% were either very much improved or much improved following the intervention. Although this study was based on a convenience sample and thus possesses limited generalizability, it strongly suggests a need for the development of an efficacious and potentially transportable treatment for youth with TTM. Moreover, effective treatment delivered closer in time to TTM symptom onset may serve as a form of prevention of the psychiatric comorbidities that appear to be the norm for adults with TTM.

In light of this clear need for the development of effective treatment for pediatric TTM, our group conducted an Exploratory/Developmental Grant for Psychosocial Treatment Research (R21) funded by the National Institute of Mental Health (NIMH) to develop and empirically evaluate a manualized behavior therapy (BT) program for pediatric TTM. That project included an initial open trial (Tolin et al., 2007) and then culminated in the first published randomized controlled trial (RCT) of any treatment for pediatric

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TTM. Results indicated a clear advantage for BT over a Minimal Attention Control (MAC) condition at post-treatment, with gains maintained through an 8-week maintenance phase for those randomized to BT (Franklin, Edson, Ledley, & Cahill, 2011a). With this encouraging work as our starting point, the current study seeks to replicate the findings in a larger sample and extend them by employing a more scientifically rigorous comparison condition, Supportive Counseling (SC), which will control for the potential contribution of non-specific factors (e.g., psychoeducation, therapist contact time).

In this paper, we will first elaborate on the rationale for the current study by providing further overview on what was known about the treatment of TTM before this trial. We will explain how our current study will build on and extend this extant literature. Next, we will review the methods for our current study including study design, measures, treatment procedures.

Many psychosocial therapies have been utilized to treat TTM in adults, including psychodynamic approaches (e.g., Koblenzer, 1999), hypnosis (e.g., Hynes, 1982), and a wide array of behavioral and cognitive-behavioral treatments (for a review see Franklin, Tolin, & Diefenbach, 2006; Keuthen, Aronowitz, Badenoch, & Wilhelm, 1999). Pharmacotherapy has also been attempted, with RCTs conducted on fluoxetine (e.g., Christenson, Mackenzie, Mitchell, & Callies, 1991), clomipramine (Swedo et al., 1989) and naltrexone (Grant, Odlaug, Schreiber, & Kim, 2014). Although successful outcomes following some of behavioral and cognitive-behavioral treatments are reported, the vast majority of the literature consists of uncontrolled case reports or small case series (Keuthen et al., 1999). In general, TTM treatment outcome studies have been limited by small sample sizes, lack of specificity regarding sample characteristics, non-random assignment, paucity of follow-up data, exclusive reliance on self-report measures, and insufficient information regarding treatment refusal and drop-out rates.

Of the behavioral and cognitive behavioral treatments that have been applied to TTM, the package that has received the most research attention for TTM and other habit/impulse control disorders is habit reversal training (HRT; Azrin & Nunn, 1973), which typically includes awareness training/self-monitoring procedures, instructions to respond to urges to pull by engaging in a competing response that uses the same muscle groups and is incompatible with pulling (e.g., fist clenching), as well as stimulus control strategies that involve removing and avoiding stimuli that trigger hair pulling. According to a recent poll among trichotillomania treatment experts, HRT is the treatment of choice for both adults and children with TTM (Flessner, Penzel, & Keuthen, 2010).

In the first RCT examining HRT for TTM in adults (Azrin, Nunn, & Frantz, 1980), HRT was more effective than negative practice, another behavior therapy intervention in which patients were instructed to repeatedly engage in the motions of hair-pulling without pulling any hair. The HRT group reported a 99% reduction in number of hair pulling episodes compared to a 58% reduction for patients in the negative practice group. The generalizability of these findings was limited by the absence of a formal treatment protocol, and exclusive reliance on self-reports as the sole outcome measure. Since then, four more RCTs have been published and their results converge to support the efficacy of BT/HRT for TTM.

In a small trial, Ninan, Rothbaum, Marsteller, Knight, and Ecard (2000) found a cognitive behavioral treatment package emphasizing HRT superior to clomipramine and placebo at post-treatment; clomipramine and placebo failed to separate from one another. van Minnen, Hoogduin, Keijsers, Hellenbrand, and Hendricks (2003) randomized 43 patients with TTM to receive either BT, fluoxetine, or waitlist for 12 weeks. Significantly more patients in the BT group showed clinically significant improvements in TTM

symptoms compared to fluoxetine or waitlist groups. Also, patients in the BT group experienced a greater reduction in their TTM symptoms than did patients in the other groups. Woods, Wetterneck, and Flessner (2006b) found a combination of Acceptance and Commitment Therapy (ACT) plus HRT superior to waitlist, although the study design did not allow for conclusions about the separate contributions of ACT and HRT, respectively. Diefenbach, Tolin, Hannan, Maltby, and Crocetto (2006) randomized 24 adult patients with TTM to a group BT intervention or a group supportive therapy intervention. Patients in the BT condition had significantly greater decreases in TTM symptoms than those in the supportive therapy condition. However, few patients in either condition showed clinically significant change at the end of treatment. Additionally, BT's advantages were not maintained during the follow-up period. The reduction of BT's potency in this trial compared to the others may have been due to the group format; however, without an individual BT comparison this conclusion cannot be made.

Single case studies examining the effects of a variety of behavioral procedures for pediatric TTM suggested the efficacy of treatment, but methodological problems across this literature render their findings inconclusive (Reeve, 1999). In two multi-case studies of BT, youth responded to treatment initially yet some relapse was evident at follow-up. Vitulano, King, Scahill, and Cohen (1992) found maintenance of treatment gains at 12-week follow-up in two of three youth who received BT. Similarly, Rapp, Miltenberger, Long, Elliot, and Lumley (1998) found that two of three youth treated with HRT and occasional booster sessions maintained their treatment gains from 18 to 27 weeks post-treatment.

The RCT conducted in the context of our R21 project is the only controlled trial of any psychosocial treatment for pediatric TTM. Data from this study attested to the efficacy of BT for pediatric TTM: BT was clearly superior to MAC at post-treatment. Small sample size and a relatively weak control condition as our comparison weakened the generalizability of our outcomes to larger samples of similar patients, and also did not permit us to draw conclusions about the specificity of BT's effects. Accordingly, we seek to address both of these key issues in this next-phase clinical research project.

Some randomized and open studies of BT that included follow-up data have suggested problems with relapse in adults. Keijsers et al. (2006); Keuthen et al. (2001); Lerner, Franklin, Meadows, Hembree, and Foa (1998); Mouton and Stanley (1996) indicated that relapse was common, whereas Azrin et al. (1980) reported maintenance of gains. It is important to note that the studies that found problems with relapse used independent assessment of TTM symptoms via semi-structured interview or a psychometrically sound self-report instrument, whereas Azrin et al.'s study relied on un-standardized patient self-report. Single case reports are also generally mixed on whether patients maintained their treatment gains (e.g., Friman, Finney, & Christopherson, 1984). Clinically, several TTM treatment experts (e.g., Christenson & Mackenzie, 1995) have observed that patients often experience recurrence of hair pulling after treatment, especially in response to external stressors. Stanley and Mouton (1996) suggested that additional attention might need to be given to extending awareness training and the use of competing responses to maximize long-term outcome. Another strategy that has been recently tested as a way to improve relapse prevention is the addition of emotion regulation strategies to behavior therapy. Following promising results in a pilot study (Keuthen et al., 2011), Keuthen et al. (2012) completed an RCT in which TTM participants were randomized to dialectical behavioral therapy (DBT)-enhanced HRT or to a minimal attention control (MAC). Participants in the DBT condition showed greater improvement than those in the MAC condition in

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