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### Journal of Anxiety Disorders



# Defining treatment response in trichotillomania: a signal detection analysis



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#### ARTICLE INFO

Article history: Received 6 April 2015 Received in revised form 7 September 2015 Accepted 14 September 2015

Keywords: Hair pulling Trichotillomania Obsessive-compulsive disorder Signal detection Psychotherapy

#### ABSTRACT

The Massachusetts General Hospital Hairpulling Scale (MGH-HPS) and the NIMH Trichotillomania Severity Scale (NIMH-TSS) are two widely used measures of trichotillomania severity. Despite their popular use, currently no empirically-supported guidelines exist to determine the degrees of change on these scales that best indicate treatment response. Determination of such criteria could aid in clinical decision-making by defining clinically significant treatment response/recovery and producing accurate power analyses for use in clinical trials research. Adults with trichotillomania (N = 69) participated in a randomized controlled trial of psychotherapy and were assessed before and after treatment. Response status was measured via the Clinical Global Impressions-Improvement Scale, and remission status was measured via the Clinical Global Impressions-Severity Scale. For treatment response, a 45% reduction or 7-point raw score change on the MGH-HPS was the best indicator of clinically significant treatment response, a down or the NIMH-TSS, a 30–40% reduction or 6-point raw score change on the MGH-HPS was the best predictor, and on the NIMH-TSS, a 65% reduction or 6-point raw score change was the best indicator of disorder remission. Implications of these findings are discussed.

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#### 1. Introduction

Researchers have demonstrated the efficacy of various treatments for reducing hair pulling in adults with Trichotillomania (TTM; Bloch et al., 2007). Such studies typically utilize psychometrically-validated measures of pulling severity (Grant, Odlaug, & Kim, 2009; Keuthen et al., 2012; Woods, Wetterneck, &

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http://dx.doi.org/10.1016/j.janxdis.2015.09.008 0887-6185/© 2015 Elsevier Ltd. All rights reserved. Flessner, 2006), the most common of which are the Massachusetts General Hospital Hairpulling Scale (MGH-HPS; Keuthen et al., 1995) and the National Institutes of Mental Health Trichotillomania Severity Scale (NIMH-TSS; Swedo et al., 1989).

The MGH-HPS is a self-report measure and the NIMH-TSS is clinician-rated. Both are dimensional scales that possess sensitivity to change in TTM treatment studies (Diefenbach, Tolin, Crocetto, Maltby, & Hannan, 2005; Swedo et al., 1989). Although existing treatments have yielded statistically significant changes in scores on both measures (Woods et al., 2006), the magnitude of reductions needed to signify clinically significant change is unclear.

When no clear cutoffs exist for a primary outcome measure, establishing the clinical significance of change requires the incorporation of additional information. For instance, clinicians might rely on a combination of qualitative and quantitative data to gauge improvement, thereby interpreting scores based on clinical judgment. An example of this type of measurement is the Clinical Global Impressions Scale (CGI; Guy, 1976), which consists of a severity index (CGI-S) and treatment improvement index (CGI-I). The CGI is a clinician-rated measure that incorporates multiple sources of data and provides a clearly interpretable metric of holistic disorder severity and treatment response. The CGI is also widely used in clinical trials (Bandelow, Baldwin, Dolberg, Andersen, & Stein, 2006; Leon et al., 1993; Leucht & Engel, 2006; Leucht et al., 2005; Spielmans & McFall, 2006; Zaider, Heimberg, Fresco, Schneier, & Liebowitz, 2003) and has been used for trichotillomania (e.g., Keuthen et al., 2011, 2012). To best determine the level of symptom reduction as measured by popular assessments of hair pulling severity, one could measure the points at which score reductions on dimensional measures (i.e., MGH-HPS and NIMH-TSS) converge best with the thresholds of clinical significance on the CGI-I and CGI-S.

Developing guidelines for clinically significant change on the MGH-HPS and NIMH-TSS would have numerous benefits in both research and clinical practice. When designing a randomized controlled trial (RCT), one ensures that the study is adequately powered to detect the desired effect size (Cohen, 1988; Kraemer & Thiemann, 1987). Recent recommendations by Kraemer and Kupfer (2006) suggest that the level of power needed in studies be based on the determination of clinically significant effects. The current study attempts to identify clinically significant cutoff criteria in commonly used TTM outcome measures, so that future studies can better approximate the power needed to identify clinically significant effects. These guidelines will also have clinical utility, as a clinically meaningful change score can give therapists a target for change and can indicate the point at which change has become significant.

A recent study examined the ability of changes in the MGH-HPS and another clinician-rated measure of hair pulling severity, the Psychiatric Institute Trichotillomania Scale (PITS; Winchel et al., 1992) to predict various meaningful outcomes (Nelson et al., 2014). Various potential clinical predictors were used, including Jacobson and Truax's (1991) clinically significant change criteria (i.e., 1.96 times the reliable change index plus a post-treatment score that was two standard deviations below the dysfunctional population mean), complete abstinence from pulling (defined as a score of 0 on MGH-HPS item 4), 25% reduction on the MGH-HPS or PITS, and the recovery criterion alone (e.g., score of  $\leq 9$  on the MGH-HPS or  $\leq 14$  on the PITS). Post-treatment abstinence from hair pulling and the MGH-HPS 25% reduction predicted several positive outcomes (i.e., decision to successfully end treatment at step 2 in the stepped-care clinical trial, treatment satisfaction, and quality of life at 3-month follow-up), but the Jacobson and Truax clinically significant change criteria on the MGH-HPS predicted only quality of life at 3-month follow-up. The 25% PITS reduction predicted no outcomes, whereas the PITS-based recovery criterion predicted decision to end treatment and the Jacobson and Truax clinically significant change criteria on the PITS predicted absence of TTM diagnosis at 3-month follow-up. As such, it appears that the ways of defining different clinical predictors leads to differential prediction of various indices of treatment response. However, no cutoff stands out as the most efficient indicator of treatment response. Determining more efficient cutoffs might be achieved through approaches that are not constrained by rigid definitions of these cutoffs, such as by testing the validity and efficiency of numerous score reductions as they converge with well-defined measures of clinically significant change (i.e., the CGI).

Indeed, five studies have performed signal detection analyses to determine such cutoffs with related conditions, such as obsessivecompulsive disorder and tic disorders. Investigators found that a 25% decrease on the Children's Yale-Brown Obsessive-Compulsive Scale was most efficient at predicting treatment response in childhood OCD, as measured by the CGI-I and the Child Obsessive-Compulsive Impact Scale (Storch, Lewin, De Nadai, & Murphy, 2010), while others found between 30 and 35% reductions on the Yale-Brown Obsessive-Compulsive Scale were most efficient in predicting adult OCD treatment response as measured by the CGI-I (Lewin et al., 2011; Tolin, Abramowitz, & Diefenbach, 2005). Likewise, a 35% reduction or 6-7 point raw score decrease on the Yale Global Tic Severity Scale (YGTSS) was found to best predict treatment response in Tourette syndrome as measured by the CGI-I (Storch et al., 2011), whereas Jeon et al. (2013) found that a 25% reduction on the YGTSS optimally predicted positive response as measured by the CGI-I in both children and adults with tic disorders. Although these studies allow clinicians to accurately predict which clients demonstrate clinically significant treatment response, no studies have determined reductions on dimensional measures of obsessive-compulsive related disorders that optimally predict disorder recovery. As was done in the Nelson et al. study on measures of treatment response in TTM, researchers have argued that estimates of clinical significance should calculate the propensity of a treatment to facilitate a decrease in symptoms within clinical individuals to those resembling normative levels (Jacobson & Truax, 1991). Thus, it would be useful to determine if certain levels of symptom reduction on dimensional scales correspond to both reliable change and recovery of normal functioning.

The present study sought to replicate the methods of previous signal detection analyses in defining treatment response for adults with TTM using both the MGH-HPS and the NIMH-TSS. In order to determine clinically significant treatment response, we used the CGI-I as the criterion measure. Similarly, the CGI-S was used as the criterion measure of TTM recovery. No a priori hypotheses were made with regard to optimal cutoff points on the measures analyzed.

#### 2. Method

#### 2.1. Participants

Although 85 participants were randomized into the clinical trial, only those who completed treatment were included in the present study. Participants were 69 adults (62 females) diagnosed with TTM whose ages ranged from 18 to 61 (M = 35.86, SD = 13.05). The sample was 85.5% Caucasian, 11.6% African–American, and 2.9% "other." Data were collected as part of a randomized controlled trial for psychotherapy for adults with TTM (Woods et al., in preparation). Both therapeutic conditions tested in the trial (i.e., Acceptance-Enhanced Behavior Therapy and psychoeducation plus supportive psychotherapy) are included in these analyses. Also, only participants who completed both the baseline and post-treatment assessments were included. At baseline, mean scores on the MGH-HPS and NIMH-TSS were 16.99 (SD = 4.68, Range = 8–26) and 14.54 (SD = 3.72, Range = 6–21), respectively.

Inclusion criteria were: (1) a current DSM-IV-TR diagnosis of TTM (2) an MGH-HPS score of  $\geq$ 12, (3) a Wechsler Test of Adult Reading score of  $\geq$ 85, (4) age 18–65, (5) English fluency, (6) able to maintain outpatient status, (7) no initiation or change in psychotropic medication status or dosage for eight weeks preceding participation or during the study, (8) not currently receiving psychotherapy for any condition, and (9) completed all 10 sessions of treatment.

Exclusion criteria included: (1) diagnosis of bipolar disorder, psychotic disorder, substance dependence (except nicotine dependence), or pervasive developmental disorder, and (2) severe mood or anxiety problems with potential suicidality. In addition, individuals who endorsed ingesting their hair after pulling were eligible Download English Version:

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