The TLC Foundation for

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Psychiatry Research, 281
functioning in pediatric trichotillomania, obsessive compulsive disorder, and healthy comparison youth.
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alterations in hair-pulling disorder (trichotillomania). Brazilian Journal of Psychiatry, 42(1), 87-104.


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Psychiatry Research, 281, 112578.

March-May 2019
pliomatricoma developing within a self-inflicted ulcer. Dermatology Online Journal, 25(2).

Demetriou, S. (2019). Emotion regulation in trichotillomania (hair-pulling disorder): The role of stress and

treatment response in trichotillomania: A meta-analysis. Progress in Neuropsychopharmacology & Biological
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June-August 2019


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Comorbidity in trichotillomania (hair-pulling disorder): A cluster analytical approach. Brain and Behavior, 9(12),
e01450.
This pilot study found that the use of dronabinol, a cannabinoid derivative containing delta-9-tetrahydrocannabinol (THC) significantly reduced trichotillomania (TTM) symptoms in a majority of subjects. The purpose of this follow-up study was to explore whether there is an identifiable difference in symptom severity of TTM between those who use cannabis recreationally and those who do not.

This study compared the TTM symptoms of 47 adult subjects, consisting of 9 cannabis users and 38 non-users, using various accredited scales for measuring TTM symptom severity. Ultimately, no significant differences were observed between the two different test groups. No measurements of participants’ cannabis consumption were included in this study outside of identifying each test subject as a user or non-user.

Although no correlations were found, the pilot study’s results warrant additional studies with more structured consumption of cannabis to corroborate or discredit any findings.
Recent research suggests heightened sensitivity to touch plays a role in BFRBs. This study tested sensory experiences using both questionnaires and physical tests of tactile sensitivity (aka sensitivity to touch), in 46 subjects with skin-picking or hair pulling disorder and 46 healthy controls.

Subjects with a BFRB scored higher than controls on all the subscales of the sensory questionnaire, and the tactile tests demonstrated people with BFRBs have a decreased tactile threshold, meaning they are faster to detect when an object is touching them.

Future research should test hair pulling and skin picking separately to see if there is a difference, and determine if BFRBs cause tactile sensitivity (or vice versa).

Although diet choice is implicated in the severity of other disorders, little research has explored the role of diet in severity of skin picking disorder (SPD) and hair pulling disorder (trichotillomania; TTM).

In this study, 32 adults with SPD, 37 with TTM, and 19 healthy control participants completed a survey for eating behavior (MEBS), scales to assess hair pulling and skin picking severity, and a subset of the group completed the Dietary Questionnaire.

No significant correlations were found between fat and sugar intake and TTM and SPD severity. Higher scores on some subsets of the MEBS (binge eating, body dissatisfaction, weight preoccupation, compensatory behavior) correlated with higher scores on the nutrition scale, but these were not significant relationships with symptom severity.

Although the study suggests no correlation between dietary choices and TTM and SPD severity, future studies further examining the role of diet and BFRB severity may help guide treatment intervention within the community.
The yearly TLC Conference is truly a one-of-a-kind environment when it comes to commingling between producers and consumers of scientific research. In no other environment do providers and patients interact on such a personal level. Renowned researchers may be sitting at one's breakfast table, parents can pose questions directly to expert clinicians during workshop sessions, and students can talk shop with the scientists (if they have the courage).

Over the past few years, in our endeavor to keep a close watch on peer-reviewed journal articles about BFRBs, we noticed some remarkable trends, and also some areas that have, to date, been seriously neglected. On the whole, our conclusion from observing the empirical literature at a bird's-eye view was that the current output of novel BFRB research is not proportional to the real-world prevalence of these disorders. That is to say, for the large number of people worldwide struggling with a BFRB, scientific advancements are not happening quickly enough to keep up. The volume of new publications is small (averaging ~150 empirical journal articles in a given year), driven mainly by a small group of dedicated scientists including The TLC Foundation's Scientific Advisory Board, and the majority of publications do not use experimental methods (i.e., they do not test a new hypothesis). By comparison, thousands of articles may be published yearly about more common mental disorders, such as depression or OCD.

For this reason, we look forward to data readouts from the BFRB Precision Medicine Initiative with excitement and impatience, but the need for research extends far beyond the BPM. So, for seasoned investigators and incipient scientists alike, here are a few humble suggestions about what kinds of studies ought to be done to continue to advance BFRB research:

**Cross-Cultural Studies**

In any given year, researchers from over 30 countries publish research on BFRBs. Some countries only publish one or two case reports, while a small minority (including Australia, Brazil, India, Iran, South Korea, and Turkey) publish a larger amount. This suggests not only that doctors in these countries are generally becoming more aware of BFRBs, but also that there are groups of specialized scientists all over the world that would willingly collaborate with groups in the US. Results from the US, especially on clinical features and treatments of BFRBs, need to be validated in different countries in order to be considered more robust.

**Studies in Minority Groups**

Similarly, we just don’t know how easily existing research translates to the general population, because these studies were oftentimes done with very homogeneous, un-representative samples. Groups like people of color, older adults, men, and LGBTQ folks may have different treatment needs, symptom profiles, or predispositions to BFRBs, so each group warrants further study in order to confirm what we think we already know.

**Medically-Focused Studies**

About two-thirds of BFRB studies are conducted by psychologists or psychiatrists, but the other one-third are carried out by other medical professionals, who may only peripherally interact with BFRB patients but still take interest. These physicians include dermatologists, dentists, surgeons, and more. An especially exciting sub-specialty is psychodermatology, because appearance is such a big part of the nature of BFRBs, and borrowing methods from dermatologists (like trichoscopy) would help physicians characterize BFRBs in a language that makes more sense to them.

**Psychophysiological Studies**

People sometimes forget that the human brain doesn’t act in a vacuum, but rather perpetually communicates and cooperates with other body systems. It may not be immediately apparent, but BFRB symptoms may intersect with the musculoskeletal, immune, nervous, or endocrine systems. These are golden opportunities for study, since much of the work defining the nature of these relationships between systems has yet to be done. Since the body as a target of BFRBs is a central feature of these disorders (it’s even in the name), it’s time to stop thinking of their effects as isolated to the brain.

**Studies on Lesser-Known BFRBs**

It has been interesting to see what new behaviors become grouped under the BFRB umbrella in some of the more recent studies. Some of these include bruxism (teeth grinding), trichotillomania (hair rubbing), and onychotillomania (picking at nails). Some of these behaviors are scientifically more worthy of the BFRB label than others, so there is a real need for the scientific community to declare once and for all which behaviors are BFRBs, and which are truly just benign “bad habits”. 
Neurosis and True Dermatosis: 
A case of ossified pilomatricoma developing within a self-inflicted ulcer

A 30-year-old woman who was previously diagnosed with skin picking disorder (SPD) went to a dermatologist for treatment of a "spot" on her skin.

For 18 years the patient suffered from a lesion that was assumed to be related to her SPD. In fact, the lesion was a benign tumor.

The non-cancerous tumor required extraction.

It is important that medical providers always investigate new medical issues or presentations, and thoroughly examine new patients, despite any previous diagnosis.

Skin Picking Disorder (SPD) is complex in the sense that it has both physical and psychological aspects. This case study aims to reiterate the importance of fully screening patients with SPD for other dermatological issues before proceeding with standard treatment.

A 30-year old woman presented at a dermatology clinic as a new patient for evaluation of a "spot" on her left cheek. Prior to coming into the dermatology clinic, the patient had been prescribed multiple medications with little to no success. Upon further physical examination, it was determined that the spot was an ulcer 3cm in length, with a central subcutaneous (i.e., located under the skin) nodule. The care provider inquired about the disrupted location on the skin; the patient said that she had the lesion for 18 years, and that she picked at it because she felt a bump under the skin which drove her to constantly pick at it, opening the wound and causing drainage of pus. The subcutaneous nodule is suspected to be a calcified cyst, resulting from the chronic trauma of SPD-based picking in the area. Histopathology testing of the suspected cyst revealed that it was actually a pilomatricoma with partial ossification: a non-cancerous skin tumor associated with hair follicles.

In conclusion, the patient, who has been diagnosed with SPD, had been living with an actual tumor underneath the skin, resulting in picking episodes in the area for 18 years. This case is a perfect example for showing the necessity of doing a full examination on new dermatology patients, even if they have already been diagnosed with SPD. Skin Picking Disorder does not eliminate the possibility of the presence of other dermatological issues, and earlier treatment of the pilomatricoma could have assisted in managing the skin picking episodes over the length of time it went untreated.

Emotion Regulation in Trichotillomania (Hair Pulling Disorder) : The role of stress and trauma  
S. Demetriou

Previous literature has explained hair pulling as an attempt to regulate emotions, putting forth the so-called ‘emotion regulation model’. Other studies have shown evidence for significantly greater severity of childhood trauma in people with TTM compared to healthy controls. However, the relationship between childhood trauma, stress, and emotion regulation in TTM remains unclear.

There were three aims in this study: to compare the rates of these three factors in TTM compared to healthy controls; to investigate if there is a relationship between hair pulling severity and difficulties in emotion regulation; and to determine whether or not there is a relationship between stress, childhood trauma, and emotion regulation difficulties in TTM, while controlling for coexisting mood and anxiety disorders.

The participants were 56 adults with TTM and 31 sex- and age-matched controls, all of whom were recruited from a previous ongoing study. All participants completed several questionnaires that assessed levels of perceived stress, childhood trauma, and difficulties in emotion regulation. TTM participants completed a questionnaire assessing severity of hair pulling disorder.

The study showed that stress, childhood trauma, and difficulties in emotion regulation were all significantly increased in TTM patients compared to the controls, but there was no statistically significant relationship between hair pulling severity and difficulties in emotion regulation, which does not support the predictions of the emotion regulation model. This study showed that rather than increased pulling, stress in individuals with TTM significantly explained difficulties in emotion regulation.

The study overall suggests that the emotion regulation model may not be best in explaining the phenomenon of trichotillomania, although more studies need to be conducted. Some limitations to this study included difficulty in controlling for the presence of coexisting disorders, which is needed to address the third aim. Another limiting factor was the collection of data across different time points, which could have caused decreased validity. Lastly, the use of self-report measures may have increased response bias in participants.

Identifying Standardized Definitions of Treatment Response in Trichotillomania: A Meta-analysis

Two of the most frequently-used surveys in trichotillomania research are the Massachusetts General Hospital Hair Pulling Scale (MGHHPS) and the National Institute of Mental Health Trichotillomania Severity Scale (NIMHTSS). However, there is no standard cutoff score that separates patients who benefited from a treatment from those who didn’t, with either of these scales, and most research uses being “pull-free” as the only indicator of recovery, an idea which is becoming less popular. The aim of this study was to look at the combined effect of several trichotillomania trials to define the best standard numbers for treatment response (aka ‘treatment response cutoff scores’) using the MGHHPS and NIMHTSS.

This study analyzed 7 trichotillomania studies to find these standard cutoff scores. 270 Total Patients

The best MGHHPS treatment response cutoff score was 7 points lower (35%).

The best NIMHTSS treatment response cutoff score was 6 points lower (50%).

4 studies in adults 3 studies used medications 4 studies used therapy 3 studies in children & adolescents

Having standard numbers for treatment responders will make it easier to consistently judge whether treatments work for trichotillomania patients.

*MGHHPS : Massachusetts General Hospital Hair-Pulling Scale
**NIMHTSS : National Institute of Mental Health Trichotillomania Severity Scale

By the Numbers: 3 Years of BFRB Research At-A-Glance

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Publications</th>
<th># Publications with TLC SAB Member as Author</th>
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<tbody>
<tr>
<td>2017</td>
<td>102</td>
<td>12</td>
</tr>
<tr>
<td>2018</td>
<td>241</td>
<td>18</td>
</tr>
<tr>
<td>2019</td>
<td>246</td>
<td>20</td>
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- **Total Publications**
  - Experimental: 59, 76, 88
  - Non-experimental (case reports, reviews, etc.): 43, 65, 58

- **Participant Age Groups in Experimental Studies**
  - Children (age 0-10): 6.9%
  - Adolescents (age 11-17): 22.7%
  - College-age (age 18-22): 38.1%
  - Adults (age 23-50): 15.4%
  - Older adults (age 51-99): 16.9%

Most-Frequently Published BFRB Authors By Geography

- Emily Ricketts, John Plackett
  - University of California, Los Angeles

- Mike Levin, Mike Tsaoch
  - Utah State University

- David Houghton
  - University of Texas Medical Branch Galveston

- Sarah Redden
  - Florida State University

- Jon Grant
  - University of Chicago

- Doug Woods, Jennifer Alexander
  - Marquette University

- Mohammad Jafferany, Arsh Patel
  - Central Michigan University

- Karen O’Connor, Marc Lavie
  - University of Montreal

- Adhipi Gupta
  - University of Toronto

- Madhukula Gupta
  - University of Western Ontario

- Nancy Keuthan
  - Massachusetts General Hospital

- Yar Snorrason
  - McLean Hospital

- Emily Olfson, Michael Bloch
  - Yale School of Medicine

- Eric Lee
  - Hartford Hospital

- Spencer Chamberlain
  - University of Cambridge (UK)

- Joyce Maas
  - Tilburg University (Netherlands)

- Brian Odfors
  - University of Copenhagen (Denmark)

- Christina Gatfet, Markus Marchener, Helge Haunssoe, Jula Winkler, Matthias Backens, Stephanie Bauer
  - University Hospital Heidelberg (Germany)

- Anne Schiende
  - University of Graz (Austria)

- Tayfun Kaya, Ismail Akaltun
  - Sadi Konuk Hospital (Turkey)

- Deniz Cildir
  - Tepecik Hospital (Turkey)

- Cicek Hocaoglu
  - Recep Tayyip Erdogan Hospital (Turkey)

- Christine Lochner
  - Stellenbosch University (South Africa)

- Renata Slikboer, Maja Nedeljkovic, Imogen Rehm
  - Swinburne University of Technology (Australia)
Prevalence and Clinical Characteristics of Skin Picking among Adults with Skin Disease Symptoms
L.J. Dixon & I. Snorrason

Many studies have been done on Skin Picking Disorder (SPD) & dermatology patients, respectively, but few studies have examined the direct correlation between SPD and dermatological conditions. The three main goals of this study were to: estimate the prevalence of skin picking urges and behaviors among those with self-reported skin diseases, examine the relationship between SPD and dermatological conditions, and examine the correlation between SPD severity and psychosocial characteristics. Based on previous studies, researchers hypothesized that SPD would be more common in women, and that those in the SPD group would report other psychiatric symptoms at a higher rate.

For this study, data was collected from participants via online survey. After a preliminary filtering of participants, researchers were left with a test group of 237 people, separated into two groups. The first group consisted of 107 participants who were identified as having some form of SPD. The second group consisted of 130 participants who did not have SPD. The final sample consisted of people between the ages of 20 and 67 years old. Of the 237 participants, 67.9% identified as female. 1-12 different dermatological conditions were acknowledged per participant, and acne was the most commonly reported condition.

The data collected appear to show that people with SPD report skin conditions at an elevated frequency, in comparison to those without SPD. Within the SPD group of 107, 52 of these participants displayed symptoms that met the criteria for pathological skin picking. Results show that although more women reported having SPD, there was not a significant sex difference in SPD prevalence. Those with SPD also reported a larger number of dermatological conditions (eczema, hives, psoriasis, etc.), and increased symptom severity. Skin picking severity was also positively associated with depression, anxiety, stress and social anxiety symptoms, confirming the association between SPD and psychosocial characteristics. In conclusion, this study reveals a relationship between SPD and dermatological symptoms, as well as psychosocial conditions such as depression and anxiety. This study is the first to specifically examine these associations. Test results may have been affected by a lack of a sizably diverse pool of participants, and follow-up studies are necessary to determine if the identified trends stand true among all social groups.

A Brief, Residential Peer-Support Retreat for Trichotillomania: A mixed methods evaluation

R. Slikboer, I.C. Rehn, S.Lam, A. Maloney, & M. Nedeljkovic

Cognitive-behavioral therapy (CBT) can be effective for treating trichotillomania, but it fails up to 50% of the time. Group-oriented therapy has similar relapse rates as CBT, but offers some therapeutic benefits that CBT doesn’t have, and many trichotillomania patients consider it effective. The purpose of this study was to observe a brief residential peer support retreat for trichotillomania, and identify which factors the patients considered most important for recovery.

The retreat was three days long, low-cost, and took place in rural Australia. Activities during the retreat included group workshops discussing trichotillomania management, self-care activities (e.g., pampering, yoga), and free leisure time. Eight women with trichotillomania took part in the retreat, and were interviewed before the retreat, as well as 1 week, 6 months, and 12 months after the retreat. Although the analysis was mainly qualitative, patients also filled out questionnaires for hair pulling severity, depression, anxiety, stress, and quality of life.

Hair pulling was reduced immediately after the retreat, but worsened to pre-retreat levels by 6 months. Quality of life also did not seem to improve long-term. However, lower levels of anxiety, depression, and stress persisted for one year post-retreat. Factors from the retreat that patients considered important to recovery on an individual level included: readiness to change (e.g., taking responsibility for their own recovery and feeling hope that recovery was possible) and self-regulation (e.g., developing emotional awareness and practicing self-care). Important factors to recovery on a group level included: sharing lived experiences, connecting with others in the community, normalizing hair pulling, and promoting feelings of safety and motivation. These feelings of social acceptance and belonging persisted even 1 year after the retreat.

Limitations of the study include the bias in memory that could occur from surveying patients long after the end of the retreat, and the fact that the sample was small and only made up of highly-motivated patients who voluntarily signed up for the retreat. In spite of these limitations, this study provided evidence of the therapeutic benefit of intensive small-group retreats. The benefit is not in hair pulling reduction, but rather in increasing hope, acceptance, and quality of life. As such, these retreats are not meant to take the place of traditional therapy like CBT, but can enhance it.
White Matter Volume Alterations in Hair Pulling Disorder (Trichotillomania)
A. Uhlmann, A. Dias, L. Taljaard, D.J. Stein, S.J. Brooks, & C. Lochner

Neuroimaging studies of individuals with trichotillomania (TTM) are scarce, but evidence from such studies so far suggests that dysfunction in circuits known to mediate cognitive, behavioral, and motor functions (circuits from the frontal lobe to the striatum, limbic system, and cerebellum) may be partly responsible. Imaging studies investigating the volume of grey matter (neuronal cell bodies) have produced conflicting evidence, and those looking at white matter (tissue that sends information back and forth between areas of grey matter) are generally understudied. To contribute to the growing body of neuroimaging studies on TTM patients, these researchers investigated differences in grey and white matter volumes between individuals with TTM and healthy controls.

The study consisted of 29 adults with a primary diagnosis of TTM and 28 healthy control adults. All the participants underwent a whole-brain scan at imaging centers in Cape Town, South Africa. The researchers then measured and analyzed grey and white matter volumes.

Only one individual in the study was male, while the rest of the participants were female. TTM participants exhibited larger white matter volumes in the parahippocampal gyrus (important for memory encoding and retrieval) and the cerebellum (important for motor function), and less volume in the postcentral gyrus (helps process sensory information), relative to the control participants. No statistically significant differences were found between the two groups in terms of grey matter volumes. Significant associations between larger white matter volumes in the temporal lobe and cerebellum were found, as well as fewer attempts to resist hair pulling.

Although illuminating, the design of this study allowed researchers to draw associations between white/grey matter and hair pulling behaviors, but no causal conclusions. The authors also note that some abnormalities in brain structure may be related to other comorbid disorders in the TTM participants. Overall, the aberrations found in the brain regions in this study suggest abnormalities in higher-order association and cognitive function in individuals with TTM. More brain imaging studies in TTM will help shed light on the mechanisms underlying the disorder, which may eventually lead to better treatments.

SciLit Wants YOU !!!

The Scientific Literacy team is looking for driven, collaborative young people who are passionate about BFRB research!

The TLC Foundation’s Young Adult Action Council (YAAC) is looking to expand our operations in the coming year, and need help providing scientific content to our community.

If you have interest in data collection, the science of BFRBs, or educating your community - we want to hear from you!

GET INVOLVED TODAY !!!

If you are a researcher/clinician specialized in BFRBs interested in collaborating with SciLit, or an incipient scientist between the ages of 18-28 interested in potentially joining our team, please send an email to kimi@bfrb.org including your name, age, affiliation (if applicable), and how you’d like to work together.
Given some shared phenomenology and pharmacological treatment traits, it's possible that TTM may have a greater relationship with tic disorders than is currently understood. When evaluating treatment, clinicians may want to evaluate treatments for tic related disorders as well as OCD-related traits. More research is needed!
Comorbidity in Trichotillomania (Hair Pulling Disorder): A cluster analytical approach

C. Lochner, N.J. Keuthen, E.E. Curley, E.S. Tung, S.A. Redden, E.J. Ricketts, & D.J. Stein

One of the ways to promote a precision medicine approach is to identify subtypes of patients with key features in common. For trichotillomania (TTM), some of the subtypes proposed to date have been age of onset, oral behaviors, self-injury, personality traits, or the well-known focused/automatic subtypes. It is difficult to say which of these are meaningful to treatment, but another way to subtype TTM is comorbidity, meaning other disorders someone may have besides TTM. The aim of this study was to explore possible TTM subtypes based on comorbidity profiles.

The study tested 304 adults in the USA and South Africa who were enrolled in a separate study on genetics. A cluster analysis was done on lifetime comorbidity data for fourteen disorders, including different anxiety disorders, depressive disorders, and OCD Spectrum disorders.

There were three distinct clusters. The first was “simple TTM,” which consisted of the patients without any comorbidities. The second cluster was “depressive TTM,” which consisted of the patients that also had depression (but nothing else). The third cluster was “complex TTM,” which consisted of the patients with other combinations of comorbidities. This also included depression, since 62% of people in the complex TTM group had depression, among other things. The other most common disorders in the complex TTM cluster were OCD (36%) and skin-picking (24%). There was a relationship between symptom severity and number of comorbidities; patients with more comorbidities tended to have more severe hair-pulling symptoms, as well as more severe depression.

This study demonstrates that TTM is not always a sign of another, more severe disorder, since one-fifth of TTM patients don’t suffer from other disorders. It also shows how large the overlap is between depression and TTM (over half of the TTM patients were also depressed) – there is no conclusive research about if one causes the other, but they can certainly influence each other. Finally, it raises questions about how treatment can change by taking comorbidities into account. The study is limited by not having treatment data for all the subjects and not having enough participants to test more disorders, but by successfully breaking TTM down into subtypes, this study has laid important groundwork for more tailored TTM treatment.
Family Functioning in Pediatric Trichotillomania, Obsessive Compulsive Disorder, and Healthy Comparison Youth

**DOMAINS OF FAMILY FUNCTION**

- **COHESION**
- **CONFLICT**
- **EXPRESSIVENESS**
- **ORGANIZATION**

**KEY FINDINGS:**

- Greater impairment in TTM families
- TTM families less expressive
- No link to symptom severity

Although several studies document impaired family functioning in pediatric OCD, few have investigated this aspect in pediatric trichotillomania (TTM). Such studies might be useful for improving TTM treatment, as the OCD research has produced interventions that directly target familial dysfunction to improve patient outcomes. This study sought to improve upon past research, to understand how family functioning in TTM and OCD might have implications for treatment development.

In the study, 30 children and adolescents with TTM, 30 with OCD, and 30 healthy controls completed several interview-based questionnaires and self-assessments related to anxiety, OCD, and TTM severity, as well as assessment of family environment and parenting behavior. Notably, 44% of the full sample self-identified as racial/ethnic minorities. The researchers compared TTM with OCD and healthy control youth on the measures of family environment and perceptions of parenting behavior.

Parents of OCD and control groups reported more cohesion amongst family members than did TTM youths, and OCD parents reported that their families expressed emotions better than parents of the children with TTM did. The healthy control individuals self-reported significantly higher cohesion and organization within their families, and lower conflict than the TTM and OCD groups. The controls reported higher expressiveness of family members than the TTM youth, as well. There were no significant differences in youth- or parent-reported perceptions of parenting behavior.

Overall, the study supports the hypothesis that family functioning is more impaired in TTM and OCD youth compared to healthy controls, particularly in the domains of conflict, cohesion, expressiveness and organization. Family functioning may be somewhat worse in the TTM versus OCD group in terms of cohesion, but not conflict. However, there was little evidence for links between severity of TTM and degree of family impairment, nor between TTM and parenting behavior. The study highlights the importance of family expressiveness and cohesion in youth TTM, and further investigation into family functioning in pediatric TTM groups may ultimately help differentiate treatment options for families. Some limitations of the study include a small sample size, recruitment only from a university-based specialty treatment program, and the inability to determine direction of effects between TTM and family functioning based on study design.
Professor YAAC’s “Making Sense of the FDA Review/Approval Process for New Drugs”

“Professor YAAC, why do we need to do clinical trials?”

“Great question! A clinical trial is one of the best ways we can see how a drug works, how well it does what it claims to do, and how safe it is, in a controlled, scientific way in humans.”

GLOSSARY:
- clinical trial: research study of a drug or treatment in humans
- Center for Drug Evaluation & Research (CDER): the FDA’s office responsible for reviewing and approving new drugs
- safety: how safe a drug is (including side effects)
- efficacy: how well a drug works
- Mechanism of Action (MOA): how the drug is supposed to work at a biological level
- Pharmacokinetics (PK): how the drug behaves in your body
- indication: the disease or group of people the drug is approved for
- package insert: long packet of information you get with a drug that includes clinical trial results, instructions, and side effects

“Professor YAAC, what does it mean when a drug is FDA-approved?”

“If a drug gets FDA approval, that means it has been assessed for benefits and risks, there is evidence that the drug’s benefit will outweigh the risk and that the drug is effective in the specified indication, and that there are strategies for managing any risks.”

Discovery: drug is developed
Preclinical: animal testing
- Phase 1: dose finding
- Phase 2: safety/efficacy
- Phase 3: comparative safety/efficacy
- Phase 4: post-marketing monitoring

“Professor YAAC, where should I go if I want more information about a specific trial?”

“It’s easy! If you want more information on any trial, you can find its listing on clinicaltrials.gov.”