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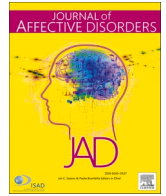
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Research paper

Transdiagnostic cognitive behavioral therapy for misophonia in youth: Methods for a clinical trial and four pilot cases

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ABSTRACT

Background: Misophonia is a condition marked by dysregulated emotions and behaviors in response to trigger sounds, often chewing, breathing, or coughing. Evidence suggests that misophonia develops in adolescence and the emotions and behaviors are a conditioned response to distress, resulting in social avoidance, stress, and family conflict. In addition, co-occurrence with other psychiatric illnesses such as anxiety, OCD, and Tourette syndrome is common. A transdiagnostic cognitive behavioral therapeutic (CBT) approach appears appropriate. There are currently no controlled studies of youth with misophonia. The current paper describes the approach to a pilot randomized, blinded family-based treatment study for youth ages 8–16 years. Preliminary results from a pilot open trial also are described.

Methods: A 2-phase dual site telehealth treatment study using a transdiagnostic CBT approach, the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents (UP-C/A; Ehrenreich-May et al., 2018), is proposed. Phase 1 consisted of a 4-case pilot of UP-C/A. Phase 2 includes a randomized trial comparing the UP-C/A to a standard relaxation and education protocol.

Results: Preliminary results from the pilot show modest improvements in evaluator-rated misophonia symptoms on the Clinical Global Impression Severity and Improvement scales.

Limitations: There is little research to inform evidence-based practice for youth with misophonia. Study limitations include lack of standardized misophonia assessment instruments and an absence of formal diagnostic criteria.

Conclusions: The current paper describes proposed methods for the first randomized controlled trial for youth with misophonia and their families along with results from a 4-case pilot.

1. Introduction

Misophonia, from the Latin *miso* ‘hatred’ and *phonia* ‘sound,’ was first described by audiologists, Jastreboff and Jastreboff (2001), to be a condition marked by a strong aversion to specific sounds and noises. Over the past decade, there have been increasing clinical reports and study of misophonia, but notably, there has been a lack of diagnostic classification in either DSM-5 or ICD-10. Merriam-Webster (n.d.) defines misophonia as:

A condition in which one or more common sounds (such as the

ticking of a clock, the hum of a fluorescent light, or the chewing or breathing of another person) cause an atypical emotional response (such as disgust, distress, panic, or anger) in the affected person hearing the sound.

The scientific and clinical communities’ descriptions of misophonia generally converge, characterizing the central nature of misophonia to be an emotional experience to sound triggers as opposed to abnormal sensory perception/pain. Abnormal hearing thresholds have not been reported in misophonia (Schröder et al., 2013). The sound’s source is often highly specific and/or context dependent. For example, the

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expectation of a sound and/or observation of someone chewing through a sound-proof window can elicit similar levels of emotional reaction. Misophonia likely has less to do with the physical properties of particular trigger sounds (e.g., frequency, intensity) than with the context and historical emotional experiences associated with the sound (Jastreboff and Jastreboff, 2001). Therefore, misophonia is best defined as selective sensitivity to sound triggers accompanied by emotional distress, physiological arousal, and possibly behavioral reactions (e.g., avoidance).

1.1. Phenomenology

Unfortunately, the literature lacks comprehensive characterizations of misophonia, and there is very little replication from the case studies and convenience samples that provide most of the extant descriptions, especially with regard to pediatric populations (Johnson et al., 2013). There are no validated biological models, and the etiology of misophonia is unknown. From the first known clinical description, misophonia has been described as emotional reactivity and autonomic arousal in the context of trigger sounds (Jastreboff and Jastreboff, 2001). Anger, irritation, distress or disgust, and intense behavioral reactions (e.g., avoidance, tantrums, aggression), which are markedly disproportional to the intensity or duration of the stimuli, are commonly reported. Anxiety, stress, and panic also are not uncommon, but people typically do not report being fearful of the sound (Edelstein et al., 2013). Physiological hyperarousal is also common (Schwartz et al., 2011). It is posited that misophonia develops via conditioning: sounds become associated with aversive emotions and physiological discomfort (Dozier, 2015; Jastreboff and Jastreboff, 2014; Lewin et al., 2015). The social context, attribution, or interpretation (e.g., presumed intent) appear to influence the subjective response to the sensory trigger (Bruxner, 2016; Rouw and Erfanian, 2018; Schröder et al., 2013). For example, individuals with misophonia may be able to replicate a sound (e.g., chewing) without experiencing the arousal or discomfort that occurs when hearing a sibling chew. While classical conditioning may explain development, operant learning mechanisms may serve to maintain misophonia-related distress and impairment. As individuals avoid contact with trigger sounds and experience immediate relief, they fail to learn to regulate negative emotions and come to rely upon escape or avoidance to manage distress (Hall et al., 2016; Jastreboff and Jastreboff, 2014).

Notably, studies suggest hearing (sensitivity) threshold for individuals with misophonia is within normal limits, possibly indicating that the condition is not simply a result of a heightened acuity to sound. Impairment is commonly reported in misophonia, with symptoms affecting functioning in work, school, and family/social relationships. Initial studies suggest onset of symptoms in childhood to early teenage years (Rouw and Erfanian, 2018; Schröder et al., 2017), although more systematic study is needed to characterize onset and course. Similarly, there are few data regarding the incidence of misophonia. Assessing incidence is further complicated by lack of formal ICD/DSM-5 diagnostic criteria. It is generally agreed that the condition is not uncommon but underreported and often not assessed, even in the context of psychiatric evaluation. A self-report survey of college students showed that 20% of the sample indicated abnormal sensitivity to sound (Wu et al., 2014). Notably, most of the sample identified symptom onset prior to adolescence (Rouw and Erfanian, 2018; Wu et al., 2014). Findings vary with regard to the presence of psychopathology in conjunction with misophonia. Approximately 50% of an internet sample of adults with misophonia reported at least one psychiatric disorder ($N = 301$; Rouw and Erfanian, 2018). In the largest clinical sample to date, Jager et al. (2020) found that 22% of the sample met criteria for at least one psychiatric disorder (major depression 6.8%; obsessive-compulsive disorder [OCD] 2.8%). Erfanian et al. (2019) found that posttraumatic stress disorder (PTSD; 15.4%), OCD (11.5%), major depression (9.6%) and anorexia nervosa (9.6%) were the most common co-occurring conditions. Furthermore, emerging evidence suggests that this relationship

may be bi-directional, especially in children and adolescents with OCD and tic spectrum disorders (Hazen et al., 2008; Lewin et al., 2015). Unfortunately, most phenomenological data on misophonia have been collected from adults in convenience samples. The paucity of studies investigating misophonia among children and adolescents limits our understanding of its prevalence and course.

1.2. Treatment research

Not surprisingly, there are no formal practice parameters for the treatment of misophonia. In fact, the misophonia treatment literature is devoid of clinical trials or any controlled studies. Thus, there is no formative guidance for treating individuals with misophonia aside from case studies and an open trial. Given the central nature of distress and emotional arousal combined with high associations with anxiety and depressive disorders, investigating psychological treatment options appears warranted. Notably, Spankovich and Hall (2014) discussed six potential directions for misophonia treatment. Two approaches were psychological (counseling and psychological/psychiatric therapy). Two other options for intervention (“misophonia retraining therapy” and “positive association and desensitization”) also fall within the scope of behavioral health and are centered around principles of operant and classical conditioning as well as selective attention and acceptance/mindfulness (e.g., pairing pleasant stimuli with unpleasant, selectively focusing attention on other stimuli). The fifth approach to treatment was a combination of autonomic calming tools such as relaxation and meditation in addition to healthy diet and exercise. Finally, the authors discussed the use of hearing protective devices (e.g., earmuffs, noise cancelling devices) to attenuate sounds. The use of hearing protective devices is not recommended because individuals with misophonia do not experience pain, but rather a strong emotional response to trigger sounds. Therefore, protective devices limit tolerance and emotional adjustment to the distress by reinforcing the belief that the sounds must be avoided. In sum, despite initial description in audiology circles, misophonia has many characteristics of a psychiatric disorder (Lewin et al., 2015; Lewin et al., 2015; Taylor, 2017) with key behavioral and emotional treatment targets. Intense negative affect in the context of sensory triggers, marked avoidance, deficit emotional regulation, poor flexibility, and potential cognitive processing biases are possible targets for intervention.

Cognitive behavioral therapy (CBT) appears to be the appropriate starting approach for developing and testing a psychotherapeutic intervention for misophonia. To date, the only relatively large trial ($N = 90$) found that 48% of adult subjects showed a significant reduction in misophonia across two measures (Much or Very Much Improved on the CGI-I and a 30% reduction in symptoms on the AMISO-S; Schröder et al., 2017). Nine percent reached symptom remission and 58% showed improvement on the CGI-I only (Much or Very Much Improved on the CGI-I). The treatment focused on four domains: (1) attentional shifting away from certain stimuli (e.g., redirect focus of attention from a trigger sound); (2) counterconditioning to disrupt classically conditioned associations between neutral/positive stimuli that have become paired with negative emotional experiences; (3) stimulus manipulation exercises (allowing the participant to manipulate the sounds to engender a sense of control); and (4) relaxation exercises to improve emotional control. The intervention was administered in groups for 7–8 sessions.

Unfortunately, there is little information about the treatment of children and adolescents with misophonia despite the likely onset during childhood (Mean age of misophonia onset = 12.5 years; Schröder et al., 2017). Similarly, in a large online sample of 301 adults with misophonia (Rouw and Erfanian, 2018), 45% reported onset in childhood, 30% during adolescence, and 15% “as long as I can remember.” Only 9% of those sampled reported that their symptoms began during adulthood. The overwhelming majority reported that their symptoms progressively worsened with age. Given (1) the majority of misophonia cases are reported to begin in childhood, (2) there is some evidence for

worsening /continuation of symptoms if untreated, (3) the limited treatment research in children and adolescents with misophonia, and (4) a better probability of remission in younger patients (Ginsburg et al., 2011), empirical examination of a CBT approach for misophonia in children and adolescents appears indicated.

1.3. Current treatment approach

For children and adolescents with misophonia, their emotional response to trigger sounds, and resulting behavioral problems and functional impairment, appear to be the primary targets for psychosocial intervention. Notably, many childhood cases occur in the context of other psychiatric disorders including OCD, Tourette, anxiety, mood, externalizing, and eating disorders. Accordingly, we needed to select a psychotherapeutic approach to be specific enough to target misophonia (distress, avoidance, tolerance, externalizing responses, etc.) but broad enough to address co-occurring internalizing and externalizing symptoms and related functional impairment. Rather than developing a “CBT for misophonia,” which may have a complex and heterogeneous presentation, established transdiagnostic approaches targeting mechanisms associated with putative processes of misophonia and associated conditions may provide a feasible solution. Transdiagnostic approaches are based on the assumption that emotional dysfunction is shaped by overlapping emotional and behavioral processes and shared risk factors. These transdiagnostic factors include poor emotional regulation ability and decreased ability to tolerate emotional (or physical) discomfort, often in the context of negative affective states. As a result of this poor tolerance of negative affective states, individuals engage in behaviors to suppress, escape, or avoid the situations eliciting such distress (e.g., avoidance, aggression, blame), which are negatively reinforced over time (Barlow et al., 2014). A number of transdiagnostic factors appear consistent with the emergence and maintenance of misophonia, including information processing biases (e.g., selective attention), increased negative arousal, poor emotional control, low tolerance of distress, heightened anxiety sensitivity, behavioral avoidance, and parenting behaviors that maintain maladaptive emotion regulation in children. The transdiagnostic targeting of distress intolerance, anxiety sensitivity, poor emotional regulation, and other factors may disrupt the maintenance of misophonia.

Pilot CBT studies have investigated some of these transdiagnostic factors in adults. Schröder and colleagues (2017) used a CBT approach, which included elements of conditioning and extinction, relaxation, attentional control, and procedures to increase one's locus of control over emotions/sensations. In a similar approach, Frank and McKay (2019) suggested that inhibitory learning within the context of exposure therapy might improve perceived control over emotional reactions, even in the absence of habituation to certain sounds. Mindfulness and acceptance-based strategies also have been suggested for inclusion in the treatment of misophonia (Schneider and Arch, 2017). Unlike models of exposure therapy with response prevention to fears/anxiety, it is not expected that individuals with misophonia would habituate to sounds. Rather, the target for therapy can better be conceptualized as the tolerance of distress in the context of sound triggers; exposure therapy may be useful for facilitating use of mindfulness, inhibitory learning, and similar approaches for emotional regulation.

1.4. Unified protocol

The Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents (UP-C/A) are manualized treatments for emotional disorders among youth (Ehrenreich-May et al., 2018). The UP-C/A utilize a transdiagnostic family-based approach to address underlying mechanisms implicated in the development and maintenance of anxiety and depressive symptoms in children and adolescents via evidence-based cognitive-behavioral and “third wave” behavioral treatment techniques, such as cognitive reappraisal,

problem-solving, mindfulness, and opposite action strategies. The hypothesized mechanisms of change in the UP-C/A are increased tolerance of distress when experiencing strong or intense emotional states. A secondary target is the reduction of (1) frequent negative affect responses to inert triggers, and (2) excessive avoidance behavior. The UP-C/A have been shown to help adolescents and children with emotional disorders (e.g., anxiety, depression) in multiple baseline, open trial, and randomized controlled trials (RCTs) across intervention and prevention contexts (Ehrenreich et al., 2009; Ehrenreich-May et al., 2017; Kennedy et al., 2019; Kennedy et al., 2018, Hawks et al., 2020). The UP-C/A appear ideally suited for patients with misophonia because of the strong evidence suggesting the protocols can improve the characterized emotional and autonomic arousal targets (Sherman and Ehrenreich-May, 2020). The UP-C/A were developed to address core dysfunctions (e.g., heightened negative affect, poor tolerance of emotions, and experiential avoidance) associated with a range of emotional or internalizing disorders, including anxiety, depression, and related conditions. The UP-C/A include modules on motivation, mindful awareness, flexible thinking, problem-solving, and opposite actions, including a range of exposure and activation techniques. The protocols have a companion caregiver-focused component to enhance adaptive parenting behaviors that may be engaged when a caregiver encounters child distress. The UP-C/A do not impose a rigid course of treatment, but rather, allow the clinician to personalize treatment components to the highest priority challenges using a core set of evidence-based strategies and assessment tools (e.g., Top Problems; Weisz et al., 2011). In particular, tools to improve emotional awareness, increase flexibility of cognitive appraisals, improve tolerance of physical/sensory sensations, and decrease emotional and situational avoidance are strongly consistent with models for treating misophonia-related distress and impairment (Frank and McKay, 2019; Hall et al., 2016).

1.5. Aims and hypotheses

In order to examine the feasibility and preliminary efficacy of a transdiagnostic approach to the behavioral treatment of misophonia among children and adolescents, a 2-phase study was designed using the UP-C/A. In Phase 1 (completed), our aim was to conduct a pilot open trial ($N = 4$) for procedural refinement followed by a small-scale randomized controlled trial (RCT; $N = 44$) in Phase 2 (ongoing). The RCT will compare the transdiagnostic approach using the UP-C/A to psychotherapy focused on misophonia education and emotional/physiological relaxation (RE). We hypothesize that, relative to the relaxation-focused approach, reduction in misophonia and overall psychiatric severity (at post-treatment) will be greater for children and adolescents receiving the UP-C/A. We also expect higher rates of treatment responders in the UP-C/A condition. The current paper outlines procedures for the RCT (Phase 2) and preliminary results from the pilot (Phase 1).

2. Methods

2.1. Procedures

All study participants will receive 10 treatment sessions and participate in 3 assessments. The assessments will occur at baseline (prior to session 1), mid-treatment (after session 5), and post-treatment (after session 10). Assessments will be conducted by independent evaluators (IE) who will be blinded to treatment condition (see Fig. 1 for a list of assessments). Participants who meet initial phone screen requirements will attend a screening visit that includes informed parent consent, child assent, and a comprehensive diagnostic assessment of inclusion/exclusion criteria.

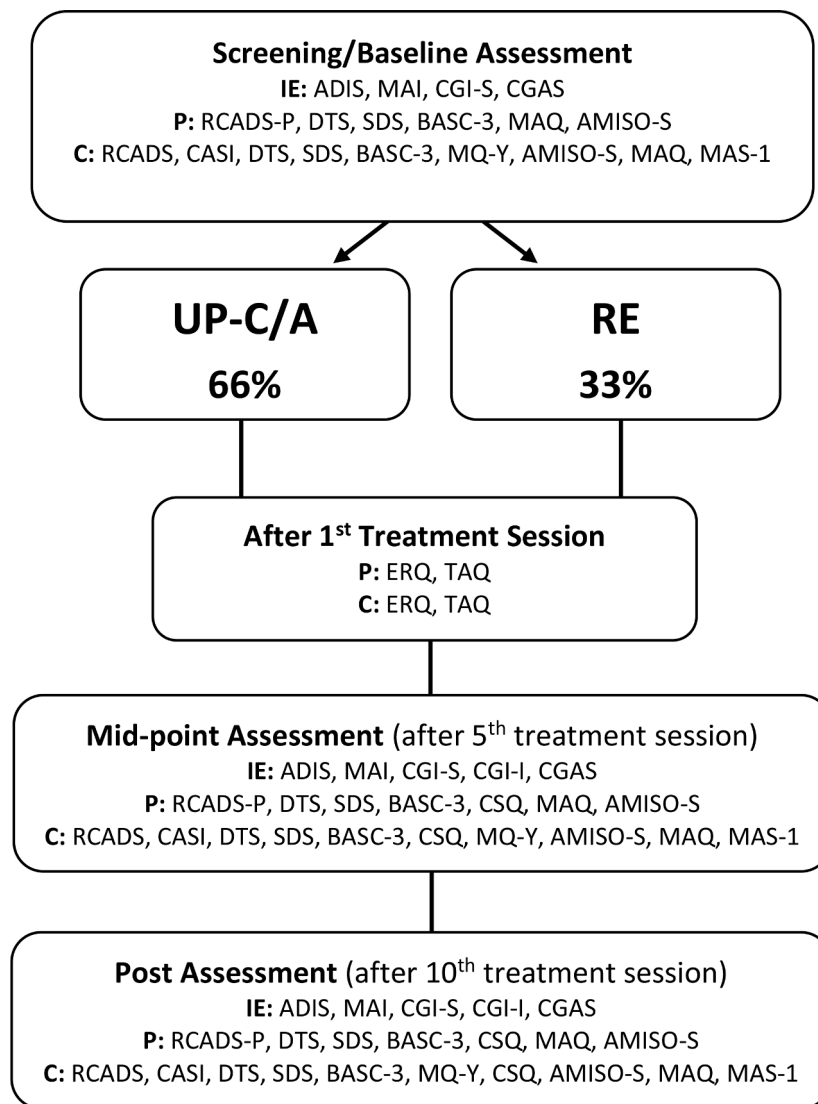


Fig. 1. Consort Diagram for the randomized trial (in progress): Recruitment, Treatment, and Measures Administered.

Note. IE = Independent Evaluator; P = Parent; C = Child; UP-C/A = Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents; RE = Relaxation and Education Therapy; For all other abbreviations please see Table 1.

2.2. Telehealth/electronic data capture

All study procedures will be conducted via telehealth. Although this change was implemented mid-way through Phase 1 due to the 2019 SARS-CoV-2, the adjustment during the pilot phase allowed for full conversion prior to the Phase 2 RCT and increased our catchment area, allowing for recruitment state-wide. Encrypted HIPAA-compliant telehealth platforms will be used and will allow for the recording of visits for integrity purposes. All assessments will be completed by participants using a HIPAA-compliant web-based interface.

2.3. Treatment sites

Recruitment for this study will occur across two sites: the University of South Florida Rothman Center for Pediatric Neuropsychiatry (USF) and the University of Miami (UM). The purpose of two sites is to both (1) increase recruitment for children and adolescents with misophonia and (2) use the combined expertise of the respective teams. The last author (co-PI) from UM and first author (overall PI) at the USF have led pilot research studies in assessment/treatment of misophonia. Participants will be recruited through normal clinic flow as well as through

advertisements with local audiologists, pediatricians, mental health professionals, and misophonia-specific patient/support organizations. All study procedures have been approved by the IRB at both study sites. The study is registered as a clinical trial (NCT04365543).

2.4. Inclusion/exclusion

Children and adolescents (ages 8–17 years) and their families who meet the following inclusion criteria will be able to participate in the study: (1) baseline misophonia symptom severity score ≥ 3 (mildly ill) on the Clinical Global Impression-Severity Scale (CGI-S, see below) and/or baseline misophonia clinician severity rating (CSR) ≥ 4 (moderate) on the Misophonia Assessment Interview (MAI, see below), (2) misophonia identified as a primary problem for treatment relative to other top problems, (3) live with their family/guardian(s), (4) have not received previous UP-C/A or misophonia treatment at either site, (5) if on psychotropic medication, have been on a stable dose for the prior four weeks (two weeks for stimulant), (6) have the ability to complete assessments and participate in treatment using English without a translator for both parent and child participants, and (7) have no current diagnosis of psychosis, bipolar disorder, intellectual disability, acute

suicidality, alcohol/substance dependence, or eating disorder due to risk/safety. Children and adolescents with comorbidities will be included, but misophonia must be identified as one of the primary problems. Inclusion is purposefully broad given (1) this is among the first controlled studies of misophonia among children and adolescents, (2) we expect diagnostic heterogeneity, and (3) the UP-C/A are transdiagnostic and equipped to treat broadly presenting symptoms. Family participation is required.

3. Assessment

3.1. Assessment of misophonia and other disorders

The Anxiety Disorders Interview Schedule for DSM-5: Parent and Child Versions (ADIS-5-C/P) is a semi-structured interview that will be used to assess for various disorders in children and adolescents (Silverman & Albano, in preparation). IEs will assign a clinician severity rating (CSR) on a scale from 0 (absent) to 8 (very severe) for each disorder. By convention, a CSR ≥ 4 is considered to represent diagnostic threshold. Since the ADIS-5 does not include a misophonia module, the Misophonia Assessment Interview (MAI) was developed by the principal investigator for this study and was designed to emulate an ADIS-5 module. Information about specific misophonia triggers, emotional responses to sound, behavioral responses, avoidance, insight/awareness, functional impairment domains, and timeframe will be collected using the interview. The IE will assign a CSR rating for misophonia, which is consistent with ADIS-5 procedures.

Primary Outcome Measures. The Clinical Global Impression Severity and Improvement Scales (CGI-S/I; Guy, 1976) and the Child's Global Assessment Scale (CGAS; (Shaffer, 1983) will be the primary outcome measures. The CGI-I is a 7-point rating that establishes treatment response from "very much improved" to "very much worse." Responder status will be defined as a CGI-I rating of "much improved" or "very much improved." The CGI-S is a 7-point rating that establishes severity of illness from "not at all ill" to "extremely ill." Misophonia remission status will be provisionally defined as (1) "borderline" or "no illness" on the CGI-I and (2) sub-diagnostic threshold on the CSR at post-treatment (Kelly and Mezuk, 2017). The CGI-S/I will be collected for both misophonia and overall presentation. The CGAS will be used to rate general functioning and impairment independent of diagnoses.

Secondary Outcome Measures. See Fig. 1 and Table 1 for all measure descriptions and assessment timeline. Therapists in both conditions will establish top problems during the first session and obtain ratings with parent and child at each session thereafter. Top problems will be rated subjectively on a scale from 0 (not at all a problem) to 8 (very much a problem). Therapists will monitor participants' response to treatment using the top problem ratings according to the procedures outlined by Weisz et al., (2011). Notably, assessment of misophonia is not well-established. As such, many of the proposed outcome measures have significant psychometric limitations. Therefore, secondary outcome measures will include broadband and narrowband scales completed by the parent and youth. Ratings of misophonia are supplemented by well-established measures of comorbid conditions and broad-based assessments. Given both the transdiagnostic nature of the UP-C/A and the typically heterogeneous clinical presentation of misophonia, we decided to examine outcomes in multiple ways. We will determine the clinical severity and improvement using the CGI-S/I. We will use the ADIS-5/MAI to examine diagnostic improvements. Broad and narrow symptom measures (e.g., BASC-3, RCADS, MAQ, AMISO-S) and measures of putative transdiagnostic processes (e.g., distress tolerance) will be used to determine global improvements in emotion regulation. Finally, parent and child top problems will be collected weekly to examine functional changes. This comprehensive approach is aimed at (1) examining group differences in misophonia treatment and (2) better understanding characterization of symptom and functional changes in youth with a complex, under-researched condition.

Table 1
Study measures.

Measure Name	Purpose	Measure Type	Psychometrics/ Reliability
ADIS-5 C/P: Anxiety Disorders Interview Schedule for DSM-5 Parent/Child (Silverman & Albano, in preparation)	Assessment of various disorders	Clinician rated diagnostic interview	See Silverman & Albano, in preparation
MAI: Misophonia Assessment Interview	Obtain information about misophonia symptoms	Clinician rated misophonia symptom interview	No psychometrics available
CGI-S: Clinical Global Impression – Severity (Guy, 1976)	Primary outcome – overall and misophonia specific severity	Clinician rating scale from 1 (no psychiatric illness) to 7 (extremely severe)	Valid clinical outcome measure (Berk et al., 2008)
CGI-I: Clinical Global Impression – Improvement (Guy, 1976)	Primary outcome – overall and misophonia specific change	Clinician rating scale from 1 (very much improved) to 7 (very much worse)	Valid clinical outcome measure (Berk et al., 2008)
CGAS: Child's Global Assessment Scale (Shaffer, 1983)	Rating of general functioning	Clinician rating scale from 1 (extremely impaired) to 100 (doing very well)	Inter-rater reliability = 0.84; test-retest reliability = 0.85 (Shaffer, 1983)
MQ-Y: Misophonia Questionnaire – Youth (Wu et al. 2014)	Examine the presence of specific sound sensitivities and emotional and behavioral reactions associated with misophonia symptoms	Youth self-report 12-item 4-point Likert scale survey	$\alpha = .89$ (Wu et al., 2014)
AMISO-S: Amsterdam Misophonia Scale (Schröder et al., 2013)	Assess misophonia symptom severity and interference	Youth self-report and parent-report 6-item 4-point Likert scale survey	No known psychometric properties
MAQ: Misophonia Assessment Questionnaire (Johnson, 2013)	Assess the impact of the misophonia symptoms on the person's activities, thoughts, and feelings	Youth self-report and parent-report 21-items 4-point Likert scale survey	No known psychometric properties
MAS-1: Misophonia Activation Scale (Misophonia, UK, 2014)	Assess severity of emotional and physical reaction to sound triggers	Youth self-report 2-items 10-point Likert scale survey	No known psychometric properties
RCADS (-P Parent Version): Revised Children's Anxiety and Depression Scale, youth self-report and parent report (Chorpita et al., 2000)	Assess anxiety and depression symptoms	Youth self-report and parent-report 47 items 4-point Likert scale surveys	$\alpha = .78$ to $.87$ depression and anxiety, respectively (Chorpita et al., 2005); $\alpha = .95$ parent version (Ebesutani et al., 2010)
BASC-3: Behavior Assessment		Youth self-report and	Extensive psychometric

(continued on next page)

Table 1 (continued)

Measure Name	Purpose	Measure Type	Psychometrics/ Reliability
System for Children (3rd edition)	Assess behavioral and emotional problems	parent-report 4-point Likert scale surveys	properties available in BASC-3 manual
SDS: Sheehan Disability Scale (Sheehan, 2000)	Measure of child/adolescent functional impairment due to misophonia symptoms	Youth self-report and parent-report 3-item 11-point Likert scale survey	$\alpha = .89$ (Sheehan, 2000)
CASI: Childhood Anxiety Sensitivity Index (Silverman et al., 1991)	Assesses the child's anxiety sensitivity	Youth self-report 18-item 3-point Likert scale survey	$\alpha = .87$; Test-retest reliability (using a retest interval of two weeks) nonclinical = .76, clinical = .79 (Silverman et al., 1991)
DTS: Distress Tolerance Scale (Simons and Gaher, 2005)	Assesses child/adolescent tolerance to emotional distress	Youth self-report and parent self-report 16-item 5-point Likert scale survey	$\alpha = .89$ (Simons and Gaher, 2005)
TAQ: Treatment Acceptability Questionnaire (Hunsley, 1992)	Assess participant's expectations of treatment	Youth self-report and parent self-report 6-item 7-point Likert scale survey	$\alpha = .8$ (Hunsley, 1992)
CSQ: Client Satisfaction Questionnaire (Larsen et al., 1979)	Assess participant's satisfaction with services	Youth self-report and parent self-report 8-item 4-point Likert scale survey	$\alpha = .91$ (Attkisson and Zwick, 1982)
ERQ: Expectancy Rating Questionnaire	Assess participant's expectations of treatment outcome and credibility belief	Youth self-report and parent self-report 5-item 10-point Likert scale survey	Adapted from Credibility/Expectancy Questionnaire (CEQ) which has demonstrated high internal consistency and good test-retest reliability (Deville and Borkovec, 2000)

Pilot (Phase 1) Outcome Measures. The current paper describes preliminary outcomes from the Phase 1 pilot trial. Specific measures of interest in Phase 1 reported here included CGI-S/I Overall and Misophonia (primary outcome measure), CSR Misophonia, Misophonia Assessment Questionnaire (MAQ; Johnson, 2013), Amsterdam Misophonia Scale (AMISO-S; Schröder et al., 2013), Revised Children's Anxiety and Depression Scale (RCADS; Chorpita et al., 2000), Distress Tolerance Questionnaire (DTS; Simons and Gaher, 2005), and a semi-structured feasibility and acceptability exit interview. MAQ scores were interpreted as raw scores and were categorized as subclinical (0-11), mild (12-24), moderate (25-37), severe (38-50), and extreme (51-63). AMISO-S scores were interpreted as raw scores and were categorized as subclinical (0-4), mild (5-9), moderate (10-14), severe (15-19), and extreme (20-24). The RCADS was interpreted using T-scores with a clinical cutoff of 65 or greater. Finally, DTS was interpreted using the total raw score where higher scores indicated greater tolerance to distress.

3.2. Planned analysis

Phase 1 analyses included descriptive statistics focused primarily on the feasibility and acceptability of the treatment approach (see below for results and discussion).

In Phase 2, comparisons between groups in terms of primary and secondary outcomes (see Table 1) will be evaluated with mixed-effects repeated measures models. Models will include a random intercept and slope, and fixed effects for site (if significant), treatment group, visit, and treatment group-by-visit interaction. Effect sizes estimates (i.e., Cohen's *d*) will be derived from covariate-adjusted estimated marginal means and standard errors. The proposed sample size of provides adequate power to detect an effect size of $f = .20$ for the interaction between group and time, which Cohen (1988) characterizes as a small to medium effect.

3.3. Rater and therapist training and supervision

Study therapists will be supervised postdoctoral fellows or advanced doctoral students with significant experience in misophonia and/or the care of children/adolescents with emotional disorders. Therapists for the UP-C/A will complete a 2-day training with the last author; a parallel training will be conducted with RE therapists. Both conditions will have weekly calls for supervision (by separate supervisors) and treatment fidelity following treatment initiation. Sessions will be recorded in Phase 2, and 10% of recordings will be reviewed for fidelity to the intervention using adapted versions of established UP-C/A fidelity and competence coding procedures. Therapists trained in the UP-C/A will not administer the RE intervention in order to prevent overlap between the two conditions. IEs will (1) undergo comparable training, weekly monitoring, and fidelity checks, (2) score sample cases to demonstrate reliability, and (3) attend weekly cross-site calls to ensure accurate ratings under supervision of the first author. All assessments will be video recorded, and 20% of interviews per year will be blindly reviewed to assess interrater reliability.

3.4. Treatment conditions

The UP-C/A and RE treatment protocols will include 10, 1-hour sessions. All participants in Phase 1 received the UP-C/A. Participants in Phase 2 ($N = 48$) will be randomized to the UP-C/A (two-thirds) or the RE (one-third) condition (see Figure 1). The treatment protocols will vary in approach to treatment of misophonia, and there will be few shared features across protocols. Some common elements will include weekly parent/child top problem ratings to monitor change over time, misophonia psychoeducation, and mindfulness skills. However, the introduction of mindfulness will occur at significantly different time points in treatment (session 3 for UP-C/A compared to session 8 for RE). Both protocols are family-based and will include parent participation in every session. These common elements are consistent with a basic CBT session structure for treatment of emotional disorders. Importantly, these similarities in structure will ensure RE is a rigorous control to the UP-C/A.

3.5. The unified protocols for transdiagnostic treatment of emotional disorders in children and adolescents (UP-C/A)

Progression through treatment will include (1) learning about the emotional and behavioral underpinnings of emotions and misophonia; identifying top problems and common triggers for the child/adolescent; (2) learning the relationship between sound triggers and automatic thoughts, feelings, and adaptive or maladaptive behaviors while also practicing "opposite action" to the emotional behavior that occurs following a sound trigger; (3) learning appropriate opposite action strategies such as present moment awareness, non-judgmental awareness, and awareness of physical sensations using interoceptive exposure with body scans; (4) identifying thinking traps and employing detective thinking and problem-solving in response to automatic negative thoughts and difficult problems; (5) developing an emotion ladder for trigger sounds; (6) exposure to trigger sounds while practicing response prevention; and (7) reviewing the treatment and planning for the future.

A significant goal for treatment of misophonia with the UP-C/A will be to improve distress tolerance. Children and adolescents with misophonia present with heightened sensitivity to sound triggers and low tolerance to discomfort, especially emotional distress. Thus, exposure will be used as a mechanism to practice distress tolerance within an inhibitory learning framework. Among the goals will be for the child to better tolerate emotional distress (to misophonic and other triggers) through practice with the therapist and at home through home learning assignments. More detail about the UP-C/A can be found in published manuals (Ehrenreich et al., 2009) and the procedural adaptation for misophonia is provided in the context of a case paper from one of our pilot participants (Tonarely et al., 2021).

3.6. Relaxation and education (RE)

We are using an active comparison condition in the randomized phase of the study. A relaxation-based treatment was chosen because (1) high rates of distress and anxiety are reported among youth with misophonia, (2) there is skepticism about the appropriateness of exposure-based treatments within the misophonia patient community, (3) the chosen protocol was feasible in previous clinical trials, and (4) relaxation-based treatments are often the cornerstone of anxiety treatments outside of specialty exposure/response prevention practice. The specific relaxation protocol chosen for this study was modified for a 10-week format from the manual used by Piacentini et al. (2011). This protocol has demonstrated a 35% response rate in comparison family-based exposure therapy (Piacentini et al., 2011). Progression through treatment will include (1) learning about misophonia and how to monitor it using a subjective units of distress scale; (2) rewarding the child/adolescent's use of relaxation strategies taught during treatment; (3) practicing a variety of relaxation strategies, including diaphragmatic breathing, progressive muscle relaxation with combined muscle groups, guided imagery, combined progressive muscle relaxation with guided imagery, and mindfulness (body scanning, mindful eating, using the five senses); and (4) reviewing the treatment and planning for the future. This condition will not include exposure with response prevention strategies.

3.7. Results from a pilot implementation

Phase 1 (completed) consisted of four pilot cases for the modified UP-C/A in order to test the feasibility of the 10-week protocol, assessment/measurement, and supervision procedures. Families also provided their input about the acceptability of the intervention. Mean age of pilot participants was 15.5 years and 75% of participants were female. Table 2 reflects the CGI-S/I scores at baseline and post-treatment for each participant's misophonia symptoms and overall distress. All four youth and their families completed the treatment with improved CGI-S/I scores (75% of participants were rated as "much improved" on the CGI-I Misophonia, which is considered a treatment responder). Table 3 reflects the CSR misophonia ratings at baseline and post-treatment. Three out of four participants were rated as improved by 1-2 points at post-treatment. Notably, the second participant ended treatment after session seven. Consequently, 2-3 fewer sessions of exposure were included,

Table 2
CGI scores at baseline and post-treatment.

Participant	Misophonia			Overall		
	Baseline CGI-S	Post CGI-S	Post CGI-I	Baseline CGI-S	Post CGI-S	Post CGI-I
UM 1*	Severe (6)	Moderate (4)	Much Improved (2)	Severe (6)	Moderate (4)	Very Much Improved (1)
UM 2	Severe (6)	Moderate (4)	Minimally Improved (3)	Moderate (4)	Moderate (4)	Much Improved (2)
USF 1	Severe (6)	Mild (3)	Much Improved (2)	Severe (6)	Moderate (4)	Much Improved (2)
USF 2	Moderate (4)	Mild (3)	Much Improved (2)	Mild (3)	Mild (3)	Much Improved (2)

*Note. A detailed case report for UM 1 is currently under-review (Tonarely et al., 2021). This paper focuses on the clinical application of the UP-C/A for a complex case with misophonia and comorbidities.

Table 3

Clinical severity rating (CSR) for misophonia scores for pilot subjects from the misophonia assessment interview (MAI).

Participant	Baseline	Post Treatment
UM 1*	Severe (6)	Moderate (4)
UM 2	Moderate (4)	Moderate (4)
USF 1	(Moderate (5)	Moderate (4)
USF 2	(Moderate (4)	Mild (3)

which might explain the less robust response (Misophonia CGI: minimally improved; Overall CGI: much improved; CSR: no change).

All participants completed the Misophonia Assessment Questionnaire (MAQ) and the Amsterdam Misophonia Scale (AMISO-S) at baseline and post-intervention. Table 4 shows the MAQ and AMISO-S raw scores from baseline to post-intervention for each participant. Three out of four participants rated improvement at post-intervention on the MAQ. Baseline scores ranged from 12 (mild) to 54 (extreme), while post-treatment scores ranged from 3 (subclinical) to 25 (moderate). One participant (UM 2) reported worsening symptoms on the MAQ, but not on the AMISO-S. All participants rated improvement at post-treatment on the AMISO-S. Baseline scores ranged from 9 (mild) to 17 (severe), while post-treatment scores ranged from 6 (mild) to 12 (moderate).

The Revised Children's Anxiety and Depression Scale (RCADS) Total Anxiety and Depression subscale and Distress Tolerance Scale (DTS) Total score were collected for most participants at baseline and post-treatment in addition to the above noted misophonia-specific questionnaires. Table 4 shows the RCADS T-scores and DTS raw scores from baseline to post-treatment for each participant. These were collected to measure global improvements in distress tolerance, anxiety, and depression given the comorbidities associated with misophonia. All participants' total DTS scores increased somewhat at post-treatment, indicating improved tolerance to distress. DTS scores ranged from 31 to 73 at baseline and 38 to 75 at post-treatment. In addition, all participants' Total Anxiety and Depression T-scores on the RCADS improved from baseline to post-treatment. T-scores ranged from 39 to 54 at baseline and 26 to 44 at post-treatment. Notably, no participants rated themselves in the clinically significant range on the RCADS Total Anxiety and Depression subscale at baseline. USF 1 did not complete enough items on the RCADS at baseline to generate a T-score.

Families provided universally positive feedback in a brief follow-up call with the study coordinator. More specifically, all participants provided the highest acceptability ratings (i.e., 4/4) when asked to report about the quality of the UP-C/A, whether they received the kind of service they wanted, whether the UP-C/A helped them deal with their problems more effectively, and whether the UP-C/A met their needs. In addition, all participants indicated they would definitely recommend the study to a friend with a similar condition. All participants rated their quality of service as excellent. Minor modifications such as greater homework specificity were noted by participants. Although not surprising, participants reported they disliked exposure, but they understood its utility and purpose.

Table 4

Secondary self-report outcome measures at baseline and post-treatment.

Participant	Baseline MAQ	Post MAQ	Baseline AMISO-S	Post AMISO-S	Baseline RCADS Total	Post RCADS Total	Baseline DTS Total	Post DTS Total
UM 1*	25	13	13	9	54	44	31	38
UM 2	18	25	15	12	46	35	39	56
USF 1	12	3	9	6	Missing	31	73	75
USF 2	54	13	17	10	39	26	65	75

*Note. MAQ, AMISO-S, and DTS scores are reported as raw scores; RCADS scores are reported as T-scores.

4. Discussion

Misophonia is a condition that typically develops in adolescence and is marked by autonomic arousal, emotion dysregulation (e.g., anxiety, anger, irritability, rage), and distress intolerance in response to trigger sounds. Misophonia is thought to develop through a process of classical and operant conditioning wherein sounds are associated with distress and maladaptive behaviors are reinforced with escape. Further, misophonia often develops alongside other psychiatric disorders such as OCD, anxiety, and Tourette syndrome. Thus, transdiagnostic, family-based CBT treatments that emphasize exposure and distress tolerance are a logical approach to treatment, particularly given that habituation to sounds *per se* is not an appropriate goal.

4.1. Contributions

The current study is among the first studies of treatment of misophonia in youth and is the first proposed RCT to compare treatment approaches. The UP-C/A is an established transdiagnostic family-based treatment for emotional disorders that emphasizes distress tolerance through opposite action using mindful approaches and exposure techniques. Some argue that exposure therapy is inappropriate for misophonia because habituation to sounds is unlikely. However, exposure may in fact be a powerful agent of change for individuals with misophonia who have underdeveloped distress tolerance. Exposure is a process by which individuals learn how to withstand distress and disconfirm prior beliefs about their ability to approach strong emotions. Exposure therapy in this study is used as a tool to enhance distress tolerance, not as a mechanism to decrease arousal via repetitive encounters with a trigger stimulus. By contrast, relaxation also may be an effective treatment component for individuals with misophonia. Differences in these potential active ingredients will be explored further through this RCT. Preliminary results suggest that individuals can tolerate distress associated with trigger sounds.

4.2. Limitations

There are some notable limitations with regard to the current RCT. Extant literature does not provide direction for screening and diagnosis of misophonia. As such, the inclusion criteria for the study are broad, and the presentation and severity of misophonia among participants is variable. Our diagnostic and assessment procedure had to be developed for this study. Further, improvement in symptoms is difficult to operationalize given the lack of formal assessment procedures. We provisionally defined remission in symptoms in a manner consistent with trials for childhood OCD, anxiety, and mood disorders. However, it is unclear if we can expect symptom remission for misophonia in a manner similar to internalizing neuropsychiatric conditions.

Authors' contribution

All authors approved the final article.

Adam B. Lewin (PI, USF), Jill Ehrenreich-May (Co-PI, UM) - contributed to drafting of manuscript, design of the study; acquisition, analysis, interpretation and implementation of the study

Brent Small - design of the study; acquisition, analysis, interpretation

and implementation of the study

Sarah Dickinson, Kelly Kudryk - contributed to drafting of manuscript; acquisition, analysis, interpretation and implementation of the study

Sherelle L. Harmon, Ashley R. Karlovich - revised draft for intellectual content; acquisition, analysis, interpretation and implementation of the study

Dominique A. Phillips, Rinatte Gruen, Niza A. Tonarely - acquisition, analysis, interpretation and implementation of the study

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Declaration of Competing Interest

Dr. Lewin receives grant funding from the Ream Foundation for this study. He has no other conflicts related to this study. He has unrelated grant support from the Centers for Disease Control and Prevention and Tourette Association of America. He receives editorial and/or publishing honorarium from Springer and Elsevier. He is on the Scientific Advisory Board for the International OCD Foundation and is a Tourette Centers of Excellence Director. He may receive travel compensation for service to the American Psychological Commission on Accreditation or Board of Directors for the American Board of Clinical Child and Adolescent Psychiatry.

Dr. Ehrenreich-May is the first author of the therapist guide and workbooks for the Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents (UP-C and UP-A) and receive royalties from these publications. She also receive payments for UP-C and UP-A clinical trainings, consultation and/or implementation support services. She has funding for current research on the UP-C and UP-A comes from the National Institutes of Health, Queensland Children's Hospital Foundation, the Ream Foundation, and contracts with Baylor University, University of Calgary, Northwell Health, and Lurie Children's Hospital.

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