Cannabinoid Medication for Adults with OCD

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Study Summary: The purpose of this pilot research study is to test whether a medication called nabilone (Cesamet) on its own or in combination with a form of cognitive-behavioral therapy (CBT) called exposure and response prevention (EX/RP) does not cause unpleasant side effects in participants with obsessive-compulsive disorder (OCD), and to see if participants with OCD find it easy to take the medication repeatedly to help them feel better. Nabilone is a synthetic cannabinoid; it acts on the brain's "endocannabinoid system," which has been hypothesized to play a role in OCD. Nabilone is approved by the FDA for the treatment of chemotherapy-induced nausea and vomiting. It is not FDA-approved for treating OCD.

Study Design

Conditions or Focus of Study: Obsessive-Compulsive Disorder

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1/2 (for trials that are a combination of phases 1 and 2)

Intervention Model: Parallel (participants assigned to one of two or more groups in parallel for the duration of the study)

Number of Arms: 2 (number of intervention groups)

Masking: Open Label (no masking is used; all involved know the identity of the intervention assignment)

Allocation: Randomized

Enrollment: Number of Subjects: 25 **Type:** Anticipated

Arm Label: Nabilone

Arm Type: Experimental

Arm Description: Will receive nabilone at 1 mg BID over 4 weeks

Arm Label: Nabilone and EX/RP

Arm Type: Experimental

Arm Description: Will receive nabilone at 1 mg BID plus therapist-guided Exposure and Response Prevention Therapy over 4 weeks.

Inclusion/Exclusion

Gender: Both

Age Limits: 18-60

Accepts Healthy Volunteers?: No

Inclusion Criteria:

- Age 18-60
- Physically healthy, not pregnant
- Primary OCD
- Patient off all psychotropic medication (except selective serotonin reuptake inhibitors) and any other medication likely to interact with nabilone
- Ability to provide informed consent
- Ability to tolerate a treatment free-period

Exclusion Criteria:

- History of violence
- Lifetime history of psychosis or bipolar disorder
- Lifetime history of intellectual disability
- Severe depression or suicide risk
- Females who are pregnant or nursing
- Patients planning to begin EX/RP or currently in EX/RP
- Current substance use disorder or positive urine toxicology at screening, or any adverse reaction to a cannabinoid
- History of any significant medical condition that may increase the risk of participation

Interventions

Intervention Name (use generic name if established): Nabilone

Intervention Type: Drug

Intervention Description (do not repeat information already included in arm/group descriptions): Nabilone is a synthetic form of THC and cannabinoid 1 receptor agonist. It acts on the brain's "endocannabinoid system," which has been hypothesized to play a role in OCD.

Intervention Name: Exposure and Response Prevention Therapy

Intervention Type: Behavioral

Intervention Description: Exposure and Response Prevention Therapy (EX/RP) is a type of Cognitive-Behavioral Therapy for OCD that involves intentionally confronting situations that trigger obsessional distress while refraining from doing compulsions.

Outcome Measures

Primary Outcome Measure 1: Feasibility of recruitment of patients with OCD into a study of nabilone

Time Frame: Total participants who consent to participate for the duration of the study

Safety Issue (Is this outcome measure assessing a safety issue?)**:** No

Primary Outcome Measure 2: Tolerability of nabilone (e.g. adverse events reported)

Time Frame: Baseline (Week 0), Week 1, Week 2, Week 3, Week 4

Safety Issue (Is this outcome measure assessing a safety issue?)**:** Yes

Primary Outcome Measure 3: Yale-Brown Obsessive-Compulsive Scale (YBOCS)

Time Frame: Weeks 0 and 4

Safety Issue (Is this outcome measure assessing a safety issue?)**:** No

Secondary Outcome Measures: Hamilton Depression Rating Scale, 17-Item (HDRS-17)

Time Frame: Weeks 0 and 4

Safety Issue?: No

Statistical Analysis Plan

For both the YBOCS and HDRS-17 measures, we will calculate change scores for the nabilone and nabilone+EX/RP groups based on the difference between Baseline (Week 0) and Week 4. This preliminary study is not designed to assess for statistical differences between groups, and thus only the overall magnitude of change between groups will be compared. We will assess feasibility of recruitment based on the total number of participants enrolled over the duration of the study. Finally, we will assess nabilone's tolerability in OCD based on weekly self-reporting of side effects using a checklist drawn from the nabilone package insert, and any other adverse events that occur over the course of the study.