Enhancing the Acceptability of Psychological Treatments for Obsessive-Compulsive Disorder

Study Protocol and Statistical Analysis Plan

Unique Protocol ID: 30006258

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Study Protocol

Individuals who contact the clinic expressing interest in the study will first complete a telephone screen in order to assess their potential eligibility. Screener questions from the ADIS-V will be used to determine their likely inclusion in the study; those who seem likely to be eligible will be invited to the clinic to complete a baseline assessment, consisting of the ADIS-V and YBOCS, as well as measures of OCD, anxious and depressive symptomatology and demographic and treatment history measures.

We will administer several measures to assess treatment acceptability. These will include the Credibility/Expectancy Questionnaire (CEQ), and the Treatment Acceptability / Adherence Scale (TAAS). The CEQ and TAAS will serve as subjective measures; objective measures will include counts of treatment refusers and dropouts across the two treatments. A refuser is defined as a participant who is deemed eligible following the initial assessment, but who declines to continue at any time after randomization, but before session 2 (the first session is for case formulation, treatment planning, and includes a comprehensive description of the treatment approach). A dropout is defined as a participant who withdraws their participation from the study any time after the beginning of session 2. Should any participant refuse or drop out of CT or ERP, we will ask them to list their reasons for this decision.

In addition to the Anxiety Disorders Interview Schedule (ADIS-V), we will administer the Yale-Brown Obsessive-Compulsive Checklist (YBOCS). Diagnostic and interview reliability will be assessed via a second trained rater who will listen to and rate recordings of interviews. In instances where there is disagreement on diagnostic status, a team meeting will be held to discuss the issues and resolve the discrepancy. Self-report measures assessing OCD symptoms (i.e., Vancouver Obsessional Compulsive Inventory, VOCI), OCD beliefs (Obsessional Beliefs Questionnaire, OBQ), process measures (e.g., Personal Significance Scale, PSS), as well as measures of depression and anxiety symptomatology (Beck Depression Inventory, 2nd Ed, BDI & Beck Anxiety Inventory, BAI) will be administered.

Eligible participants will be block randomized (to ensure equal numbers of participants per treatment condition) via www.randomizer.org, and will begin session 1 of either ERP or CT with one of 2 therapists (see below). Participants will be asked to complete the PSS and VOCI before the start of each session. At all time points, assessors will be blind to treatment assignment, such that they will not know whether a participant has been offered or is receiving ERP or CT. After the 3rd, 6th, and 12th and final session, and at each follow- up point, participants will be asked to complete the CEQ and TAAS in order to assess their views of the acceptability of the treatment they receive. After session 6, participants will complete a mid-therapy assessment consisting of the YBOCS, VOCI, OBQ, PSS, BAI and BDI.

This RCT will involve trial administration (shared by the Investigators and the study coordinator), an assessment team (research assistant and graduate student), and a team of 3 therapists (post-doctoral fellow(s) and a senior graduate student). This will allow for comparisons of therapist effects, as well as the effects of therapist experience on outcome and acceptability. The first 6 months of the project are reserved for training team members on relevant tasks. Training will be overseen by the NPA, and offered by all project investigators.

ERP (12 sessions) will be based on a standard, commonly-used manual, and will comprise 1 session of case formulation and treatment planning, 10 sessions of ERP, plus 1 final session on relapse prevention. Exposures in this protocol are prolonged and repeated, requiring clients/patients to engage in a series of exposures to feared stimuli (e.g., contaminants, doubts, intrusive thoughts), and to refrain from engaging in compulsive behaviour until their anxiety subsides. ERP is well-established, and known to be highly effective for OCD.

CT (12 sessions) will be modularized, and based on elements from our three primary treatment packages. It will begin with 1 session of case formulation and treatment planning, followed by 10 sessions focused on evidence gathering and behavioural experiments (which are importantly different from prolonged exposure), plus 1 final session on relapse prevention. The 3 treatment packages share a number of common features – they include focus on reducing inflated responsibility, target the personal significance of the participant's thoughts or compulsions, etc. Each also incorporates other elements specific to the primary symptom (e.g., beliefs about memory in compulsive checking, a perceived violation in mental contamination, or thought-action fusion in association with obsessions), allowing CT to be tailored to the individual beliefs and concerns of each participant. Many of these cognitive areas of focus are highly novel, and have not been assessed in previously conducted RCT's of CT, although our focus on problematic beliefs and appraisals in general is entirely consistent with established CT for OCD packages.

All sessions will be recorded in situ for the purposes of assessing treatment fidelity; this will be done on an ongoing basis via trained coders, blind to hypotheses and to condition assignment who will be asked to assess the proportion of session content allocated to a focus on behaviour/exposure vs. cognition/reappraisal. Audio recording devices will be made available to participants and their use is a standard enhancement of treatment interventions to help make them more memorable, and to clarify any questions that may arise between sessions.

At the end of treatment, and at 6- and12-month follow-up periods, participants will complete the mid-therapy assessment measures again, in addition to the ADIS-V.

Statistical Plan

Primary hypotheses will be tested by comparing our indices of acceptability across the two treatments. Specifically, participant ratings of treatment acceptability, and the relative numbers of treatment refusers and dropouts will be assessed. Independent samples *t*-tests will be used to compare the two treatments groups on self-reported treatment acceptability on the CEQ and the TAAS. Furthermore, chi-squared tests will be used to compare treatments on the number of refusers and drop outs.

Completer and intent-to-treat analyses will be conducted on YBOCS and VOCI total scores (i.e., OCD symptom severity) measured at multiple time points. ANCOVA will compare treatments on changes in OCD symptom severity across all measurement periods, with baseline scores as covariates. Although we have reason to suspect that our CT may outperform more traditional cognitive approaches to the treatment of OCD, we expect that both ERP and CT will be similarly effective (as has been shown in numerous trials, and in a recent comprehensive review), perhaps with intent-to-treat analyses showing a small advantage of CT over ERP, yet we do not expect to be powered to detect significant differences.