Family Accommodation Reduction in Adult Obsessive Compulsive Disorder: A Randomized Controlled Trial

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1.0 Background and Rationale

Obsessive compulsive disorder (OCD) is a common and debilitating psychiatric disorder with a lifetime prevalence of approximately 3% (Kessler et al., 2012); it is ranked as one of the top 10 most disabling mental illnesses by the World Health Organization (2008). OCD diminishes one's quality of life, causes significant distress for individuals and their family members, and leads to functional impairment in one's occupation, education, social functioning, and family life (American Psychiatric Association, 2022; Markarian et al., 2010; Ruscio et al., 2010). OCD is time-consuming, where individuals spend an average of four to five hours per day engaging in their obsessions and/or compulsions (Rahman & Kamal, 2010). The economic burden of OCD is estimated in the billions of dollars due to healthcare costs and lost work productivity (Kochar et al., 2023). Patients and families with OCD struggle for many years before getting evidence-based treatments (Perris et al., 2023). The first-line and most effective treatment for OCD is cognitive behavioural therapy (CBT) with exposure and response prevention (ERP). ERP involves gradual exposure to obsessions while refraining from engaging in compulsions. ERP aims to facilitate tolerance of distress and challenge predictions and disconfirm feared outcomes. A meta-analysis by Öst et al. (2015) found that CBT is the most effective treatment for OCD, leading to markedly greater effect sizes than antidepressant medications. However, about 30% of patients do not respond and up to 60% are only partial responders (Farris et al., 2013; Öst et al., 2015). Given OCD's prevalence, chronicity, partial treatment response rate, and associated burdens, it is of utmost importance to prioritize efforts aimed at improving CBT treatment efficacy.

A promising approach to improving treatment outcomes of CBT for OCD is by addressing *family accommodation* of OCD symptoms. The term "family accommodation" (FA) is used when family members of individuals with OCD modify their behaviours to prevent or reduce their loved one's distress (Calvocoressi et al., 1999). In many cases, patients with OCD may demand that their family members engage in "helping" behaviours to alleviate their distress (Lebowitz et al., 2011a, 2011b; Stengler-Wenzke et al., 2006). Typical FA behaviours include family members actively participating in patients' rituals, providing excessive reassurance, removing contact with patients' feared stimuli, and changing family routines.

The rationale for targeting FA in adults with OCD is grounded in several key research findings. First, FA in OCD is nearly universal, occurring in up to 95% of adult patients' families (Renshaw et al., 2005), suggesting that interventions that target FA may be applicable for almost all patients with the disorder. Second, higher FA levels are associated with greater OCD symptom severity and impairment in patients (Albert et al., 2017; Calvocoressi et al., 1999). Third, baseline FA is associated with poorer CBT treatment outcomes (Amir et al., 2000; Renshaw et al., 2005; Garcia et al., 2010). Fourth, greater FA reduction in pediatric samples is associated with lower levels of OCD symptom severity post-CBT (Merlo et al., 2009; van den

Berg et al., 2022). Fifth, improvement in FA during CBT may precede subsequent improvement in OCD symptoms (Piacenti et al., 2011). Finally, meta-analytic evidence indicates that although high levels of FA do not fully prevent positive response to CBT (Hermida-Barros et al., 2024), they are associated with poorer outcomes (Amir et al., 2000; Renshaw et al., 2005; Garcia et al., 2010). Thus, reduction of FA is a promising target when attempting to improve the outcomes and limitations of CBT for adults with OCD.

Most existing CBT protocols for OCD in adults do not systematically address FA or involve family members. Most FA research applies to pediatric populations (Lebowitz et al., 2013; Storch et al., 2024), which demonstrates the robust effectiveness of using a skill-building approach to reduce FA in parents of children with OCD. Although FA reduction studies in adult OCD are scarce, there is preliminary evidence that interventions aiming to reduce FA may improve treatment outcomes. In general, FA reduction efforts can be divided into Family Psychoeducation, Family-Integrated CBT interventions, and separate FA reduction interventions provided for family members only. First, Family Psychoeducation (FP) focuses on building a common understanding of the symptoms and treatment of OCD (Skarphedinsson & Weidle, 2018). Meta-analytic studies suggest that providing FP to family members of patients diagnosed with other chronic conditions such as depression (Katskuki et al., 2022) or dementia (Sun et al., 2022) is associated with moderate levels of symptom reduction in patients. A second, more systematic FA reduction approach consists of Family-Integrated CBT modules, in which family members join CBT sessions with the patient and act as co-therapists in ERP work. A meta-analysis (Stewart et al., 2020) suggests that Family-Integrated CBT is associated with reductions of OCD symptoms, though only 7/15 included studies had a control group. Finally, a third and more focused FA reduction approach relies on administering specific FA reduction modules for family members only. Here, the power of psychoeducation is combined with a skills-based focus on helping the family member reduce their own accommodation behavior, rather than on training them as ERP co-therapists. Arguably, separate FA reduction modules for family members may carry practical and theoretical benefits over Family-Integrated CBT. Practical advantages include provision of a safe space for family members to address their challenges and frustrations during FA reduction work (Brownings et al., 2023) as well as more flexibility to schedule one person vs an entire family. Theoretical advantages include the ability to focus on FA reduction and accurately measure the impact of FA reduction on patient outcomes.

The only randomized clinical trial that has been conducted in adults (Thompson-Hollands et al., 2015) evaluated the benefits of adding a two-session FA reduction intervention to weekly individual CBT for OCD, compared to CBT for OCD alone. The first session focused on psychoeducation and the second emphasized skill-development for family members. Patients whose family members received the FA reduction intervention demonstrated greater reductions in OCD symptom severity across treatment compared to controls ($d = 1.27$). Additionally, change in FA from baseline accounted for a significant amount of variance in later OCD symptoms ($\beta = .45$, $p = .02$). Although these are promising findings, the interpretation of findings is limited by a small sample size ($N = 18$), lack of an active control group, a varying number of CBT sessions received, and the absence of follow-up data to evaluate the durability of improvements. Furthermore, having only two family sessions allowed little opportunity for skill building; research on learning suggests a minimum of 6 sessions to effectively address habitual behaviours

(Howard et al., 1986; Gardner et al., 2012). Finally, while this study (and others) investigated change in family accommodation as a *predictor* of OCD symptoms change, more work is needed to precisely pinpoint change in family accommodation as a *mediator* of change in OCD symptoms. From a theoretical perspective, FA is a clear mechanism by which CBT might affect change. FA facilitates avoidance, providing short-term relief, which reinforces obsessional fear and the use of compulsions (Storch et al., 2007). In other words, FA shares the same function as compulsions and avoidance, reduction of which allows individuals with OCD to learn that their feared outcomes do not occur (Elsner et al., 2022). It is imperative to understand whether the main purported ingredient in FAR, reduction in FA, is indeed the mechanism at work. Clarifying this will help determine how family-based interventions influence the effectiveness of CBT outcomes.

2.0 Research Questions, Goals, and Hypotheses

The proposed two-site study aims to leverage a longstanding, highly successful collaborative relationship between the two largest OCD treatment centres in the country to evaluate the clinical efficacy of **Family Accommodation Reduction (FAR)**, a novel skill-building intervention provided to family members of adults with OCD, designed to improve patient outcomes for patients receiving group CBT (GCBT). FAR is a six-session intervention that, in addition to providing psychoeducation on FA in OCD, focuses on gradual exposure work aimed at reducing FA. Using an RCT design, we will compare FAR, who has a focus on skill building, to a Family Psychoeducation course, that focus on increasing knowledge and insight on OCD. Specifically, we will compare two groups: 1) FAR + GCBT, where family members receive FAR prior to patients receiving GCBT, and 2) Family Psychoeducation (FP) + GCBT. **The overarching hypothesis of the study is that adding FAR will be associated with improved outcomes in subsequent GCBT as compared to adding FP.**

Primary Goals: 1) To measure the efficacy of FAR in augmenting outcomes of GCBT.
Secondary Goals: 2) To study family-reported FA changes as a mediator of patient-reported symptom changes across standard GCBT.

2.1 Primary Goals and hypotheses

Question 1: Is the addition of FAR associated with superior outcomes at the end of standard GCBT and at 3 month follow up in comparison to our control group? *Hypothesis 1a***:** We predict that the FAR+GCBT group will experience significantly greater reduction in OCD symptom severity in comparison to FP+GCBT. *Hypothesis 1b:* We predict that the FAR+GCBT group will demonstrate significantly greater improvement in quality of life and functional impairment in comparison to FP+GCBT. *Hypothesis 1c:* We predict that FAR will lead to greater reduction in FA as compared to FP.

2.2 Secondary Goals and hypotheses

Question 2: Is reduction in FA a mechanism by which FAR is impacting the outcomes of GCBT? *Hypothesis 2***:** We predict that there will be a significant indirect mediator effect of reductions in FA on GCBT outcomes. We predict indirect vs direct mediation because FA likely impacts GCBT outcomes through its impact on other treatment-relevant variables.

3.0 Methods

3.1 Study Design

The proposed trial design is a two-site, four-year, two-arm single blind RCT. Adults with a primary DSM-5 diagnosis of OCD (18-65) at the Anxiety Treatment and Research Clinic (ATRC), St. Joseph's Healthcare Hamilton and the Thompson Anxiety Disorders Centre (TADC), Sunnybrook Health Sciences Centre Toronto will be recruited along with one of their family members. Family members will be randomly assigned to receive 6-weeks of FAR or 6-weeks of FP followed by 12-week GCBT for all patients with OCD.

3.2 Interventions. Both FAR and FP will be administered by all study therapists to avoid a therapist by treatment confound. Training on the family-based interventions involves reviewing FAR and FP manuals in detail and receiving supervision on at least one course of each intervention from the co-PIs via audio-recorded sessions. Every effort will be made to have clinicians who are not providing FAR/FP facilitating GCBT. All therapists involved in the study will be registered healthcare professionals with experience treating clients with OCD using CBT.

3.2.1 FAR: includes six weekly 60-minute sessions, individually delivered to one family member of each adult patient with OCD, administered by post-doctoral fellows or a senior clinic staff. In line with our pilot study, FAR will be administered individually, and may be done online using Zoom, which was the preferred mode by family members, or in-person depending on the preference of the family member. FAR relies on a skill-building, gradual exposure approach towards FA reduction. Sessions: #1 includes psychoeducation about OCD, definition of FA with examples, and initial homework focused on monitoring FA; #2: a focus on creating FA hierarchy based on Subjective Units of Distress, identifying an initial FA reduction goal; #3-5 debriefing FA reduction exercises and problem-solving challenges, moving forward with FA hierarchy; #6: review overall progress, discuss ongoing plan for FA reduction. Therapists will provide weekly ratings of family member completion of FAR exercises. Adherence to the manual will be assessed by independent coders.

3.2.2 Family Psychoeducation (FP): includes six weekly 60-minute sessions, individually delivered to one family member of each adult patient with OCD by the same personnel as FAR. The sessions may be done online using Zoom or in-person, depending on the family member's preference. FP's manual is based on our manualized protocol for family members of children with OCD, modified to address adult OCD. The goal of FP for OCD is to increase knowledge and insight on OCD through information and reflection. FP covers information about OCD, symptoms, course, prognosis, impact on family, FA and evidence-based treatments. While FP will include information on FA, it will not include skill-learning work and no assigned exercises. Thus, we expect some reduction in FA from FP, but less potent than in FAR. Time will be left in each session to reflect on the information, ask and respond to questions. Adherence to the manual will be assessed by independent coders. Sessions: #1 General information about OCD, with a focus on identifying obsessions and compulsions; #2: De-stigmatization and biology of OCD; #3 The mechanics of the disorder- learning about the cognitive-behavioral model of OCD; #4 The treatment landscape: evidence based interventions for OCD; #5 The family dynamic I:

discussing expressed emotion in OCD; #6 The family dynamic II: Family accommodation in OCD.

3.2.3 GCBT: GCBT is a manualized, well-studied intervention which has already been unified across the two sites to support longstanding collaborative studies involving CBT for OCD. Session content over the 12-session weekly protocol includes psychoeducation, symptom self-monitoring, engaging in in- and out-of-session exposures with response prevention (ERP), cognitive exercises (e.g., responsibility pie, cumulative probability technique), and relapse prevention. Collaborative research from ATRC and TADC suggests this intervention is similarly effective when offered in-person or virtually (Lisi et al., 2024). GCBT will be delivered by clinic staff. Adherence to the manual is assessed by a session-by-session checklist of core content completed by therapist after each session.

3.3 Risks and Benefits for Participants

For both family members and patients, there could be mild discomfort or distress in answering some of the questionnaires. We do not expect increased risk of OCD worsening due to enrollment and wait time for the study because the typical wait time for clinical services exceeds the total length of wait from recruitment, FAR/FP intervention and beginning of GCBT. If the FAR/FP therapist or GCBT facilitators have any reason to believe that a participant is experiencing acute deterioration in symptoms, a physician consult will be offered. Our pilot study suggests that family members who participated in FAR may experience transient distress during the initial two sessions that significantly subsides by the final two sessions. For family members whose distress is extreme or has not subsided by the fourth FAR session, we will arrange an assessment with a clinician. All participants will receive a handout with mental health resources at the beginning of the study. Family members and participants are also free to withdraw from the study at any time. GCBT in the proposed study follows our existing, well-studied and published protocols. Of note, GCBT protocols across the two participating sites are the same. As such, it is anticipated that most patients who participate in the study (regardless of allocation of their family member) will experience improvement in symptoms of OCD and overall well-being.

3.4 Randomization

To enhance internal validity, minimize confounding, and increase comparability between groups, we will use stratified block randomization at each site. Based on Kang et al. (2008), family members will first be stratified based on gender and severity of FA (equal to/above or below a mean score of 31 on the FAS-PV, the mean score found in previous research; Flessner et al., 2011) followed by block randomization within each stratum to evenly distribute them into the two intervention arms.

3.5 Recruitment Procedures

Recruitment will take place through standard referrals to either speciality clinic. Patients will be informed of the study during intake at the ATRC and TADC and asked to provide verbal consent to be contacted by a research assistant who will call patients to review the study details, review inclusion and exclusion criteria, and describe the required family involvement. If the patient is

willing to consider the study and can identify a willing family member, a research assistant will then contact the family member to confirm eligibility and interest.

3.6 Inclusion and Exclusion Criteria
Inclusion and exclusion criteria will be reviewed at the time of screening for the study.

3.6.1 Patients with OCD: 1) 18-65 years, 2) primary diagnosis of OCD based on DSM-5, 3) clinically significant obsessive compulsive symptoms (Yale-Brown Obsessive-Compulsive Scale, 2nd edition > 20), and 4) if on medications for OCD, must be on a stable (at least 6 weeks) prior to the initiation of the study. Exclusion criteria: 1) severe mood disorder, schizophrenia/psychotic disorders or significant substance abuse/dependence, 2) suspected organic pathology, 3) full course of CBT for OCD within the past year (i.e., more than 8 sessions), and 4) an active comorbid medical condition that may require urgent intervention during the treatment. Participants incapable of providing informed consent will be excluded.

3.6.2 Family members: Consistent with other research, the term "family member" is broadly applied to indicate an individual who is:1) 18-65 years old, 2) has been sharing accommodations with the patient for a minimum of 9 of the last 12 months, 3) is a parent, spouse, partner, sibling or an adult child of the patient with OCD 4) reports at least moderate FA levels based on the Family Accommodation Scale for Obsessive-Compulsive Disorder-Self-Rated Version score>14 (Pinto et al., 2013), 5) no known current diagnosis of schizophrenia, bipolar disorder or organic brain illness (which will be asked about in the Family Member Phone Screen), and 6) has access to a Zoom capable device, a stable internet connection, and a private location to attend sessions. Of note, if more than one eligible family member expresses interest in the study, we will include the family member endorsed by the patient who is the most frequently present to participate with OCD triggers.

After phone screening with the research assistant, patients with OCD and their family member who meet inclusion criteria will be sent the Consent Form on REDcap to review in detail. The research assistant will be available in person, by virtual meeting, or by phone to answer any questions about the Consent Form and procedures. If the patient and family member would like to proceed, they will electronically sign the consent form via REDcap and receive a copy of the signed consent.

Next, patients will be administered the Diagnostic Research Assessment Tool for DSM-5 (McCabe et al., 2017) to confirm the presence of OCD and comorbid conditions as per standard clinic procedures. After completion of the DART, patients with OCD will be referred to GCBT at the clinic.

Family members will then be randomized to either FAR or FP. All patients with OCD will receive 12 weekly GCBT sessions, slated to begin within 2-4 weeks of the final FAR or FP session. Medications will be monitored throughout the duration of the study by therapist and reviewed by the PIs. Medication changes (i.e. medication type and dosage) will be examined

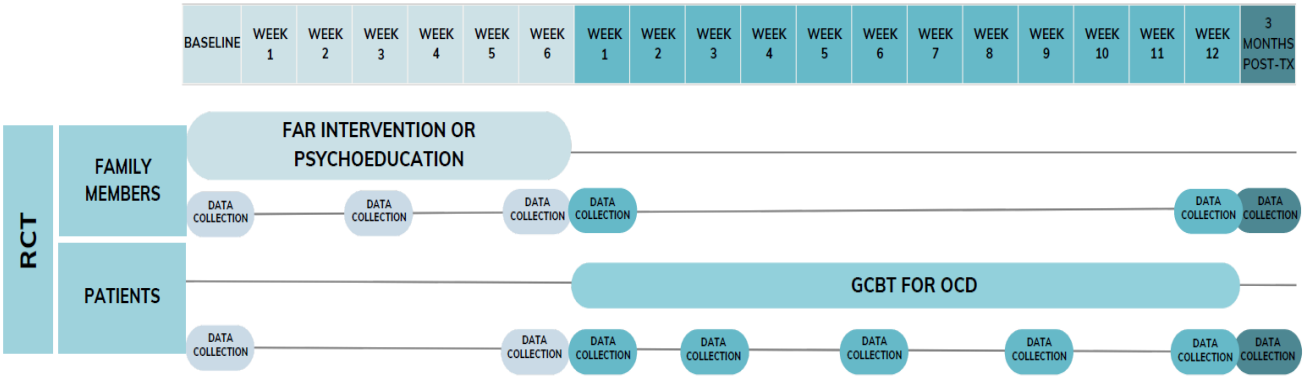
statistically in relation to treatment response during the duration of the study. Recruitment will take place across the four years of the study.

3.7 Sample Size

We propose a sample size of 240 individuals with OCD to allow us to randomly assign 240 corresponding family members. Although Thompson-Holland et al. (2015) reported a large effect size of d=1.27 for family FA reduction + CBT, it was based on small sample and did not include an active comparator. Thus, we conservatively based our sample size calculation on a smaller effect size estimate for hypothesis 1 (d=.35, α=.05 and β=.2), halfway between conventional cutoffs for small (.2) and medium (.5) effects. Using computer simulation in R (v.4.5.1, R Core Team, 2025 ; simstudy package v.0.8.1, Goldfeld & Wujciak-Jens, 2020), we performed a power analysis for the test of FAR vs. FP at each follow up time point, based on the proposed mixed-effects model for repeated measures (MMRM) controlling for baseline symptom severity, assuming a conservative estimation of the correlations between measurement points (r = .6, informed by ATRC datasets of pre/post and weekly scores through CBT for OCD), and accounting for a predicted ~20% total non-compliance and loss to follow-up from CBT or the family condition. From these simulations we arrived at a final N = 240 (120 per group). For hypothesis 2 (mediation analysis), we assessed the potential minimum detectable effect sizes for the indirect and direct standardized regression coefficients in the mediation analysis given the sample sizes determined for the primary analysis via the simulation software provided by Qin (2023). We should be adequately powered to detect effects halfway between small and medium.

4.0 Measures

Figure 1: Schedule of Assessments



Note. FAR/psychoeducation will be initiated within 4 weeks of baseline assessment and will be completed between 2-4 weeks ahead of GCBT.

Data from patients with OCD, family members and clinicians will be collected using REDcap online survey software (see Figure 1 for schedule).

4.1 Primary Patient Outcome Measures

The primary outcome measure is OCD symptom severity as measured by the self-report *Yale-Brown Obsessive-Compulsive Scale, Second Edition (*Y-*BOCS-II*; Storch et al., 2010). The Y-BOCS-II has 10 items pertaining to obsessions and compulsions rated on a Likert scale. Psychometric qualities of this measure are strong, and it is correlated 0.8 with a clinician-administered version (Rowa et al., 2025).

4.2 Secondary Patient Outcome Measures

1) *Illness Intrusiveness Rating Scale* (*IIRS*; Devins, 1994) is a 13-item self-report measure of the degree to which symptoms interfere with important life domains (e.g., work, family relationships); 2) *SDS;* Sheehan et al., 1983) is a brief measure of disability and functional impairment due to psychiatric or medical symptoms focused on work, social life/leisure activities, and family life/home responsibilities; 3) *Depression Anxiety Stress Scale-21* (*DASS-21*; Lovibond & Lovibond, 1995) is a 21-item self-report measure designed to assess the severity of depression, anxiety, and stress symptoms; 4) *Family Accommodation Scale for Obsessive-Compulsive Disorder-Patient Version (FAS-PV;* Wu et al., 2016) is a 19-item self-report measure that gathers information about the degree to which an OCD patient's family member participates in accommodating behaviours; 5) *Brief Dyadic Scale of Expressed Emotion* (Medina-Pradas et al., 2011) is a 14 item scale assessing patients' perceptions of loved ones' expressed emotions; 6) *Family Functioning Scale* (Stewart et al., 2017) is a self-report scale of how much family impairment arises from OCD symptoms.

4.3 Family Member Outcome Measures

1) *Family Accommodation Scale for Obsessive-Compulsive Disorder – Self-Rated Version* (*FAS-SR*, Pinto et al., 2013) is a 19-item self-report measure that gathers information about the degree to which family members participate in accommodating behaviours; 2) self-report *Yale-Brown Obsessive-Compulsive Scale, Second Edition (Y-BOCS-II*; Storch et al., 2010) will be administered to family members as well given the tendency for OCD symptoms to cluster within families; 3) *Depression Anxiety Stress Scale-21* (*DASS-21*; Lovibond & Lovibond, 1995) is a 21-item self-report measure designed to assess the severity of depression, anxiety, and stress symptoms; 4) *Family Questionnaire* (*FQ*; Wiedemann, Rayki, Feinstein, & Hahlweg, 2002) is a 20 items self-report measure of criticism and emotional overinvolvement; 5) *Family Functioning Scale* (Stewart et al., 2017) is a self-report scale of how much family impairment arises from OCD. We will also have open text boxes at baseline and session 6 to ask participants what they hope to obtain from the sessions (baseline) and to share what has changed and what they learned at the end of sessions. This will complement the quantitative data from questionnaires.

4.4 Sex/Gender

We will use a two-step approach delineating between assigned sex at birth (as reported on the birth certificate) and gender identification. We will provide gender-identity options, incorporating open-ended questions to capture gender identity, expression, and external manifestation of gender.

5.0 Data Analysis Plan

We will follow an intention-to-treat (ITT) framework where all individuals are included in the analysis regardless of whether GCBT was completed and how much data they provided. For

hypothesis 1a (OCD symptom improvement), we will use a mixed-effects model for repeated measures (MMRM, Mallinckrod et al., 2008) initially fit with an unstructured within-participant covariance structure, though other structures will also be investigated (e.g., compound symmetric, spatial exponential). The model will include the change in OCD symptom severity from baseline to each time point as the outcome, and treatment condition, time, site (ATRC, TADC), and the treatment-by-time interaction as predictors. We will also include the stratification variables (sex of the participant and family member and FA severity) as well as baseline OCD symptom severity, age and depression scores as covariates as well as covariate interactions with time (Schuler, 2022) to improve model fit and reduce bias. We will then compare the FAR/FP model-derived least squares means at the post-treatment time points to assess the treatment effect, and plot least squares mean changes from baseline for each treatment over time. We will assess the contrast of treatment effects between the post-treatment time points (post and 3-month follow-up) to assess the stability of the treatment effect over this period. We will additionally investigate whether there is a potential difference in the treatment effect among sites and among the sexes of the participant and the sexes of the family member via 3-way interactions among treatment, time, and site/sex, however we acknowledge that tests of these interaction effects are only powered to detect medium-large effects. For hypothesis 1b (quality of life/functional impairment), we will analyze the data as in hypothesis 1a, but with functional impairment/quality of life in place of OCD symptom severity. For hypothesis 2, we will assess the effect of FA as a potential mediating mechanism underlying the effects of FAR on CBT outcome using a mediation analysis in an ANCOVA framework (Valente & MacKinnon, 2017) with OCD symptoms at post GCBT as the outcome, FA at post FAR/FP as the mediator, and treatment as the predictor, with both the outcome and mediator models including FA and OCD at baseline as covariates, as well as the covariates used in hypothesis 1. We will fit separate models for OCD symptoms at post and at 3-month follow up to assess the stability over time. We also intend to conduct secondary analyses to explore whether FA change and patient outcomes differ when the participating family member has clinically significant OCD or anxiety symptoms. Finally, we will assess the sensitivity of the above analyses by varying aspects of the analysis protocol, including the inclusion or exclusion of outliers, deviations from the intention-to-treat framework, missing data handling techniques, etc.

6.0 Knowledge Translation Plan

Findings will be disseminated in several ways including presentation at national and international conferences (e.g., Association of Behavioral and Cognitive Therapies) and submitted for publication in journals such as the Journal of Anxiety Disorders. A series of workshops for clinicians will also be developed based on findings, facilitated through an ongoing partnership K. Rowa has with the McMaster Online CBT workshops. Workshop topics could include "Understanding Family Accommodation in OCD" and "Implementing FAR". Infographics about family accommodation and how to manage it will be co-created by a communications graduate student from McMaster, a person with lived experience of OCD, and a family member and posted on ATRC's and TADC's websites and Instagram pages. If our primary hypothesis is supported, we will hold promotional virtual talks on FAR for interested families across Canada advertised through Anxiety Canada, a not-for-profit organization designed to provide science-based anxiety and OCD relief.

7.0 Privacy, Confidentiality, and Data Handling

All documents containing participant names and/or contact information will be stored on a separate database from the data and be password-protected. All forms sent through REDcap will only contain participant ID. Any data from individuals who are screened but not eligible for the study will be kept in REDcap without a research ID (anonymous) so we can keep track of number and reason for screen failures. All electronic personal health information will be stored on secure institutional servers in password-protected documents that can only be accessed by members of the research team. The data will be kept in storage for a 10-year period after which it will be anonymized. Records will be anonymized by deleting the key that links the participants' identifier with their name and contact information. As such, no identifying information will remain in the database, and the remaining information cannot be linked back to any particular participant without this key. Data will be anonymized and not disposed of in order to maintain the data for possible secondary analyses, including meta analyses by other authors. Drs. Rowa and Rector will be responsible for this. Every effort will be made to prevent security breaches. Potential harm from a security breach could include personal embarrassment, which would be addressed directly with the affected patient.