THE UNIVERSITY OF BRITISH COLUMBIA

BC Children's Hospital
An agency of the Provincial Health Services Authority

**CONSENT FORM:** Flexibly Dosed Intensive Exposure and Response Prevention as a Means to Maximize Outcomes for Youth with Obsessive Compulsive Disorder

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**Introduction:**
Obsessive-compulsive disorder (OCD) is psychiatric disorder that affects both children and adults. It often makes many parts of youths' and their families' lives challenging and, without treatment, it often does not get better. Exposure and response prevention (ERP) is a type of treatment for youth with OCD that involves encouraging youth to face their fears while not completing the rituals that they regularly use to reduce their distress. In the long term this has been shown to reduce symptoms of OCD. However, the amount of treatment youth need may vary and the best strategies for providing this treatment have not been identified.

**Why are we doing this study?**
You (**throughout the consent form "you" can refer to "you/your child")** are being invited to participate in this research study because you are interested in receiving treatment for OCD. This study is investigating whether it is feasible to provide ERP treatment for youth with OCD in an intensive, but flexible, format. We are hoping to identify that this way of providing treatment works and, in doing so, determine the number of intensive ERP sessions families need or want in order to successfully manage OCD. In addition, we will be comparing how the treatment setting (community vs hospital) impacts how easily we can provide treatment and how well the

treatment works. By doing this study we hope to establish that we can run a research study of this type and better understand the best ways to provide intensive ERP for youth with OCD.

**What happens in the study?**

A) Study Screening and Diagnostic Assessment

What happens at the beginning of the study depends on whether or not you have previously completed a clinical assessment through the Provincial OCD Program at BC Children's Hospital (POP) and consented to the OCD Registry. Once you consent to the study, data you provide will be kept even if you are determined not to be eligible for all parts of the study. If you do not wish this data to be kept you may request to remove/withdraw your research information by any means and at any time.

*Screening Procedures for Participants Utilizing OCD Registry Data*

You will complete the following screening procedures if you consented to the OCD Registry and completed a POP assessment within the past 30 days. Your POP assessment report will be reviewed by the team and your OCD Registry data will be used for the present study. You will proceed directly to the baseline assessment and introductory session.

If you consented to the OCD Registry and completed a POP assessment within the past year but over 30 days ago, study staff will review your POP assessment report and OCD Registry data with you over the phone to ensure it is still accurate (completed by parent OR parent and youth). If review of the data determines you are no longer eligible, you will exit the study and not complete any of the following. You will be provided with a list of resources regarding other assessment and treatment options for OCD available in the community. If you are still eligible you will proceed to Treatment Phase 1.

*Screening Procedures for Participants Not Utilizing OCD Registry Data*

The following screening procedures will be used if you: a) have never been assessed by the POP; b) were assessed by the POP but over one year ago; or c) were assessed by the POP within the past year but chose not to consent to the OCD Registry.

| Time | Visit | Description | Online Questionnaires | Outcomes |
|---|---|---|---|---|
| 30 min | Screen | Interview with parent about current symptoms and appropriateness for study participation (telephone) | Parent A: None<br>Parent B: None<br>Youth: None | *If eligible*: Continue to Diagnostic Assessment<br>*If not eligible:* Exit the study and receive list of community treatment resources |
| 3 hrs | Diagnostic Assessment | Detailed in-person interview with youth and parent to assess OCD and other mental health symptoms (at hospital) | Parent A: 1 hour<br>Parent B: None<br>Youth: None | *If eligible*: Proceed to Treatment Phase I. Get randomized to receive treatment at the hospital or your home/locations relevant to symptoms<br>*If not eligible:* Exit the study and receive list of community treatment resources |

B) Treatment Phase 1: Standardized Brief Intensive
Treatment Phase 1 occurs over a 3 week period and involves the following components:

| Time | Visit | Description | Online Questionnaires | Outcomes |
|---|---|---|---|---|
| 1.5 hrs | Baseline Assessment | Therapist conducts an updated assessment of OCD symptoms (at randomized location) | Parent A: 1 hour<br>Parent B: 1 hour<br>Youth: 30 min | *Everyone:* Proceed to Introductory Session (same day) |
| 1.5 hrs | Introductory Session | Therapist provides information about OCD and treatment model, and development of treatment plan (at randomized location) | Parent A: None<br>Parent B: None<br>Youth: None | *Everyone:* Proceed to ERP Session 1 (1 week later) |
| 3 hrs | ERP Session 1 | Therapist provides ERP treatment (at randomized location) | Parent A: 15 min<br>Parent B: None<br>Youth: 15 min | *Everyone:* Proceed to ERP Session 2 (1-week later) |
| 3 hrs | ERP Session 2 | Therapist provides ERP treatment (at randomized location) | Parent A: 15 min<br>Parent B: None<br>Youth: 15 min | *Everyone:* Proceed to Post-Treatment Assessment 1 (1 week later) |
| 30 min | Post-Treatment Assessment 1 | Updated assessment of OCD symptoms (telephone) | Parent A: 30 min<br>Parent B: 30 min<br>Youth: 30 min | *If OCD is no longer a big problem:* Proceed to Follow-Up (1 week later)<br>*If OCD is still a big problem:* Enter Treatment Phase II, proceed to 1st Treatment Decision Point (4 days later) |

C) Treatment Phase 2: Flexible Patient Driven Intensive
Treatment Phase 2 can last between 1 – 8 weeks depending on the choices you make as a family. Treatment Phase 2 involves the following components:

| Time | Visit | Description | Online Questionnaires | Outcomes |
|---|---|---|---|---|
| 15 min | Treatment Decision Points (TDP) | Family independently meets to discuss and decide how to proceed with treatment/study for the upcoming week | Parent A: 15 min<br>Parent B: None<br>Youth: 15 min | *Let's Meet:* You have the next ERP session (3 days later). You can choose Let's Meet for up to 4 ERP sessions during Phase II.<br>*Let's Wait:* You do not have an ERP session that week. You complete a TDP again (1 week later). You can choose Let's Wait a max of two times.<br>*We're Finished:* You choose to stop having ERP sessions. You complete Post-Treatment Assessment 2 (3 days later) and enter follow-up. |

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|---|---|---|---|---|
| 3 hrs | ERP Sessions 3-6 | Therapist provides ERP treatment (at randomized location) | Parent A: 15 min<br>Parent B: None<br>Youth: 15 min | *Following ERP Sessions 3-5:* Proceed to another Treatment Decision Point (4 days later)<br>*Following ERP Session 6:* Proceed to Post-Treatment Assessment 2 (1 week later) |
| 30 min | Post-Treatment Assessment 2 | Updated assessment of OCD symptoms (telephone) | Parent A: 30 min<br>Parent B: 30 min<br>Youth: 30 min | *Everyone:* Enter Follow-Up, proceed to 1st Booster Call (1 week later) |

D) Follow-Up Phase
The follow-up phase lasts a total of 6-months and involves the following components:

| Time | Visit | Description | Online Questionnaires | Outcomes |
|---|---|---|---|---|
| 30 min | 3 Booster Calls | Therapist provides support around any remaining symptoms and strategies to prevent symptom return (telephone) | Parent A: None<br>Parent B: None<br>Youth: None | *Following Booster Calls 1-2:* Proceed to next booster call (1 week later)<br>*Following Booster Call 3:* Proceed to 1-Month Follow Up (1 week later) |
| 1 hr | 1-Month Follow-Up | Updated assessment of OCD symptoms (telephone) | Parent A: 1 hour<br>Parent B: 1 hour<br>Youth: 30 min | *Everyone:* Proceed to 6-Month Follow-Up (5 months later). Free to access any services outside of the study (e.g., medication changes, additional therapy) |
| 1 hr | 6-Month Follow-Up | Updated assessment of OCD symptoms (telephone) | Parent A: 1 hour<br>Parent B: 1 hour<br>Youth: 30 min | *Everyone:* Study complete |

**What else should I know about what happens during the study?**
All treatment in the study is provided under the direction and supervision of a registered psychologist specialized in OCD and ERP. A registered clinician (i.e. psychologist or clinical counsellor) will be present for the baseline assessment/introductory session and first ERP session while additional ERP sessions will be provided by either a registered clinician or a graduate psychology trainee under supervision.

Between sessions, you will be expected to complete daily treatment homework (i.e. 30 – 60 minutes of ERP exercises).

Parent(s) will be involved in at least part of each session so that they can learn about OCD, ERP, and how to best support youth. The amount of parent involvement in treatment sessions will depend on how they are involved with, and/or affected by, the youth's symptoms as well as the child's age and independence. Attendance of sessions may be shared/alternated by parents as long as both parents have consented to study participation.

Sessions may take place during school hours. As a result, participating in the study may require you to miss school, work, or other activities.

All sessions you have will be private, so only youth and parents will know about participation in this study. Every effort will be made to ensure confidentiality is maintained at all times.

**Study Results**
The results of this study may be published in academic journal articles. They may also be used for educational purposes (public awareness events, medical conferences, teaching of healthcare professionals) and funding purposes. Your name will never be published and your identity will be kept confidential. Only results of combined data will be published, individual results will not be published.

**Do I have to take part in this study?**
Your participation is entirely voluntary. If you wish to participate, you will be invited to sign this consent form. If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you or your child are entitled or are presently receiving. Future studies that involve collection of new data will require separate consent/assent forms (please see option at the end of this consent/assent form regarding future contact).

**What if I change my mind?**
If you do decide to take part, you are still free to withdraw at any time without providing a reason. Any information about you, up to the point of withdrawal, will be kept for analysis. At any time, you may request to remove/withdraw your research information by any means.

**Is there any way this study could be bad for you?**
We do not think there is anything in this study which could harm or be bad for you. Some of the questions we ask may appear sensitive or personal. You may refuse to answer any questions if you feel uncomfortable. Attending the therapy and confronting your fears can be challenging and provoke anxiety or distress in the moment; however, ERP for OCD has been shown in research to help reduce youth with OCD's symptoms and improve their quality of life.

**Other than the study, what are my options?**
Participating in this study is completely up to you. If I choose not to participate in this study or to withdraw at a later date, there are other treatment options that are known to reduce the symptoms of OCD:

- Medication, particularly selective serotonin reuptake inhibitors (SSRIs)
- Cognitive behavioural treatments that include ERP can also be accessed in the community.
    - You can access free therapy through your local Child and Youth Mental Health Team, although not all teams have therapists with expertise in this treatment.
    - You can also pay for therapy (typically $200/hr) with a private therapist in the community who has expertise in providing ERP for OCD.
- If you are eligible (requires a separate referral), the Provincial OCD Program also offers a Weekly CBT Group and a Summer Intensive Program for youth with OCD at no cost.

If you want to learn more about these other treatment options, you may contact the study team at any time.

**Who should not do this study?**
You should not join the study if:

- You do not have OCD or if you do not want to receive/participate in treatment for OCD.
- If, at this time, you cannot, or are unwilling to, commit to the time necessary to complete study procedures, including the potential need to take time away from work, school, or other activities.
- If you have a diagnosis of bipolar disorder, psychosis, intellectual disability, an autism spectrum disorder that necessitates substantial support, current substance dependence/abuse, or other mental health symptoms that should be treated prior to receiving treatment for OCD (e.g., self-harm, severe depression or ADHD).
- You live outside of the Greater Vancouver Area (longer than 60-minutes drive from BCCH).

In addition, if you have recently started or changed psychotropic medications, you will need to wait to participate until your medications are stable (i.e. at least 10 weeks since first initiation of a serotonin reuptake inhibitor (SRI) and 3 weeks since initiation of any other psychotropic medications as well as 3 weeks since any dose adjustment of any psychotropic medications).

**Will being in this study help you in any way?**
You will receive a comprehensive assessment of OCD and other psychiatric disorders that may provide helpful information about what symptoms you are experiencing. You will receive evidence-based treatment strategies for youth who experience OCD and therefore may experience reduced levels of OCD symptoms and improved quality of life.

Participation in the study will help us to understand whether or not we can feasibly conduct a research study of this nature and improve our understanding of the most effective treatments for children who experience OCD.

**How will your privacy be maintained?**
Your confidentiality will be respected. No information or records that disclose your identity will be published, nor will any information or records that disclose your child's identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you or your child during the course of this study, such that your identity (i.e., your name or any other information that could identify you) as a participant in this study will be kept confidential. Information that contains your identity will remain only with Dr. Stewart and/or her designate within the Provincial OCD Program. The list that matches your name to the unique identifier on your research-related information will not be removed or released without your consent unless required by law. Any forms, such as this consent form, which have identifying data will be kept separately in a locked cabinet in a Provincial OCD Program office.

Your de-identified information will be entered into a secured electronic database (Research Electronic Data Capture (REDCap) system) in the BCCH Research Institute's Clinical Research Support Unit (CRSU) located on-site in Vancouver, BC. De-identified data entered into REDCap can only be accessed by limited, authorized members of the research team with appropriate electronic signatures. The CRSU stores the data in a secure, firewall-protected server; the web-server uses Secure Socket Layer (SSL) technology for the transfer of data between the participating computer and the server. The actual data centre is a physically secured and protected area, with very limited access. BCCH information technology and security personnel control and record authorization and access linked to identification cards in this area. The data centre is patrolled by onsite security personnel, monitored by surveillance cameras, and protected by a fire suppression system

Please be aware that personal information may be necessary to be disclosed to relevant authorities if at any point during the study the following is revealed: a clear and substantial risk of serious and imminent harm to yourself or towards someone else; an incident that involves abuse and/or neglect of a child or vulnerable adult; or in response to any other lawful requirements to do so.

You and your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available upon request to Dr. Stewart.

**Will you be paid for your time?**
You will receive a parking coupon and $25 per visit to the hospital in order to cover expenses associated with travel. Therefore, you will receive $25 for attending the study diagnostic assessment (unless the assessment was completed through the POP prior to study enrolment) and, if you are randomized to the hospital group, you will also receive $75 for completion of the sessions during Phase 1 and up to $100 based on the number of sessions attended during Phase 2.

In addition, participants will receive a $25 gift card for completion of both child- and parent-report online questionnaires at baseline, post-assessment 1, post-assessment 2 (if needed), 1-month follow-up, and 6-month follow-up ($100-125 total).

**Investigator Remuneration**
The investigators conducting this study will not receive any personal payments for conducting this study. In addition, none of the investigators or staff conducting this study will receive any direct financial benefit from conducting this study.

**Who can you contact if you have any questions about the study?**
If you have any questions or concerns or would like more information about this study at any time during your involvement, you may contact Zainab Naqqash at (604) 875-2000 (ext. 3068) or zainab.naqqash@bcchr.ca or Dr. Stewart at (604) 875-2000 (ext. 4741) or estewart@bcchr.ca.

**Who can you contact if you have complaints or concerns about the study?**
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at (604) 822-8598 or if long-distance email RSIL@ors.ubc.ca or call toll free: 1-877-822-8598. Please reference the study number (H18-01654) when contacting the Complaint Line so the staff can better assist you.

**Options for data sharing (please check the option you prefer):**

**In the future we may have the opportunity to work together, and share data, with other centres investigating OCD or other psychiatric disorders. This would allow the data to be combined and analysed on a larger scale, allowing for knowledge to be gained that would not be possible in smaller scale, one centre studies. Any study related data sent outside of Canadian borders may increase the risk of disclosure of information because the laws in these countries (for example, the Patriot Act in the United States) dealing with protection of information may not be as strict as in Canada. However, all study-related data that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information). Information will not be shared in this way without your consent.**

☐ **I agree** that my de-identified information may be shared with other research centres studying OCD and other psychiatric disorders **within and outside Canada**.

☐ **I agree** that my de-identified information may be shared with other research centres studying OCD and other psychiatric disorders **within Canada only**.

☐ I **do not agree** that my de-identified data may be shared with other centers completing research into OCD and other psychiatric disorders.

| Participant's or Substitute Decision-Maker's (Parent's) Signature | Printed Name | Date |
|---|---|---|

**My signature on this consent form means:**

- I have read and understood the participant information and consent form.
- I have had enough time to consider the information provided and to ask for advice if necessary.
- I have had the chance to ask questions and have had responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive and without affecting my participation in concurrent or future studies
- I understand that I can choose to withdraw by any means without providing a reason, and that data collected up to this point will be confidentially kept for research purposes unless removal of this data is requested.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I have read this form and I freely consent to participate in this study.
- I understand that I will receive a dated and signed copy of this consent form for my own records.

**I consent to participate in this study.**

**If I am a substitute decision-maker (parent), I also consent for my child to participate in this study.**

| | | |
|---|---|---|
| Participant's or Substitute Decision-Maker's (Parent's) Signature | Printed Name | Date |
| Study Personnel Signature | Printed Name and Role | Date |