



## **Parent Information and Consent Form**

- Study Title:** The CATHI Pilot Study: Evaluating the Acceptability of a Voice Recognition System in Children's Mental Health Care (CIHR Team in Access to Children's Mental Health Services, Project 3c)
- Principal Investigator:** Patrick McGrath, Ph.D., Professor of Psychology, Pediatrics, Psychiatry, Dalhousie University; Vice President of Research, Psychologist, IWK Health Centre
- Co-investigator:** Charles Cunningham, Ph.D., Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University, Jack Laidlaw Chair in Patient-Centered Health Care
- Granting Agency:** Canadian Institutes of Health Research

### **Introduction**

You are being invited to take part in the research study named above. This form provides information about the study. Before you decide if you want to take part, it is important that you understand the purpose of the study, the risks and benefits and what you will be asked to do. You do not have to take part in this study. Taking part is entirely voluntary (your choice). Informed consent starts with the initial contact about the study and continues until the end of the study. A staff member will be available to answer any questions you have. You may decide not to take part or you may withdraw from the study at anytime. This will not affect the care you or your family members will receive from the IWK Health Centre.

### **Why are the researchers doing the study?**

The purpose of the CATHI Pilot Study is to learn if parents like working with a voice recognition system designed to complement a treatment program called Family Help.

The Family Help Program is a distance treatment program that was developed at the IWK Health Centre. This means that families do not have to come to the IWK Health Centre to receive help. Currently, the Family Help "Parenting the Active Child" Program includes weekly phone calls between parents and 'coaches' who provide support to families, respond to parents' questions and highlight the skills included in a handbook.

In this study, parents would work on the materials and then call in to a telephone-based computer system, called CATHI. CATHI stands for Computer Automated Telephone Help and Information System. CATHI is designed to provide similar telephone support that is provided by a Family Help

Coach. CATHI can review the information in the handbook, review families’ outcomes and progress, and provide encouragement. By adding CATHI to Family Help, more families will be able to use the program at one time; parents can call CATHI anytime any or night and CATHI can provide a more time efficient option to parents who prefer self-help style support.

**How will the researchers do the study?**

The CATHI Pilot Study will run for 5 weeks (1 introduction week and 4 weeks of the program) with 20 participants involved. Participants will be parents of 4 to 12 year olds from Nova Scotia with mild to moderate behaviour problems. The investigators will assess two different ways that parents could work with a live coach versus CATHI. The difference is the amount of time that parents work with a coach. Parents are assigned to a group based on when they are determined to be eligible for the study. See below for outline of differences.

<b>First 10 participants are the CATHI Supported Group</b>	<b>Last 10 participants are the Coach and CATHI Supported Group</b>
<ul style="list-style-type: none"> <li>• Parents will get an introduction to the study from a live coach</li> <li>• Parents will get an introduction to CATHI from a live coach</li> <li>• Parents will then work through four sessions with CATHI every week</li> </ul>	<ul style="list-style-type: none"> <li>• Parents will get an introduction to the study from a live coach</li> <li>• Parents will get an introduction to CATHI from a live coach</li> <li>• Parents will work through the first session with a live coach</li> <li>• Parents will then work through the next three sessions with CATHI every week</li> </ul>
<p><b>Each participant will:</b></p> <ul style="list-style-type: none"> <li>• Complete an initial screening telephone questionnaire to determine study eligibility</li> <li>• Work through Sessions 1-4 of the Family Help, “Parenting the Active Child Handbook”</li> <li>• Watch the accompanying videos</li> <li>• Interact with a Coach and the CATHI system</li> <li>• Answer three brief questionnaires over the phone with a trained member of the study staff</li> </ul>	

The questionnaires are designed to provide the researchers with feedback on patient satisfaction with the services received, CATHI system satisfaction, and explore the interaction experience between the participant and the CATHI system. The interaction between the participant and CATHI will be recorded by the voice recognition system to provide the investigators with more information about how people interact with the CATHI system. The interaction between the participant and the coach will also be recorded, as it is standard procedure for the traditional Family Help program.

This is not a multi-center project; research will take place at the IWK Health Centre only.

**What will I be asked to do?**

If you decide to participate, your participation in the study would take place over 5 weeks and cover 4 sessions from the Family Help Program. Traditionally, the program is 12 weeks in total. However, for this study we are using a shortened version to see how parents like working with CATHI. This study is done in your home at your convenience.

After 5 weeks, if you decide you would like to receive the eight remaining Family Help Sessions, you will be referred to the IWK Mental Health Services for assessment and triage for services per their usual processes. No preferential treatment will be given to families who have been referred by the study.

In the first week you would first participate in the Brief Child and Family Phone Interview over the phone to determine if you and your child are eligible for this study. This assessment tells us about how significant your child's behaviour problems are and takes about 30 minutes to complete. Only those children who have mild to moderate behaviour problems will be eligible. You will receive a phone call about the results letting you know if you are eligible to take part in this study. You would be notified if the assessment showed that your child requires more urgent care.

If you are eligible and you would still like to participate, you would receive a package in the mail that contains:

- Sessions 1-4 of the 'Parenting the Active Child' Handbook that includes information on 'Working with CATHI'
- The video that accompanies the Family Help Handbook
- A collection of Dr. Pat articles
- You will also receive a Progress Report about half-way through the study

Each of the remaining four weeks you would:

- Work through a session of the Parenting the Active Child Handbook
- Watch the accompanying videos
- Interact with the CATHI system and/or a Coach

You will receive a call from study staff to ensure that you have received the above study materials and provide you with an introduction to the study.

<p><b>CATHI Supported Group</b> For the next four weeks you will:</p> <ul style="list-style-type: none"> <li>• Read through a session</li> <li>• Complete the handbook exercises</li> <li>• Practice your skills for a week (about 5-7 days)</li> <li>• Then you will call CATHI</li> </ul>	<p><b>Coach and CATHI Supported Group</b> A live coach will schedule a time to review Session 1 with you. Before your call to your coach you will:</p> <ul style="list-style-type: none"> <li>• Read through Session 1</li> <li>• Complete the handbook exercises</li> <li>• Practice your skills for a week (about 5-7 days)</li> </ul> <p>You will work through Sessions 2-4 with CATHI. But before you make your call for Session 2, you will receive a call from a live coach for an introduction to using CATHI.</p>
<p><b>For both Groups:</b> You will be contacted within 24-48 hours of completing your fourth session to answer three questionnaires over the phone. The questionnaires will ask you about how you liked working with CATHI.</p>	
<p><b>Time Commitment:</b> The study would take place over five weeks. During this time, we expect that participation in this study would take about 5 or 6 hours of your time. Reading the four sessions and watching the video would take about 45 minutes each week, for a total of about 3 hours. You are not required to travel to the IWK Health Centre at any time.</p>	
<p><b>CATHI Supported Group</b> You will be on the phone for about 2 hours (40 minutes for 4, 10 minute CATHI calls and 20 minutes for the study introduction call from a coach).</p>	<p><b>Coach and CATHI Supported Group</b> You will be on the phone for about 3 hours because of the one session with a coach.</p>

**What are the burdens, harms, and potential harms?**

There are no recognized risks to participants. Participants are not required to discuss or answer any questions that they find uncomfortable and are able to withdraw from the study at any time.

**What are the possible benefits?**

You may benefit from taking part in this study because you will receive Family Help materials designed to help you manage your child's challenging behaviour. In addition to benefits at the individual family level, the knowledge gained from this study may lead to a more accommodating version of Family Help. CATHI has the potential to decrease program delivery costs and improve access for families to evidence-based children's mental health treatment.

If CATHI proves to be successful after the completion of all research phases, it is possible that the system may be available as a service option to parents in the future.

**What alternatives to participation do I have?**

If you choose not to participate at this time, but you are interested in receiving help for you and your child, we can make a direct referral to IWK Mental Health Services for you.

Choosing to not participate will not affect the care you or your family members will receive from the IWK Health Centre.

**Can I withdraw from the study?**

Participation in the study is entirely voluntary (your choice). You may decide not to sign the consent form or you may withdraw from the study at any time. If you decide to withdraw, you may request that your data be removed from the study (documents with your information will be shredded and voice files will be deleted). Choosing to withdraw will not affect the care you or your family members will receive from the IWK Health Centre. If you do withdraw from the study, but you are still interested in receiving help for you and your child we can make a direct referral to the IWK Mental Health Services for you. You will still be reimbursed for your time commitment to the study.

**Will the study cost me anything and, if so, how will I be reimbursed?**

Participation in this study will not result in any expenses to you. All materials are provided free of charge and if you are required to return forms to the Family Help Office, a postage-paid envelope will be provided. If you do not have the appropriate devices needed to participate the study (such as a DVD player) these will be provided on loan for the duration of the study.

To thank you for your time, we will mail you movie money that can be used at Empire Theatres at the end of the study. The amount of movie money that will be given is based on your time commitment to the study. Each week of participation would be worth \$10 in movie money. For example, if you complete Week 1 only, you would be given movie money in the amount of \$10. If you complete all 5 weeks, you will receive movie money in the amount of \$50. The movie money will be sent when the study is complete (at the end of 5 weeks).

**Are there any conflicts of interest?**

The primary investigator, Dr. McGrath, will ensure that he is not part of the Research Ethics Board review process, as he is Vice President of Research at the IWK Health Centre. There is no actual, perceived or potential conflict of interest on the part of the researchers and/or institutions.

**How will I be informed of the study results?**

On the signature page (the last page of this form), you may indicate whether or not you would like to receive a summary of the results of this study. If you are interested in receiving the results, they can be sent to you through the mail. Please note that you may not receive results for several months following participation in this study.

**How will my privacy be protected?**

Any information that is learned about you and your family will be kept confidential. You will not be identified in publication of the results.

The telephone calls will be recorded during this study. This includes when you interact with CATHI and/or when you speak with a coach. You are not required to respond to any questions that you are not comfortable answering.

Study staff will listen to your interactions with CATHI. Your signature on this form indicates that you have authorized this. Additionally you should be aware that the law requires us to report any evidence of child abuse or neglect to the appropriate authorities.

All study records and recorded material will be stored in a locked filing cabinet in the Centre for Research and Family Health on the 8<sup>th</sup> floor of the IWK Health Centre. Recorded materials will be stored on secure servers located in the IWK Information Technology Department. The study material will be kept for 7 years after publication of this research as required by the IWK Research Ethics Board. Records may be shown to the granting agency, CIHR, or to the IWK Health Centre Research Ethics Board, in case of an audit.

**What if I have study questions or problems?**

If you have any questions or concerns following your enrolment, you may directly contact the Research Project Administrator, Meredith Whitney. She may be reached by phone: 902-470-6387, Monday to Friday between 8:30am and 4:30pm or by email: Meredith.Whitney@iwk.nshealth.ca.

**What are my research rights?**

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator, or involved institutions from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8765, Monday to Friday between 9am and 5pm.

**To be completed by Family Help Staff:**

Screen ID \_\_\_\_\_  
Study ID \_\_\_\_\_  
Staff (initial) \_\_\_\_\_ Date \_\_\_\_\_

**Study Title: The CATHI Pilot Study: Evaluating the Acceptability of a Voice Recognition System in Children’s Mental Health Care (CIHR Team in Access to Children’s Mental Health Services, Project 3c)**

**Participant Consent**

I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks involved (if any). I understand that I have the right to withdraw from the study at any time without affecting my care in any way. I have received a copy of the Information and Consent Form for future reference. I freely agree to participate in this research study.

*To be completed by participant in consultation with Study Staff by Telephone:*

Name: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**RESEARCH FINDINGS**

Would you like to receive a summary of the research findings once the study is completed?

YES NO

Would you like to be contacted for future studies by Dr. McGrath’s staff?

YES NO

Would you like to have a copy of the Information and Consent Form sent to your:

Family physician Specify name (1): \_\_\_\_\_

Other health care provider: \_\_\_\_\_ Specify name (2): \_\_\_\_\_

Would you like to have a copy of the Progress Report you receive sent to your:

Family physician  Other health care provider: \_\_\_\_\_

*To be completed by Study Staff:*

**STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY**

I have explained the nature and demand of the research study and judge that the participant named above understands the nature and demand of the study.

Name (Print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**STATEMENT BY PERSON OBTAINING CONSENT**

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name (Print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

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