

Understanding impulsivity and motor activity, including self-regulation, in children with and without Attention Deficit Hyperactivity Disorder (ADHD)

A study aimed at supporting better understanding, earlier diagnosis, and more targeted intervention in children with attention and regulation difficulties

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WHAT IS THIS STUDY ABOUT?

Primary purpose of study and rationale

ADHD is one of the most common childhood disorders, present in about 5-10% of school age children. ADHD is characterized by pronounced difficulties with focus, hyperactivity, and impulsivity, all which impact self-regulation. In fact, even children without ADHD can experience difficulties with impulsive behaviours and motor activity, which interfere with their ability to focus, self-regulate, and achieve goals. Children who present with more of these behaviours are often viewed as more 'oppositional' and uncooperative, even those many of these behaviours may be unintentional. Difficulties in these areas pose long-term consequences for children's academic achievement, social success, mental health, and quality of life, and are also challenging for those living with, working with, teaching, and supporting these children. However, despite how common these types of difficulties are and their repercussions, they are poorly understood.

The objectives of this study are to investigate how control and self-regulation of motor behaviours and attention develop during childhood and how this may or may not differ in children with ADHD. Our study will provide a better understanding of impulsivity, focus, motor activity, and self-regulation in children both with and without ADHD. We will also investigate some key indicators of differences in these processes, which may help with early identification of those children most at risk for ongoing problems in these areas to support more timely and targeted intervention.

We feel that the information gained from this study will help us better understand some of the challenges faced by children with attention difficulties, including ADHD, and will potentially lead to earlier diagnosis and more timely and effective interventions, treatments and supports.

WHAT ARE THE BENEFITS AND RISKS OF PARTICIPATING IN THIS STUDY?

Benefits

- This study will provide important practical information about how children with and without attention problems regulate their motor behaviours, informing us about impulsivity, self-regulation and focus.
- The information gained from this study will help with identifying those children most at risk for ongoing attention problems and will potentially help inform the following:
 - Earlier diagnosis
 - More timely interventions
 - Specific treatments and interventions
 - Practical strategies to help manage these behaviours.
- Participating children will have the opportunity to come to the Child Development Lab at the University of Victoria and engage with a University of Victoria research team. Many children enjoy coming to the University, 1:1 interactions with our research team, and participating in this type of project.
- Information from the study will be shared with participating families and schools/districts so that they may benefit from what we learned, with a focus on practical applications of our findings.
- Information from this study will be shared in scientific outlets, both in journals and at conferences, so participants will be contributing to improving science and practice for these children.

Risks

- There are no serious risks anticipated for this study. Of the minor risks possible:
 - Participating in this study will take time on the part of children and families. The time commitment is not onerous and we will schedule the appointments at times that work best for individual children and families, typically weekends.
 - Most children enjoy the tasks, but some children might feel bored or frustrated by some of the tasks. These tasks are no more frustrating than what might be encountered in a regular school day. We have an experienced team, provide frequent breaks, positive behaviour supports, rewards, and debriefs, to mitigate these factors. If a child decides he/she does not want to continue, he/she is able to withdraw at any time without explanation or repercussion and will still receive his/her rewards.
 - Children with ADHD who are taking medication will be asked to refrain from taking their medication for 48 hours before coming in for the study. This is a typical procedure in this type of study and many parents of children with ADHD regularly give their children 'medication holidays' on weekends and at times where optimal focus is not required. This criteria will be discussed carefully with parents who are interested in participating. If this is a concern for the family or child, or problematic based on the type of medication, they would not be asked to participate.
 - Some children may not be eligible to participate in this study by virtue of having other types of diagnoses. If this is disappointing for them and/or their family, we will give them the opportunity to leave their name so they can be contacted for participation in future studies, if they wish.
 - We are not able, due to our ethics requirements, to provide families with individualized information about their child's ADHD status or performance, although we will share overall study findings. Families concerned about their child's ADHD status and its management will be referred back to their GP or mental health practitioner. It will be clear to families from the start that we are not able to provide individualized information and the reasons why.

WHAT WILL BE ASKED OF US SHOULD WE CHOOSE TO PARTICIPATE?

Roles and Responsibilities

Children

- Children are required to provide consent before participating in the study. Full informed consent will be taken when they come in to participate.
- Participating children will spend 2-2.5 hours at the University of Victoria Child Development Lab, completing a variety of paper-and-pencil and computerized tasks.
- Children will be asked to give activities their best try, but will be assured that there is no pass or fail for these activities.

Parents

- Parents who would like their child to participate will be asked to complete a screening interview to determine their child's eligibility.
- Parents will be required to sign consent before their child can participate.
- Parents will be asked to bring their child into the Child Development Lab at the University of Victoria at a scheduled time that is convenient for them.
- Parents will be asked to complete two behavioural rating scales, a brief history form, and a short interview about their child's attention and behaviour. This is typically done when they bring their child into the Child Development lab, but can be done at other times based on the family's preference.

School District

- We will ask participating schools to hand out flyers and a 'consent to be contacted' forms to potentially eligible families (this includes children ages 6-13 years, who have undiagnosed attention problems, a diagnosis of ADHD, and children who have no diagnoses/designations). Forms may be distributed by classroom teachers, LS/IS teachers or administrators, based on what works best for the school.
- Parents have the option of giving 2 behavioural rating scales to their child's Classroom Teacher. Teachers have the option to complete these forms and mail back to us, or not. Form completion is entirely voluntary, although teacher perspectives are very valuable in informing this type of research.

Research Team

- Our research team is responsible for all aspects of this study, with the exception of disseminating information and possibly collecting 'consent to be contacted' forms.
- Trained UVic students under the direct supervision of Dr. Macoun and her senior Clinical Psychology students will contact interested families, conduct screening interviews, and schedule appointment times at the Child Development Lab.
- Trained UVic students under direct supervision will meet with parents and children at the Child Development Lab at their scheduled appointment time. They will then conduct interviews with parents, will support them in completing rating scales, and will conduct the activities with the children.
- Any follow-up or debriefing required with individual families will be done by the research team.
- The research team will provide summaries of study results to families/children and participating schools/districts. This will be done in the format that is requested and may include written documentation, formal presentations/talks, or informal meetings.

WHO ARE WE?

The research team

Dr. Macoun's research team consists of two senior PhD students in Clinical Psychology, a Master's student in Clinical Psychology, and several trained undergraduate psychology students, many of who intend to go on to become psychology practitioners and who already work with children. Dr. Macoun works out of the Child Development Lab at the University of Victoria, which has specifically been established for working with children and their families.

The Child Development Lab, led by Dr.'s Sarah Macoun and Ulrich Mueller, is located in the Cornett Building at the University of Victoria. Out of this lab we conduct applied research with children ranging in ages from preschool to late adolescence. Our research and research teams are focused on better understanding children and their development, including children who do and who do not have developmental difficulties. We have a collaborative and community-based approach and actively partner with children, families, and community to conduct research that is practical and relevant.

Dr. Macoun is a Ph.D. level psychologist with a faculty appointment at the University of Victoria in the Psychology Department. Dr. Macoun has been a Registered Psychologist in the province of B.C. since 2003 and is trained in Clinical Psychology, with a speciality in pediatric neuropsychology. She has extensive experience working with children with neurodevelopmental disorders, particularly those with attention and self-regulation problems, including children with ADHD, ASD, FASD, and Learning Disorders. She has particularly clinical and research expertise with ADHD and Autism Spectrum Disorders and with rehabilitation of attention, executive function, and regulation difficulties. Prior to her appointment at the University of Victoria, Dr. Macoun worked as a practicing psychologist within schools and has over 15 years of practical experience working with children and their families, school teams, and community teams/ agencies. She continues to engage in consultation with families and schools, and is heavily involved in training and supervision of new psychology professionals. Her research is applied with a primary focus on practical applications in real-world contexts. As the primary investigator and team lead, Dr. Macoun is responsible for directly overseeing all aspects of this project.

Drew Halliday is a Ph.D. graduate student, within the Clinical Psychology Department, who has extensive training working with child and adolescent populations, including children with neurodevelopmental conditions. Mr. Halliday has been administering a wide range of standardized tests to children, adolescents and adults for over five years, at practicum sites and in other research laboratories in Canada and the UK. Mr. Halliday has additional training in applied behaviour analysis therapy and has worked with children with complex behavioural needs. As a Ph.D. lead, Mr. Halliday is involved in all aspects of this project, including supervision and training.

Sheliza Ali is a Ph.D. graduate student on this team, within the Clinical Psychology Department. Ms. Ali has training in neuropsychological assessment and is currently completing her final practicum at the Queen Alexandra Center for Children's Health where she works with children with a wide range of neurological and neurodevelopmental conditions. She has also worked with children and adolescents in therapy settings providing one-on-one and group therapy. Ms. Ali is an international student and has an additional interest in cross-cultural applications of neuropsychological assessments and research findings. As a Ph.D. lead, Ms. Ali is involved in all aspects of this project, including supervision and training.

Amie Kim is a recent graduate from UVic Psychology Honours Program, whose research interest lies along the line of neurodevelopmental disorders in children, including ASD and ADHD. Her experiences with children, both typical and with special needs, are diverse. She is applying for graduate studies in clinical psychology this year. Meanwhile, she works as a support worker for a child on the spectrum and volunteers at different sites involving children with special needs. As a study manager of the project, she is responsible for both administrative and testing duties.

IS THERE ANY COMPENSATION FOR PARTICIPATING?

- Small monetary rewards and prizes will be provided to thank children and families for their time.
- These rewards/prizes have been approved by UVIC Human Ethics Committee, to ensure that they are not 'coercive' in nature (i.e., not of a size to convince families, who would otherwise choose not to participate, to participate).
- The goal of the incentives is to reward children and thank them for their hard work, and to compensate families for some of their time and expenses.

Incentives and compensation for parents

- Parents will be reimbursed for their cost of parking at the University of Victoria.
- Parents will be provided with \$10.00 for completing behavioural rating scales.

Incentives and compensation for children

- Children will be provided with \$10.00 for participating.
- Children will be provided with small prizes (approximately \$5.00 value) during testing.
- Children will be entered into an iPad mini raffle, to be drawn at the end of the study.

Note: should a child choose to withdraw part way through the study he/she will still receive his/her rewards

Incentives and compensation for teachers

- Should a teacher choose to complete behavioural rating scales for a participating child, we will thank the teacher with a \$5.00 coffee card upon receipt of forms.

WHAT ARE THIS STUDY'S PROCEDURES AND TIMELINES?

Broad study timeline

- This study started in July 2017 and we are currently seeing participants at the Child Development Lab. Our ideal is to complete this study by December, 2017.
- However, the study will run until we have a sufficient number of participants (we require a minimum of 30 children with ADHD, 30 children with attention problems (not with ADHD), and 30 children without attention difficulties). Our goal is to find enough participants to make our findings valid and relevant to a broad range of children.

Study procedures and measures: children

Child participants will be seen at the University of Victoria Child Development Lab, individually, over a 2-2.5 (maximum 3) hour duration. Appointments will be scheduled at a time that does not interfere with the child's activities or schooling, based on parent preference (typically weekends).

Participation time will depend on the individual child and the number of breaks he/she requires, but will not exceed 3 hours (currently we are finding participation time is about 2.5 hours).

Informed consent will be reviewed and confirmed with parents and children at the start of the appointment.

Children will be asked to complete a mix of paper-and-pencil, hands-on, and computerized tasks that look at verbal/nonverbal problem solving, focus, impulsivity, drawing, and fine motor control. All tasks are specifically designed for children, have no pass or fail, and will be administered by experienced examiners.

Study procedures and measures: Parents

Parents will be contacted by email/telephone for a brief screening interview and to schedule an appointment for their child at the Child Development Lab.

During their child's appointment time, parents will be given the option to complete behavioural rating scales, a brief history questionnaire, and an interview about attention.

Should it not be convenient for the parent to complete the rating scales or the interview during their child's appointment, they may complete the forms or interview at a later time.

Behaviour rating scales and parent interviews will ask about attention, activity levels, general behaviour, and self-regulation. We will also ask parents for some brief demographic information.

Study procedures and measures: Teachers

Parents will be given the option of giving two behavioural rating scales to their child's teacher, along with a self-addressed and stamped envelope.

Behaviour rating scales will ask about attention, activity levels, and general behaviour and will take approximately 20 minutes to complete.

These rating scales are voluntary. The decision to give teachers a self-addressed/stamped envelope is so that they may complete/return the forms directly to us if they choose, minimizing any pressure for them to complete forms.

Appendix 1 – Cover letter to send home to families

SCHOOL DISTRICT LETTERHEAD

Dear families,

We are providing the following information to inform you of a new opportunity at the University of Victoria, conducted through the Psychology (Dr. Macoun) Department. Your child might be eligible to participate in this opportunity. Attached you will find more information.

Please note that Dr. Macoun, her research team, and the University of Victoria do not have any personal information about you or your child. We are disseminating this information on behalf of the university research team, simply to inform you of the study. Please note that not all interested families may be eligible to participate, and that a brief telephone interview will be conducted to determine eligibility.

Should you be interested in participating, please review the attached letter, which contains specific information about the study, how to contact Dr. Macoun and how to indicate your interest. If you have more questions please feel free to contact Dr. Macoun at 250-721-7534 or sjmacoun@uvic.ca

Sincerely,

XX School District

Appendix 2- Invitation to participate and consent to be contacted (to be provided to schools to send to parents along with part 1)



Faculty of Social Sciences | Department of Psychology
Cornett Building, Room A236, PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
T 250-721-7534 | F 250-721-8929 | sjmacoun.uvic.ca

***WOULD YOUR CHILD LIKE TO PARTICIPATE IN
A STUDY AT THE UNIVERSITY OF VICTORIA?***

ENTITLED:

Understanding impulsivity and motor activity in children with and without ADHD

Many children experience difficulties with impulsive behaviours, which interfere with their ability to focus, self-regulate, and achieve goals, particularly those with attention difficulties. Despite how common these types of difficulties are, they are poorly understood.

We are seeking children, ages 6 to 13 years with a diagnosis of ADHD, and children who do not have ADHD or any other known neurological or learning difficulties. Our study will provide a better understanding of impulsivity and self-regulation in children both with and without ADHD. We feel that the information gained from this study will help us better understand some of the challenges faced by children with ADHD, and to provide more effective services/treatment for these children.

This study has been approved by the University of Victoria and is being conducted through the Psychology Department at the University of Victoria. For children who participate in this study, we will be collecting information on their abilities at the university. Parents/caregivers will also be asked to fill out several forms related to their child's behaviours and to complete a brief interview to discuss their child's diagnoses, where relevant. Parents/caregivers may also choose to provide their child's teacher with optional forms regarding attention and behaviours at school. During the study, children will be asked to complete some paper and pencil and computerized tasks assessing attention, concentration and motor abilities. These tasks will take approximately 2.5 hours, but we will provide breaks! Prior to participating, children will also be asked to consent to their participation in the study. Many children enjoy these kinds of tasks and find participating in such studies interesting. Children will need to refrain from taking their ADHD medications for 48 hours prior to study participation, but can start taking their medication again immediately upon finishing the testing session.

All personal and identifying information regarding your child's participation will be kept confidential; only those directly involved in the study will know of the details of the study and your child's participation. At the end of the study, study results will be shared with families and participating organizations, so that you all may benefit from information gained through their participation. However, your child's individual results from this study will not be shared or made available.

Primary risks and considerations for participation include the time commitment, potential fatigue and inconvenience of refraining from medication for 48-hours. In appreciation for your participation in the study, you and your child will receive small monetary 'thank you' gift following the assessment. Your child will receive \$10.00 for his/her participation, small motivational prizes, and will be entered into a draw to win an iPad mini. Should your child decide he/she wishes not to participate part way through the activities, he/she will receive his/her reward for the day and will be entered into the iPad draw and he/she will not be required to participate any further in the study. You will receive \$10.00 for your time completing forms and you will be reimbursed your cost of parking at the University. Testing times are flexible, and

we will work with you to find a time that works for you.

Should you be interested in participating, please provide your contact information and signature below and return to _____ so that we have permission to contact you. Alternately, you may contact Dr. Sarah Macoun, Assistant Professor, Psychology Department at macounlab@uvic.ca (250-472-4195) for more information.

Thank you for taking the time to consider this opportunity. We look forward to speaking with you!

Parent Name _____ Telephone number _____

Email _____

By signing below, I give Dr. Sarah Macoun's research team at the University of Victoria permission to contact me to discuss this opportunity

Signature

Date

Appendix 3- Parent Full Consent form (to be completed with research team upon study participation)

Faculty of Social Sciences | Department of Psychology



Cornett Building, Room A236, PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
250-721-7534 | F 250-721-8929 | sjmacoun@uvic.ca

Understanding Impulsivity and Motor Activity in Children with and without ADHD

You and your child are invited to participate in a study entitled Understanding Impulsivity and Motor Activity in Children with and without ADHD. The study is being conducted by Dr. Sarah Macoun (Psychology Department), at the University of Victoria. Dr. Macoun is a Registered Psychologist in B.C. with a specialty in child neuropsychology.

Many children experience difficulties with impulsive behaviours and motor activity levels, which interfere with their ability to focus, self-regulate, and achieve goals, particularly those with attention difficulties. The purpose of this study is to provide a better understanding of impulsivity and motor activity develop in children both with and without ADHD. We feel that the information gained from this study will help us better understand some of the challenges faced by children with ADHD, and to provide more effective services and interventions.

During the study, your child will be asked to complete several paper-pencil and computerized tasks examining attention, concentration and motor abilities. Children will also complete a brief screening of general ability. Most children do not find the tasks any more stressful or frustrating than the regular types of activities that they engage in at school. Your child will need to refrain from taking his/her medication for ADHD for 48 hours prior to study participation, given that this type of medication has a direct effect on the abilities we are studying. Your child may start taking their medication again, immediately following the testing session. These activities will take approximately 2 hours and breaks will be provided. You will also be asked to complete several forms to provide information about your child and will be asked to participate in a brief interview to discuss your child's diagnoses, if this is relevant. You may find that reflecting on your child's history and abilities through your participation brings about feelings of discomfort and we welcome you to consider this prior to participation.

In appreciation for your participation in the study, you and your child will receive small 'thank you' gifts. You will receive \$10 for completing the forms. Your child will receive \$10, a small dollar store type prize (approximately \$5.00 value), and will be entered into a draw to win an iPad mini. You will be compensated for the cost of parking at the University of Victoria. It is important for you to know that it is unethical for us to provide undue compensation or inducements to research participants; if you agree to participate in this study, the compensation discussed above should not be your only reason for participating.

Your child will be asked to sign a consent or assent form indicating his or her willingness to participate in this project. If you and your child agree to participate, you may also choose to involve your child's teacher and to ask him/her to complete questionnaires regarding your child's attention and behaviour at school. It is important for you to know that this is voluntary for you and for your child's teacher, and that you will be provided with a return envelope to give to your child's teacher so that he/she may return the forms independently if he/she chooses to complete them. Should you wish your child to participate but your child does not wish to participate in the study, he/she will not be required to participate in the study.

Participation is entirely voluntary. You or your child may withdraw at any time from this study, without explanation, with the option of having all relevant data destroyed. You also have the option of allowing us to use the data collected to that point. Primary risks and considerations for participation include the time commitment, potential fatigue and inconvenience of refraining from medication for 48-hours.

Participant's anonymity will be guaranteed by using code numbers, rather than names, to identify the obtained results. Raw data (e.g., filled-out questionnaires, paper and pencil tasks, etc.) will be kept in a locked filing cabinet within Dr. Macoun's locked research office at the University of Victoria. Only Dr. Macoun and direct members of the research team will have access to raw data. The key linking code numbers with individual participants will be stored in a password-protected data file, and will be deleted one year following completion of data analysis. The principal investigator will shred original paperwork five years following completion of the study. Anonymous data will be stored in a password-protected computer file indefinitely. The information gathered from this research project may be used for publication (such as in a journal or at a scholarly meeting) now or in

the future. Individual names or identifying information will not be included in any of the information gathered in this project. You will receive a written summary of the findings about 3 months following completion of the study. The summary will share overall results of the study, but your child's individual results will not be made available. We are not able to offer diagnoses or diagnostic information within the context of this study as we are not doing full diagnostic assessments.

Data from this study may be used in the future to compare to results from children with other developmental conditions. Again, your child's data would remain anonymous and all analyses would be conducted on the clinical group's performance and not your individual child's results. Please initial here if you consent to future use of your child's data for purposes such as these: _____
(initial)

You may contact Dr. Macoun at 250-721-7534 (sjmacoun@uvic.ca) if you have any questions or concerns at any point during the project. In addition, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria (250-472-4545).

Your signature below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers.

Name of Child/Youth Participant

Parent Signature

Date

Name of Parent

Telephone Number

Appendix 4- Child Full Consent form (to be completed with research team upon study participation)

Faculty of Social Sciences | Department of Psychology



Cornett Building, Room A236, PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
250-721-7534 | F 250-721-8929 | sjmacoun@uvic.ca

CHILD CONSENT

We would like to ask if you'd like to be part a research study called Understanding Attention and Behaviour in Children. This project is being done by Dr. Sarah Macoun who works at the University of Victoria. We want to find out how our attention and behaviour changes as we get older and how it might be different in different types of kids. Some kids might have a harder time paying attention and staying focused and we want to understand why this might be so that we can help them to focus better. What we are asking you to do today is to try some different tasks that will take about 2 hours in total. Some of them will be on a computer and some of them will be more like school work where you'll use a pencil. We will work for a bit, take a break, then do some more work!

On all these tasks, we just ask you to try your best because they can be hard! There is no pass or fail and all that matters is that you try your best. As part of the study, we will also ask your parent(s) some questions we may ask your teacher some questions, to find out more about you.

To thank you for doing this and trying your hardest we will give you a \$10 prize, because we know it will be a lot of thinking and some hard work! Also, your name will be put in a draw for an iPad mini, along with other kids who participants and we will pick one name out of a hat and then that kid will get the iPad. There will be about 60 kids in total.

If once we get started, you no longer want to do it, you can stop. You would not be in trouble with anybody, you would still get to keep your prize and your name would still go into the draw.

If you say yes, this means that you understood all the stuff about the study and that we answered all of your questions and that you still want to be in the study.

Name of Child Participant

*Child Signature or Examiner's signature
(for assent)*

Date

Witness

Appendix 5: University of Victoria Human Ethics Approval



Office of Research Services | Human Research Ethics Board
Administrative Services Building Rm B202 PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
T 250-472-4545 | F 250-721-8960 | uvic.ca/research | ethics@uvic.ca

Certificate of Approval

PRINCIPAL INVESTIGATOR: Sarah Macoun	ETHICS PROTOCOL NUMBER: 17-184 Minimal Risk Review - Board members
UVic STATUS: Faculty	ORIGINAL APPROVAL DATE: 15-Jun-17
UVic DEPARTMENT: PSYC	APPROVED ON: 15-Jun-17
	APPROVAL EXPIRY DATE: 14-Jun-18
PROJECT TITLE: Understanding Impulsivity and Motor Activity in Children with and without ADHD	
RESEARCH TEAM MEMBER Co-investigator: Stuart MacDonald (UVic); Student Co-investigator: Drew Halliday (UVic)	
DECLARED PROJECT FUNDING: None	
CONDITIONS OF APPROVAL	
This Certificate of Approval is valid for the above term provided there is no change in the protocol.	
Modifications To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.	
Renewals Your ethics approval must be current for the period during which you are recruiting participants or collecting data. To renew your protocol, please submit a "Request for Renewal" form before the expiry date on your certificate. You will be sent an emailed reminder prompting you to renew your protocol about six weeks before your expiry date.	
Project Closures When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.	
Certification	
This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.	
 _____ Dr. Rachael Scarth Associate Vice-President Research Operations	

Certificate Issued On: 15-Jun-17

