

This research is being carried out in partial fulfilment of a Research Masters Degree via La Trobe University, under the supervision of Professor Leeanne Carey & Anoo Bhopti. The following researchers will be conducting the study:		
Role	Name	Organisation
Chief Investigator	Professor Leeanne Carey	La Trobe University
Student Researcher	Leiemma Canty	Invermay Allied Health & La Trobe University
Associate Investigator	Anoo Bhopti	La Trobe University
This research is supported by in kind support by La Trobe University.		

1. What is the study about?

This is an invitation for your child to take part in a study. The study is about children with attention deficit hyperactivity disorder (ADHD) who may also have a Development Coordination Disorder (DCD). Some children with DCD may experience anxiety and depression. We hope this study will help us understand if an occupational therapy approach to screen for and then treat DCD in children with ADHD reduces these symptoms if they so occur.

2. Does my child have to participate?

Being part of this study is voluntary. We ask that you discuss the study with your child when you are deciding if you want your child to take part. If you decide together for your child to be part of the study, we ask that you read this information carefully and ask us any questions.

If you decide together you do not want your child to take part this won't affect the treatment your child is currently receiving. This decision also won't affect your relationship with La Trobe University or any other listed organisation. You can read the information below and decide at the end if you do not want your child to take part.

3. Who is being asked to participate?

Your child has been asked to participate because they:

- have a diagnosis of ADHD and are aged 8-12 years
- have no other pre-existing motor disorder
- receive medication as one form of treatment for their ADHD
- are currently seeing a Paediatrician at least six monthly
- can participate in the occupational therapy program (this means your child can attend and understand the strategies to be used in this study)
- live in Northern Tasmania.

4. What will my child be asked to do?

There are two parts to this study. If your child wants to take part in this study, we will ask you and your child to complete the following:

A/ First face-to-face visit (1-1.5 hours, at Invermay Allied Health)

- Parent/Guardian to discuss the project and provide informed consent.
- Parent/Guardian to bring past medical, allied health, school reports and any other information you wish to share.
- Parent/Guardian and child to complete screening checklist which looks at developmental history, current daily living skills and a clinical examination of muscle tone and joint mobility.
- Parent/Guardian to complete Developmental Coordination Disorder Questionnaire 2007 (DCDQ'07) which is a brief parent questionnaire designed to screen for coordination disorders in children.
- Your child will be asked to complete an assessment of their fine and gross motor skills during the initial assessment – the Bruininks-Oseretsky Test of Motor Proficiency 2nd Ed. (BOT-2).
- We will ask for your consent to contact your Paediatrician to provide medical and health information as part of your child's participation in the study.

These tests will be used to confirm if your child has a Development Coordination Disorder (DCD). If they do, you may be invited to join in occupational therapy training over the next 28 weeks. If you agree to participate you and your child will be asked to:

B/ Occupational Therapy Intervention (up to 28 weeks)

- **Assessment & Goal Setting (weeks 1-4, once per week, 1.5hrs face-to-face 1st session and then five minute weekly phone calls):** Your child will participate in one additional face-to-face assessment session of 1-1.5 hours where a further three assessments will be completed. Assessments will focus on current activity participation, anxiety and/or depressive symptoms, plus goal setting, and will occur over four weeks.
- **OT Intervention (weeks 5-20, twice a week, a 30 minute face-to-face session then a five minute phone call):** At the nominated clinical practice, use of an intervention known as the CO-OP Approach will be conducted. This is an intervention program focused on learning new skills and tasks identified by you and your child. CO-OP is a problem-solving method to improving motor skills. Three motor skills will be selected by you and your child, with one to two goals focused on at a time over the 10-15 weeks. We will video tape components of the weekly CO-OP sessions and call you every week for 5 minutes to discuss your goals.
- **Home Practice (weeks 5-20, four times a week, 10 minutes per goal):** You and your child will need to complete brief practice of tasks at home.
- **Follow-up (weeks 24 & 28, five minute phone calls):** We will call you 4 and 8 weeks after the OT intervention has finished to monitor your progress.

The table below is to you understand the tasks and time commitment:

	Assessment/task	Screening Time for Study A Time: 1.5 hours	Assessment & Goal Setting for Study B Weeks 1-4 Time: 1.5 hours	OT Intervention Weeks 5-20 Time: 30 minute face-to-face session & 5 minute phone call	Follow-up 4 & 8 weeks post-intervention Weeks 24 & 28 Time: 5 minute phone call
Study procedures	Informed consent	x			
	Screening checklist	x			
	DCDQ'07	x			
	BOT-2	x			
	Medical Information from Paediatrician	x			
	Assessment and Setting Participant Goals		x		
	Occupational Therapy Intervention			x (twice per week: 1 st session face to face; 2 nd session via phone)	
	Home practice			x (four times per week, 10 minutes per goal)	
	Follow-up phone-call				x

5. What are the benefits?

The benefit of your child taking part in this study is you should see an improvement in your child's overall performance skills and added benefits to their physical and mental health.

6. What are the risks?

With any study there are (1) risks we know about, (2) risks we don't know about, and (3) risks we don't expect.

We have listed the risks we know about below. This will help you decide if you want your child to be part of the study.

- possible discomfort in the form of physical exertion during the motor skill assessment or mild frustration at completion of some of the tasks.
- we may pick-up your child has underlying symptoms of anxiety and/or depression

We will work with you to refer your child to any health professionals that may assist you with any of the risks stated above or you are free to withdraw at any time.

If your child experiences something that you aren't sure about, please contact us immediately so we can discuss the best way to manage your concerns.

Name/Organisation	Position	Telephone	Email
Leiemma Canty Invermay Allied Health	Occupational Therapist; Onsite Student Researcher	0478 613 593 (work mobile)	leiemmacanty.ot@gmail.com
Anoo Bhopti	Occupational Therapist	+61 3 9479 5667	a.bhopti@latrobe.edu.au

7. Will we be paid to be part of this study?

There will be no reimbursements and minimal cost, which include the travel expenses incurred for you and your child to be part of this study and the expectation the family will supply most of the equipment for child goals as per the CO-OP Approach standard practice ie. if the child wishes to learn how to tie their shoelaces, their own shoes with laces are brought in from home. This ensures equipment is familiar and remains with the child at the end of the intervention for continued use and practice in the long term.

8. What will happen to information about me?

We will collect and store information about your child in ways that only we will know who your child is. Any information that reveals your child's identity will be kept confidential, and will only be disclosed with your permission, unless we are required by law to reveal this information. The Human Research Ethics Committee, monitors and regulatory bodies may also access information about your child, if possible, these people will not know who your child is.

The way we store and find out the results of the study means your child cannot be identified in any type of publication from this study.

With your consent below, data from this research project may potentially be used for other studies. Separate ethics approval will be sought for any future projects. We will keep your child's information for 7 years after the project is completed. After this time, we will destroy all of your child's data. If you consent to extended or future use of this data,

We will collect, store and destroy your child's data in accordance with La Trobe Universities Research Data Management Policy which can be viewed online using the following link:

<https://policies.latrobe.edu.au/document/view.php?id=106/>.

The information you and your child provide is personal information for the purposes of the relevant privacy legislation. You and your child have the right to access personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the Information Privacy Act.

9. Will I hear about the results of the study?

We will let you know about the results of the study by email if you wish in a format suitable for both parents and children. Group results will be released with de-identified data.

10. What if I change my mind?

At any time you or your child can choose to no longer be part of the study. You can let us know by:

1. Completing the 'Withdrawal of Consent Form' (provided at the end of this document);
2. Calling us;
3. Emailing us

Your or your child's decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

When you withdraw we will stop asking you for information. Any identifiable information about your child will be withdrawn from the research study. However, once the results have been analysed we can only withdraw information, such as your child's name and contact details. If results haven't been analysed you can choose if we use those results or not.

11. Who can I contact for questions or want more information?

If you would like to speak to us, please use the contact details below:

Name/Organisation	Position	Telephone	Email
Leiemma Canty Invermay Allied Health	Occupational Therapist; Onsite Student Researcher	0478 613 593 (work mobile)	leiemmacanty.ot@gmail.com
Leeanne Carey La Trobe University	Professor in Occupational Therapy – Discipline Lead	+613 9479 5600	L.Carey@latrobe.edu.au

12. What if I have a complaint?

If you have a complaint about any part of this study, please contact:

Ethics Reference Number	Position	Telephone	Email
HEC18239	Senior Research Ethics Officer	+613 9479 1443	humanethics@latrobe.edu.au

Consent Form – Declaration by Participant

I (the parent/guardian) have read (or, where appropriate, have had read to me) and understood the parent/guardian information statement, and any questions have been answered to my satisfaction. I understand I am being asked to provide consent for my child to be part of this study. I agree for my child to participate in the study, I know either myself or my child can withdraw at any time. I agree information provided by my child or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that my child cannot be identified.

I give permission for my child’s doctors, health professionals, hospitals and/or laboratories to release information concerning my child’s health and treatment for the purposes of this study. I understand this information will remain confidential.

I would like my child’s information collected for this research study to be:

- Only used for this specific study;
 Used for future related studies;
 Used for any future studies.

Parent/Guardian Signature

- I have received a signed copy of the Parent/Guardian Information Statement to keep
 If appropriate - I have discussed the study with my child and through these discussions they have shown to me they want to be part of the study.

Parent/Guardian printed name	
Parent/Guardian signature	
Date	

Declaration by Researcher

- I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;
 I am a person qualified to explain the study, the risks and answer questions

Researcher’s printed name	
Researcher’s signature	
Date	

* All parties must sign and date their own signature

Withdrawal of Consent

I wish to withdraw my consent for my child to participate in this study. I understand withdrawal will not affect my or my child's relationship with La Trobe University or any other organisation or professionals listed in the Participant Information Statement. I understand my child's information will be withdrawn as outlined below:

I understand my information will be withdrawn as outlined below:

- ✓ Any identifiable information about my child will be withdrawn from the study
- ✓ The researchers will withdraw my contact details and my child's contact details so we cannot be contacted by them in the future.

I would like my child's already collected and unanalysed data

- Destroyed and not used for any analysis
 Used for analysis

Parent/Guardian Signature

Parent/Guardian printed name	
Parent/Guardian signature	
Date	

Please forward this form to:

CI Name	Professor Leeanne Carey
Email	L.Carey@latrobe.edu.au
Phone	613 9479 5600
Postal Address	School of Allied Health, College of Science Health & Engineering, La Trobe University, Victoria, 3086