Faculty of Medicine, Health and Human Sciences



Participant Information and Consent Form

Project Title: Cognitive-Behavioural Therapy for Adolescent Body Dysmorphic

Disorder

Protocol Number: 52021948928846

Student Investigator: Cassie Lavell

Email: cassie.lavell@students.mq.edu.au

Research Supervisors: Distinguished Professor Ron Rapee

Email: ron.rapee@mq.edu.au

Dr Ella Oar

Email: ella.oar@mq.edu.au

1. What is the purpose of the study?

This study seeks to examine the effectiveness of a new treatment for body dysmorphic disorder (BDD) in adolescents (ages 12 to 17 years). BDD refers to a preoccupation with perceived "flaws" in physical appearance. BDD causes significant distress, therefore it is important to develop effective treatment approaches. All adolescents who participate in this study will receive assessment and treatment for their BDD.

2. Who is conducting the study?

The study is being conducted by PhD candidate Cassie Lavell, whose research is supervised by Prof. Ron Rapee and Dr Ella Oar within Centre for Emotional Health, Department of Psychology, Macquarie University.

3. What does participation in the study involve?

Participation in this treatment study involves:

A thorough diagnostic assessment of BDD and other emotional problems via videoconference with a registered psychologist. This diagnostic assessment will determine your child's eligibility for the study. Following this online assessment, should your child be eligible, your child symptoms will then be monitored weekly via brief online questionnaires for either 1, 2 or 3 weeks (this will be randomly assigned like the flip of a coin).

You and your child will then participate in 12 weekly sessions (90mins each) of cognitive behaviour therapy (CBT) for their BDD, including exposure with response prevention (ERP), which is an evidence-based treatment shown to be effective in adolescents and adults with BDD.

Following treatment, you and your child will participate follow-up assessments 1-week after treatment, and again 2-months later. You and your child will also be asked to complete online questionnaires before and after treatment.

All treatment sessions will be conducted with the student investigator Cassie Lavell who is a trained clinical psychologist. Post-treatment assessment sessions will be completed by psychologists with general or provisional registration, under the supervision of experienced clinical psychologists.

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Study outline:

Session	Duration	Location
Pre-Assessment	2 hours	Videoconference (Zoom)
Baseline Symptom Monitoring for 1 week, 2 weeks or 3 weeks	10 minutes per week	Online Questionnaires
Treatment 1 – Education	1.5 hours	Videoconference (Zoom)
Treatment 2-11 – ERP	1.5 hours each	Videoconference (Zoom)
Treatment 12 – Relapse Prevention	1.5 hours	Videoconference (Zoom)
1-Week Post-Treatment Assessment	2 hours	Phone + Online Questionnaires
2-Months Post-Treatment Assessment	2 hours	Phone + Online Questionnaires

Please note that because sessions are conducted via videoconference, internet connection problems may interrupt your child's treatment session. If during your child's session the internet connection becomes frozen or drops out, our team will contact you via telephone. If we are unable to restore a secure internet connection, we will either continue the session via phone or reschedule your appointment for another time and/or location with a more secure connection.

4. Participation is voluntary

Your and your child's participation in this study is voluntary and neither you, nor your child is under any obligation to consent to participate in this research. Non-participation will not involve any penalty or affect any future involvement with Macquarie University and the Centre for Emotional Health or Department of Psychology. If you choose to allow your child to participate, he/she may discontinue participation at any time without penalty or without providing an explanation.

Your child may be removed from the study without your consent if:

- Your child does not qualify to be in the study because he/she does not meet the study requirements. Ask the Investigator if you would like more information about this.
- The investigator decides that continuing in the study would be harmful to your child.
- Study assessments have a bad effect on your child.
- The study is cancelled and/or other administrative reasons.

Should you wish to withdraw at any time, or if your child is not eligible to participate, we will provide you with details for other psychological assessment and/or treatment options, should you desire. For example, support for children, adolescents and their parents, for wide range of psychological problems, can be sought from:

Macquarie University Psychology Clinic 02 9850 8000

Find a Psychologist (APS)
 www.psychology.org.au/Find-a-Psychologist

Headspace
 www.headspace.org.au

CYMHS QLD 07 3310 9444
 NSW CAMHS 1800 011 511
 South Australia CAMHS 1300 222 647
 Western Australia CAMHS 08 6389 5800
 Tasmania CAMHS 1800 332 388

Victoria CAMHS www.health.vic.gov.au/mentalhealthservices/child

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Treatment services specifically for body image and anxiety problems in adults, children, adolescents, and parents can be sought from:

•	Centre for Emotional Health Clinic (Sydney)	02 9850 8711
•	BDD and Body Image Clinic (Sydney)	0431 136 523
•	Anxiety House (Brisbane)	07 3399 9480
•	The Moore Centre (Brisbane)	0468 446 030
•	The Talbot Centre (NSW)	02 8814 5703
•	Children's Centre for Anxiety & OCD (Gold Coast)	0444 576 966
•	Dr Ben Buchanan – Foundation Psychology (VIC)	03 9039 2177
•	Lawson Clinical Psychology (Perth)	08 6143 4499
•	Melbourne Wellbeing Group (VIC)	03 9882 8874
•	The Butterfly Foundation	https://butterfly.org.au/

If you become concerned about your child's safety at any time, please see below for mental health crisis numbers in each state:

•	Australian Capital Territory	1800 629 354
•	New South Wales	1800 011 511
•	Queensland	1300 642 255
•	Northern Territory	1800 682 288
•	South Australia	13 14 65
•	Western Australia	1800 676 822
•	Tasmania	1800 332 388

Victoria http://www.health.vic.gov.au/mentalhealthservices/child/index.htm

(Please see website for contact details for VIC emergency mental health services in your area)

5. Video/Audio Taping

All study appointments will be audio recorded for research purposes via videoconference software Zoom (https://zoom.us/). Audio files will be stored on a password-protected university storage drive. Recordings will only be reviewed by the research team and will be deleted at the completion of the trial.

6. What are the possible benefits of taking part?

Your child will receive treatment for body dysmorphic disorder. Although we cannot guarantee your child will have a positive outcome from this study, the treatment used in this research has helped adults and adolescents with BDD before.

Participation in the study will also help to improve our understanding of treatments for body dysmorphic disorder in adolescents.

To thank you for your participation, you will receive a gift voucher of \$30 after completing **both** the post-treatment and the 2-month follow-up appointments.

7. What are the risks of taking part in this research?

Participation in this study may make you and/or your child feel uncomfortable or distressed when they are discussing their worries, fears or problems. ERP (the core treatment component of this study) involves gradually facing fears in a slow and controlled way, which may cause your child to

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experience temporary anxiety. However, this anxiety is only short-term, and ERP is an effective treatment for BDD and related disorders.

Furthermore, all assessments and treatment sessions are conducted in a safe environment with a trained clinical psychologist. Children do not have to answer any questions or discuss any topics that make you feel uneasy nor will they ever be asked to do anything they are not prepared to do.

Your participation will take up time, as well as the use of your home internet and computer at your own cost.

8. What will happen when the study ends?

A summary of the overall research findings will be posted on the Macquarie University Centre for Emotional Health Facebook page. If you would like information in your child's individual results, you will be welcome to contact the research team via email.

9. What will happen to the information collected about me?

All data from this study will be kept <u>confidential</u>. Any identifying information will be removed and replaced with numerical codes only. The data collected from this research will be reported in general terms only and will not involve identifying information about children who participated.

In some cases, data collected as part of this study may be shared with other researchers. With your consent we would like to keep your data for the purposes of future, unspecified research projects. Any research that will be conducted using your data will be approved by a Human Research Ethics Committee, conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007) and only deidentified information would be shared.

For more information about the privacy of you and your child's data, please refer to the university's privacy policy: https://www.mq.edu.au/about/about-the-university/governance/privacy.

10. Who has reviewed this study?

This study has been reviewed and given ethical approval by the Macquarie University Human Research Ethics Committee (HREC; Humanities and Social Sciences). This research meets the requirements of the *National Statement on Ethical Conduct in Human Research* (2007) which is available at the following website:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics (telephone (02) 9850 7854; email ethics@mq.edu.au).

11. Providing written and informed consent

If you agree to participate in this study, as well as allow your child to take part in this study, and your child wants to participate in the study, please complete the attached Consent Form.

Please do not hesitate to contact the student investigator Cassie Lavell at the contact details provided above if you wish to discuss the study in any way.

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Teenager Information Form

Project Title: Cognitive-Behavioural Therapy for Adolescent Body Dysmorphic

Disorder

Protocol Number: 52021948928846

Student Investigator: Cassie Lavell

Email: cassie.lavell@students.mq.edu.au

Research Supervisors: Distinguished Professor Ron Rapee

Email: ron.rapee@mq.edu.au

Dr Ella Oar

Email: ella.oar@mq.edu.au

I have been invited to participate in a study at Macquarie University for teenagers who worry about their looks/body. It has been explained to me in detail what I will have to do as part of being involved in the study. I understand that:

- 1. I will complete online questionnaires, interviews, and treatment sessions as part of this study via Zoom videocalls.
- After my treatment, I will complete post-treatment assessment sessions over the phone
 with a member of the research team 1 week after treatment, and again 2 months after
 treatment. I will also complete post-treatment online questionnaires.
- 3. Everything I tell the research team will be kept private (e.g., confidential) and only discussed with my parents and the study team.
- 4. The only time my information will not be kept private will be if the study team believes there is a risk of harm coming to me or someone else.
- 5. My participation is voluntary, and I understand that I will not get into trouble if I decide I don't want to be involved in the study anymore.
- 6. I understand my sessions will be voice recorded and listened to by members of the research team.
- 7. Talking about my fears may make me feel uncomfortable. However, I understand that I do not have to answer questions if I do not want to.

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Date: _____

		Parent and Teenager	Consent Form
Proje	ect Title:	Cognitive-Behavioural The	erapy for Adolescent Body Dysmorphic Disorde
Protocol Number:		52021948928846	
Student Investigator:		Cassie Lavell Email: cassie.lavell@students.mq.edu.au	
Rese	arch Supervisors:	Distinguished Professor R Email: ron.rapee@mq.edu Dr Ella Oar Email: ella.oar@mq.edu.a	<u>i.au</u>
By sigr		that I have read and unders	stood the Information Sheet, and
1.	I understand that my child and I (parent/guardian) I will be involved in completing online questionnaires, diagnostic interviews and 12 treatment sessions via videoconference (Zoom) as part of the "Cognitive Behavioural Therapy for Adolescent Body Dysmorphic Disorder" study at Macquarie University		
2.	My child and I will be randomly assigned to one of three baseline monitoring conditions: 1 week, 2 weeks or 3 weeks. This will involve completing brief online questionnaires once per week.		
3.	After my child's treatment, we will complete post-treatment assessment sessions over the phone with a member of the research team 1 week after treatment, and again 2 months after treatment. We will also complete post-treatment online questionnaires.		
4.	I understand the sessions will be voice recorded and reviewed for reliability purposes by members of the research team		
5.	I understand the risks and benefits involved		
6.	I understand that any reports or publications from this study will be reported in general terms and will not include any identifying information		
7.	I understand that my own and my child's participation in this study is voluntary and that we are free to withdraw from the study at any time without consequence		
8.	I understand that I can contact the Director of Research Ethics, at Macquarie University Human Research Ethics Committee on (telephone (02) 9850 7854; email ethics@mq.edu.au) if I have any concerns about ethical conduct		
9.	I agree to allow my child to participate in this study, and my child agrees to participate in this study.		
	Optional: I give permission for my child's and my own data from this study to be used in future studies approved by the Macquarie University Human Research Ethics Committee		
Parent Nam	ne:	Child Name:	Investigator Name:
Signature: _		Signature:	Signature:

Date: ______ Date: _____