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| **ONLINE PARTICIPANT INFORMATION STATEMENT – Parent Guardian****Courage Quest Plus - Optimising the “Courage Quest” Intervention for Children with Anxiety: A Randomised Controlled Trial**Jennie Hudson, Wendy Chen, Deanna Francis, Chloe Lim, Abigail Allsop, Paige Todd, Emma McDermott, Gemma Sicouri, Annabel Songco, and Melissa Aji,  |

## What is the research study about?

You and your child are invited to take part in this research study. Researchers at the Black Dog Institute have developed a digital exposure-focused intervention (the Courage Quest Plus intervention) for children aged 8-12 years with anxiety disorders. In this study, we are conducting a randomised controlled clinical trial to evaluate five additional features to this intervention to determine the best version of this digital exposure-focused intervention, which would lead to greatest reductions in anxiety disorders and symptoms.

We are aiming to answer the following research question:

*Testing Courage Quest Plus. What combination of additional features will create the optimal version of the Courage Quest intervention, which will lead to greater reductions in anxiety symptoms and result in greater remission of anxiety disorders for children aged 8 to 12 years?”*

## Who is conducting this research?

This research is being conducted by Jennie Hudson (Chief Investigator), Wendy Chen (Clinical Psychology Registrar and Post-doctoral Researcher), Deanna Francis (Post-doctoral Researcher), Chloe Lim (Post-doctoral Researcher), Abigail Allsop (Project Manager), Paige Todd (Project Manager), Emma McDermott (Research Assistant), Gemma Sicouri (Senior Research Associate), Annabel Songco (Post-doctoral Researcher), Melissa Aji (Clinical Psychology Registrar), and Wendy Chen (Clinical Psychology Registrar and Post-doctoral Researcher) at the Black Dog Institute.

This research is funded by Australian Rotary Health and the National Health and Medical Research Council. These funders will be provided with regular updates about the study progress but will not inform the design or implementation of the study goals.

## Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you and your child to take part. The research study is aiming to recruit children (and their parent/carer) who:

* + Are aged 8 to 12 years
	+ Have anxiety (the child does not need a previous diagnosis; we will ask questions to see if your child meets this criteria)
	+ Have the capacity to complete questions (with help if needed)

We want to ensure that both programs we offer are the right fit for you and your child. We are unable to recruit children who:

* Struggle with feeling sad a lot of the time, are very impulsive or have significant difficulty obeying rules and/or concentrating at school. If your responses indicate that your child might experience one of these, we think the program is not the best fit at this time and we will provide alternative referral suggestions.
* Have a diagnosed intellectual disability
* Are currently receiving psychological CBT-based therapy for anxiety (this includes through a psychologist or an online program, but does not include school counsellor support)
* Are currently prescribed medication for anxiety
* Are currently experiencing life-threating suicidal ideation and/or had serious suicidal ideation in the last month

## Do I have to take part in this research study?

Participation in any research study is voluntary. If you do not want to take part, you do not have to. Our study offers a low-intensity digital intervention. If you want to receive a more intensive intervention involving face to face weekly treatment for your child and do not want to participate in this study, you can do so by seeing a psychologist who can deliver Cognitive Behavioural Therapy (CBT). To access alternative treatment options, we recommend you visit your child’s GP or paediatrician for a mental health care plan.

If you decide to take part then change your mind, you can withdraw from the study following the instructions in section 9 of this information.

## What does participation in this research require, and are there any risks involved?

If you decide you want to take part in the research study, you will be asked to:

* + Complete screening questions to determine if you and your child are eligible to participate (more information below)
	+ Read the information carefully (ask questions if necessary)
	+ Complete the online consent form
	+ Complete an online clinical interview to find out about your child’s mental health (more information below)
	+ After being randomly allocated to a test condition, download the intervention app using the instructions we provide you (more information on randomisation and the intervention below)
	+ Complete the demographic and assessment questionnaires (more information below)

**Screening Questions:** Before you provide your consent and contact details, we will ask you some questions to see if you are eligible to continue in the study. These questions will ask you about you and your child (e.g., age, experience with psychological therapy and medication, etc.) as well as information about your child’s anxiety and whether or not your child has thoughts of suicide. These questions will take approximately 10 minutes.

**Online Clinical Questionnaire:** If the study is the right fit for you and your child,, a researcher will contact you by phone to schedule the online clinical questionnaire. The online clinical questionnaire will be 1-hour long, and you can complete it in your own time, taking breaks whenever you need to. This clinical questionnaire will provide information to us about your child’s mental health and determine if the study continues to be the right fit for you and your child. Whether the study is the right fit or not, we will give you a 5-minute phone call and you will receive a feedback report from this clinical questionnaire providing you information about your child’s mental health upon completion.

If the study is the right fit for you, we will ask you to complete the online clinical questionnaire again after the immediate post-intervention assessment and delayed follow-up assessment, where a researcher will contact you by phone to schedule in the online clinical questionnaire.

**Randomisation**: If you decide to take part, you and your child receive the Courage Quest Plus Intervention and will be randomly allocated (like the flip of a coin) to be in a condition with a random combination of up to 5 additional evidence-based features. Please see below for more information about the Courage Quest Plus intervention.

**Digital Exposure-Focused Intervention (Courage Quest Plus)**: The Courage Quest Plus intervention includes 10 weekly modules (depending on how many features are allocated to you) to teach you and your child skills in graded exposure. These activities involve watching videos, practicing skills in the real world, and answering questions. You can complete the Courage Quest Plus intervention on a device at home (e.g., a mobile, iPad, etc.). The intervention requires the following commitment:

* Parent and child complete 10 to 13 x weekly modules at home (can be split across multiple days); these take a minimum 20 minutes per week, but we recommend that the more time you engage with the program, the more benefits you will likely see.
* Parent completes 3 x 20-minute support sessions with a therapist over the phone or telehealth
* Schedule and complete regular home practice activities (approximately 5-10 minutes daily practice)

**Assessments:** If you and your child participate in this study, you and your child will be invited to complete questionnaires at three time points:

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| **Baseline Assessment**(questionnaires) |
| **10-13 weeks of intervention**(Courage Quest Plus Intervention with up to 5 additional modules) |
| **Immediate Post-intervention Assessment**(questionnaires and online clinical interview) |
| **Delayed 6-month Follow-up Assessment**(questionnaires and online clinical interview) |

These questionnaires will be online for you to complete. The baseline assessment will ask some demographic questions (e.g., gender identity, ethnicity, demographics) and questions about your child’s mental health. This should take approximately 10-15 minutes to complete.

The post-intervention assessment will include questionnaires that ask about your child’s mental health, as well as your experience with the intervention and should take approximately 15-20 minutes to complete. Following these questionnaires, you will be invited to complete the online clinical interview (details above).

The delayed follow-up assessment questionnaires will include questions that ask about your child’s mental health and should take approximately 10-15 minutes to complete. Following these questionnaires, you will be invited to complete the online clinical interview again (details above).

**Additional Costs**: There are no costs associated with participating in this research project.

**Psychological Distress:** It is possible, and often expected, that children may become anxious when completing anxiety interventions. However, if you or your child becomes upset or distressed as a result of participating in the research project, we recommend following up with the below services:

## If you are in immediate danger, call 000

* NSW Health Mental Health Line (1800 011 511)
* [Beyond Blue](https://www.beyondblue.org.au/) – 1300 22 4636
* [Lifeline Australia](http://www.lifeline.org.au/) – 13 11 14
* The Kids Helpline (1800 55 1800)
* [Suicide Call Back Service](http://www.suicidecallbackservice.org.au/) – 1300 659 467

## What are the possible benefits to participation?

If you choose to complete the online clinical interview, you will receive a feedback report with information about your child’s mental health (even if you are not eligible for the rest of the study) within 1 week of completing the online clinical interview.

If you choose to participate in the study, you will receive evidence-based strategies to support your child’s anxiety. However, we cannot guarantee your child will show improvements in their mental health following their participation in this study. Nonetheless, you will receive resources to support your child’s anxiety.

In terms of reimbursement, you will receive $30 for completing the first assessment, $50 for the second, and $70 for completing both the program and the third assessment, totalling to $150 for the entire study. These will be paid as a gift card within 30 days of completing each assessment.

## What will happen to information about me and my child?

By signing the consent form, you consent to the research team collecting and using information about you and your child for the research study, including data from the screening questions. Your identifiable data will not be shared with anyone outside of the research team unless there is a risk of serious harm to you, your child, or others, or if there is a risk of a serious crime.

The research team will store the data collected for this research project for a minimum of 15 years after the completion of the research or until the participants reach 25 years of age, as per the retention period for clinical trials involving children. Questionnaire data and participant data collected will be stored online via Qualtrics. Participant data collected through Qualtrics will be encrypted and stored within UNSW. This research will be stored electronically on a UNSW password protected OneDrive only accessible to the approved research investigators. Your data will be stored in a non-identifiable format where you and your child’s identities will be linked to a unique Participant ID. Only the research team will be able to link your Participant ID to your identifiable information.

If other researchers want access to your data for future research studies, they will need to obtain ethics approval before doing so. In these cases, your data will be de-identified so that you and your child’s identities will be unknown to these other researchers. The data will also be transferred to these other researchers through a secure UNSW OneDrive folder.

Data from the Courage Quest Plus app will be stored using the Amazon Relational Database Service (RDS) and Amazon DynamoDB. This information is stored in Amazon’s secured Amazon Web Services (AWS) servers in Australia. Amazon is the world’s leading cloud IT infrastructure provider providing high-performing, robust and secure infrastructure maintaining several compliance certifications, including ISO 27001, SOC1, SOC2, SOC3, PCI DSS, IRAP, ISO 9001, CSA, ICO 27017 and ISO 27018.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to 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 PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy](https://www.legal.unsw.edu.au/compliance/privacyhome.html) [Management Plan.](https://www.legal.unsw.edu.au/compliance/privacyhome.html)

## How and when will I find out what the results of the research study are?

The research team intend to publish results of the research in peer reviewed journals. We will also write a brief summary of the main research outcomes on the BDI website at the end of this trial. All Information will be published in a way that will not identify you or your child. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

## What if I want to withdraw from the research study?

If you do consent for you and your child to participate, you may withdraw at any time by completing the withdrawal of consent form which will be made available to you via email. Alternatively, you can ring the research team [see contact details below] or email childmentalhealth@blackdog.org.auand tell them you and your child no longer want to participate. If you decide to leave the research study, no additional information will be collected. If you decide to leave the research study, you can request that data already collected be excluded from the study. Your decision not to participate or to withdraw you or your child from the study, will not affect you or your child’s relationship with UNSW Sydney or the Black Dog Institute.

## What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact childmentalhealth@blackdog.org.au or you can contact the following member/s of the research team individually:

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| **Name** | Wendy (Wenting) Chen |
| **Position** | Co-Investigator and Clinical Psychology Registrar |
| **Telephone** | 9065 8146 |
| **Email** | wenting.chen@blackdog.org.au |
| **Name** | Chloe Lim |
| **Position** | Co-Investigator |
| **Telephone** | (02) 9065 9061 |
| **Email** | chloe.lim@blackdog.org.au |
| **Name** | Paige Todd |
| **Position** | Project Manager |
| **Telephone** | (02) 9065 9201 |
| **Email** | p.todd@blackdog.org.au |
| **Name** | Abigail Allsop |
| **Position** | Project Manager |
| **Telephone** | (02) 9065 9163 |
| **Email** | a.allsop@blackdog.org.au |
| **Name** | Melissa Aji |
| **Position** | Clinical Psychology Registrar |
| **Telephone** | (02) 9065 9173 |
| **Email** | m.aji@blackdog.org |
| **Name** | Gemma Sicouri |
| **Position** | Clinical Psychologist |
| **Telephone** | (02) 9065 9269 |
| **Email** | g.sicouri@blackdog.org.au  |

## Chief Investigator

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| **Name** | Jennie Hudson |
| **Position** | Chief Investigator |
| **Telephone** | (02) 9065 9251 |
| **Email** | jennie.hudson@blackdog.org.au |

1. **What if I have a complaint or any concerns about the research study?**

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

**Complaints Contact**

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| **Position** | Human Research Ethics Coordinator |
| **Telephone** | + 61 2 9385 6222 |
| **Email** | humanethics@unsw.edu.au |
| **HC Reference Number** | HC230509 |

# Online Consent Form – Parent providing own consent

Thank you for your interest in this research. If you are a parent/carer of a child and would like to participate in this study, please carefully read the information below, complete your details at the bottom of this page, and select “I agree and give consent for both myself and my child”.

Please note that your child will still have to complete a consent form for themselves.

If you **do not** want to participate in this study, please select “I do not give consent” By selecting the "I agree" button below:

* I understand I am being asked to provide consent to participate in this research study;
* I understand I will be contacted by the research team to complete questionnaires
* I have read the Participant Information Sheet, or it has been provided to me in a language that I understand;
* I understand the purposes, study tasks and risks of the research described in the study;
* I provide my consent for the information collected about me and my child from the screening questions to be used for the purpose of this research study.
* I provide my consent for information to be collected about me and my child. I understand this information will be used for the purpose of this research study.
* I understand that my data will not be shared with anyone outside of the research team unless there is a risk of serious harm to me, my child, or others, or if there is a risk of a serious crime.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received;
* I understand that I can download a copy of this consent form from [INSERT weblink]
* I understand that the results of the research will be made available on the Black Dog Institute Website.
* I freely agree to participate in this research study as described and understand that my child and I am free to withdraw at any time during the study and withdrawal will not affect me or my child’s relationship with any of the named organisations and/or research team members;
* I provide my consent for the information collected about me and my child to be made available to other researchers as described at section 7 of the Participant Information Statement (insert link here). I provide my consent for de-identified information collected about me or my child to be made available for future ethics-approved research studies with the same research aims.

Access to study results:

□ I would like to receive a copy of the study results via email, using the contact details provided below;

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| Full name of parent/carer |  |
| Full name of child |  |
| Parent/Carer’s email address |  |
| Parent/Carer’s mobile number |  |

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| **I agree and give consent for both myself and my child** |
| **I do not give consent** |

# Online Form for Withdrawal of Participation

I wish to **WITHDRAW** consent for both myself and my child to participate in the “Courage Quest Plus” research study.

I understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales or the Black Dog Institute.

* I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
* I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.
* I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

Please enter your details below. These details are not for us to contact you, but to ensure we properly withdraw you from the study:

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| Full name of parent/carer |  |
| Full name of child |  |
| Parent/carer’s email address |  |
| Parent/carer’s mobile number |  |

Submit withdrawal of consent for both myself and my child:

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| Submit withdrawal |
| Cancel (i.e., **do not** withdraw me or my child) |