



THE COOLKIDS & ADOLESCENT HEALTH PROGRAM

Information and Consent Form

About the Emotional Health Clinic

The Centre for Emotional Health (CEH) Clinic is a specialist research clinic aimed at furthering our understanding of child and adult emotional disorders and improving our methods of treatment. The Clinic is part of the Centre for Emotional Health, at Macquarie University. Families who seek help at the CEH Clinic will receive state of the art assessment and treatment based on research that has been conducted by our team over the past 20 years. The Centre for Emotional Health is a world leader in research in child and adolescent emotional health, has won numerous international awards for its treatment programs and is considered an international centre of expertise in the assessment and treatment of child and adolescent anxiety. Assessment and treatment services at the CEH Clinic are provided by a range of qualified personnel. We also function as a training clinic for psychologists who are completing postgraduate clinical psychology degrees. *All staff at the CEH Clinic also complete specialised training in child and adolescent anxiety and receive supervision from senior clinical psychologists who have expertise in this area.*

What is the purpose of the current treatment study for children and adolescents?

Some children and adolescents suffer from recurring physical (somatic) symptoms which can be quite distressing, although no organic cause has been identified. The most common somatic-health complaints experienced by children include recurring abdominal (stomach) pain, gastrointestinal symptoms, recurring headaches, dizziness, chest pain and nausea. The purpose of this study is to evaluate a psychological therapy program for children and adolescents aged between 7 to 17 years who have been experiencing recurring somatic-health complaints for at least 3-months and who are also experiencing some anxiety or depression.

Who is the CoolKids and Adolescent Health Program Study designed for?

For your child to be offered a place in the CoolKids and Adolescent Health Program he or she must meet a list of criteria, including:

- Children must be at least 7 years old and in grades 1 through 12.
- Your child has reported experiencing repeated somatic-health complaints (e.g., recurring headaches, stomach-aches, chest pain) for at least 3-months and the doctor has not identified any organic cause.
- The somatic complaints are significantly affecting your child's day-to-day life.
- Your child is experiencing some anxiety and/or depression.
- Your child must not be receiving other psychological treatment.

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- We suggest that children on medication should be on a stable dosage before starting treatment (and we advise to keep this stable during treatment).

The CoolKids and Adolescent Health program will not be suitable for your child if he or she is currently experiencing any of the following issues:

- Significant behavioural (oppositional) problems away from the family environment.
- Significant hyperactive behaviour that is unmanaged, i.e., ADHD.
- Significant learning delays that prevent mainstream class placement.
- Autism or related disorders (a separate program is available for children who are high functioning Autism Spectrum).
- Considered at-risk due to abuse, or neglect.
- Currently suicidal and/or are self-harming.

These exclusions are in place to ensure that our treatment programs are delivered to children and adolescents who are most likely to benefit from the program and for whom we are best equipped to offer services. Each child will be carefully assessed to determine whether our treatments are really the most appropriate or whether other programs or services may be better.

Who is conducting this study?

This study is being conducted at the Centre for Emotional Health (CEH) and the Department of Psychology at Macquarie University. The researchers include Associate Professor Maria Kangas, Distinguished Professor Ronald Rapee and Professor Mike Jones. Staff members include the clinicians who will be working under the supervision of Assoc. Professor Kangas. This study is funded by an Australian Rotary Health Grant (Mental Health of Young Australians Research Grant).

What does the study involve?

Initial Assessment:

Before you can participate in treatment, we have to thoroughly assess your child and family. The information we collect from you is used to determine whether our treatment program will be suitable and beneficial for your child. We would like you to complete a number of questionnaires about somatic (physical) symptoms, thoughts, feelings and behaviours, as well as a clinical assessment interview. Assessment interviews are videotaped for quality assurance purposes (that is, so that the results can be checked by a second researcher to ensure that an accurate diagnosis has been made).

The clinical assessment includes interviews separately for a child and their primary caregiver and typically takes 3-4 hours. This assessment will be conducted by a registered psychologist or intern clinical psychologist. Prior to attending the interview appointment, you and your child will also be asked to complete a survey booklet of questionnaires about your child's somatic symptoms, thoughts, feelings and behaviours. You will also be asked to complete several questionnaires asking you about your quality of life including parental stress. After the assessment, if you decide that you do not want to proceed with treatment then you will have 3 months to take up the offer before needing to complete another initial assessment. It is important for us to have current information about your child.

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What happens after the assessment?

Within two-weeks following the initial assessment interview you will be contacted by a member of our staff and we will inform you whether our treatment program will be suitable and beneficial for your child. If our treatment program is suitable for your child we will let you know when the treatment program will begin (see details below). If however, we evaluate that our treatment program is not suitable for your child, we will let you know the reasons for this, and if appropriate we will recommend an alternative program we are conducting at our clinic, or refer you to more suitable therapy programs available at hospital or community health centres in the Sydney metropolitan area.

What does the treatment involve?

If you decide to participate, you and your child will be allocated to one of two treatment commencement periods [early start or delayed-start (wait-list)]:

- Early Start: If you and your child are allocated to begin the treatment program early, this means that you will be invited to attend the initial therapy session within one-to-two weeks following confirmation of your child's suitability to this treatment study.
- Delayed Start/Wait-List: If you and your child are allocated to the wait-list condition, you will be offered the treatment at a later stage. In particular, you will be invited to attend a second assessment interview 10-weeks after your initial assessment and thereafter you will be invited to attend the initial therapy session.

Whether you and your child are allocated to the early versus delayed-start condition, you will be provided with the CoolKids and Adolescent Health Program.

The CoolKids and Adolescent Health Program is an individual treatment that is based on a cognitive behavioural approach to manage how to cope with child somatic complaints as well as anxiety and depressive problems. This program will involve 10 x 1 hour weekly sessions, held over 10 consecutive weeks at the CEH Clinic at Macquarie University, Ryde NSW. For families who are unable to attend in person, from 2016 the program is also available via interactive (live) Skype or teleconference (i.e. telephone) sessions. This is inclusive of the initial assessment. Part of the treatment requires that one parent attends the first session without the child/adolescent. The remaining 9 sessions will involve the child/adolescent attending each of the sessions. The reason for parent involvement is so that you can assist your child to manage their somatic distress as well as help them practice the stress management skills and 'homework' exercises between sessions. This program will teach your child how to manage and cope with their somatic symptoms as well as with any anxiety or depression they may also be experiencing. This program does not involve taking medication.

The CoolKids and Adolescent Health Program is manual based. That is, there is set content for every session. Making sure the treatment sessions are the same (i.e., standardised) allows us to examine the effectiveness of this treatment program across a number of children and adolescents. The therapist must cover the content outlined in the manual, however, he/she is able to tailor the application of that content to the needs of each child and family. In order to check that our clinicians are adhering to the

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recommended therapy procedures, the therapy sessions will be videotaped (in-person) or audio-taped (for Skype or Teleconference options).

For families who opt to take part in this program via Skype, we cannot guarantee full confidentiality due to security limitations as Skype is not 100% secure. We therefore recommend that families who select this option that they are using a private, password protected, encrypted device for access to the internet.

Who decides the treatment start period?

The treatment commencement period to which you are allocated is decided randomly, like drawing names out of a hat. The decision as to which therapist you will have is also decided randomly.

Who will be the therapist?

The therapists include psychologists, clinical psychologists and post-graduate psychology students (i.e., provisionally Registered Psychologists). All staff will be supervised by Associate Professor Kangas and Professor Ron Rapee.

What happens after treatment?

At the end of the 10 week therapy program you and your child will be asked to complete an end of therapy assessment interview (within one week) of completing this program (as well as completing the same set of questionnaires completed at the initial assessment). The format of this clinical assessment will be the same as the initial assessment. At 3-months, 6-months, and then finally at 9-months following the completion of the CoolKids and Adolescent Health Program you and your child will be asked to complete the final three follow-up assessments, which once again will take the same format as the initial assessment.

The follow-up assessments are an important part of our treatment program. These assessments serve two purposes: (a) to evaluate the individual progress your child has made; and (b) to allow us to evaluate the effectiveness of our program. Hence, these follow-up assessments are integral to our research.

How much will it cost?

We commit to provide the service to you at a reduced cost. All costs are subsidised by your participation in this research trial.

The initial assessment is **\$160** (normal cost \$290).

The treatment program is **\$550** (normal cost \$1450). This cost includes all treatment materials and participation in 10 x 1 hour therapy sessions.

In return for participating in the ongoing assessments you will receive **up to \$300 in rebates** (\$50 for clinic based assessments conducted within one-week and 3-months following completion of the therapy program; and \$100 each for the 6-months and 9-months follow-ups).

In summary, ***the total net-cost of the initial comprehensive assessment and treatment, if each of the 4 follow-up assessments are completed, is \$410.***

Please be aware that our fees are subsidised for research purposes and therefore rebates are not available through Medicare or Private Health funds. Fees paid by families are non-refundable. The same fees apply whether families opt to attend the assessment

therapy sessions in-person or via Skype/telephone. For families experiencing significant financial hardship, a reduced therapy fee for the 10-week program may apply.

Will our information be confidential?

The Centre for Emotional Health (CEH) Clinic is a training and research clinic. For research purposes CEH staff will use deidentified information collected during your assessment and treatment. All responses are confidential and will not be disclosed to third parties without written consent. The only limits to our confidentiality agreement is if any information is disclosed during the course of the interview by your child or you that indicates illegal activity (e.g., child abuse), we are required by law to disclose this information to relevant authorities.

When results of our research are published only average scores will be included and no personal identifying information will be released. You are free to withdraw from the study at any time or choose not to participate without affecting your relationship with the Emotional Health Clinic or Macquarie University. If you choose to withdraw, this will not affect your access to future treatment.

Further Information:

If you have any questions regarding this study please contact Associate Professor Maria Kangas on (02) 9850 8599 (or via email: maria.kangas@mq.edu.au).

What do I do now?

Participation in this study is entirely voluntary. If you and your child decide to take part, you and/or your child can withdraw consent at any time without having to give a reason. Your choice to do so will not affect your relationship with the CEH Clinic or Macquarie University.

If you would like your child to be assessed in order to be considered for the CoolKids and Adolescent Health Program, please complete the attached consent form and contact Associate Professor's clinical team on (02) 9850 4082 to schedule an assessment interview or via email: CoolKidsHealth@mq.edu.au. You may also directly contact Assoc. Professor Kangas on (02) 9850 8599 (email: maria.kangas@mq.edu.au).

Crisis Services

The Emotional Health Clinic does not have the resources to provide after-hours or crisis assistance. If you believe that your child is at any risk in terms of hurting themselves or others, it is important that you take action immediately. Contact your local Community Health Centre, Area Crisis or Extended Hours team, a telephone counselling service such as Lifeline (13 11 14) or the Suicide Helpline (1800 191 919), or the Emergency Department of your local hospital.



The CoolKids and Adolescent Health Program
CONSENT FORM

I, [parent name]

Of[address]

..... [Phone number]

have read and understand the information regarding the above named research study.

I have discussed the procedures with my child, _____,

and we are willing to act as voluntary participants.

I understand that my child and I have the freedom to withdraw our consent to participate and can discontinue our involvement at any time without prejudice to any future relationship with the investigators or the university.

Parent's SIGNATURE:

DATE:

Investigator's Signature: _____

DATE:

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. 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). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

Participant's Copy [Please Keep]

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Investigator's Copy [Please return to the Emotional Health Clinic]

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REQUEST for STUDY SUMMARY REPORT

The CoolKids and Adolescent Health Program

If you would like to receive a copy of the report summarising the findings from this study at the completion of the study, please complete the details on this form. The study will be completed by December 2017. The summary report is expected to be available by February/March 2018.

Name: _____

Mailing Address: _____

or Email Address: _____

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