Internet-delivered parenting program for prevention and early intervention of a	nxiety
problems in young children: Randomized controlled trial	

Running title: Internet-delivered parenting program

Keywords: Anxiety disorders, Children, Internet, Prevention, Parenting

Abstract

Objective

The 'Cool Little Kids' parenting group program is an effective intervention for preventing anxiety disorders in young children who are at risk due to inhibited temperament. The program has 6 group sessions delivered by trained psychologists to parents of 3-6 year old children. An online adaptation (Cool Little Kids Online) has been developed to overcome barriers to its wide dissemination in the community. This study tested the efficacy of Cool Little Kids Online in a randomized controlled trial.

Method

433 parents of a child aged 3-6 years with an inhibited temperament were randomized to the online parenting program or to a 24-week waitlist. The online program has 8 interactive modules providing strategies parents can implement with their child to manage their child's avoidant coping, reduce parental overprotection and encourage child independence. Parents were provided telephone consultation support with a psychologist when requested. Parents completed self-report questionnaires at baseline, and 12 and 24 weeks after baseline.

Results

The intervention group showed significantly greater improvement over time in child anxiety symptoms compared to the control group, d = 0.38. The intervention group also showed greater reductions in anxiety life interference (ds = 0.33-0.35) and lower rates of anxiety disorders than the control group (40% vs 54%), but there were minimal effects on broader internalizing symptoms or overprotective parenting.

Conclusions

Results provide empirical support for the efficacy of online delivery of the Cool Little Kids program.

Online dissemination may improve access to an evidence-based prevention program for child anxiety disorders.

Introduction

Anxiety disorders are recognized as prevalent mental health problems in children and adolescents,¹ affecting approximately 7% of children in any year and contributing to half of all mental health problems in youth.² Anxiety disorders can also be identified in early childhood and rates vary between 1.5-9.4%.^{3,4} Furthermore, half of anxiety disorders diagnosed in adults first occurred in childhood.⁵ Child anxiety disorders interfere with family functioning, peer relationships, and school achievement and increase the risk of developing other mental health problems such as depression and substance misuse.^{6,7} Identifying children who are at risk of developing anxiety disorders and intervening early in life could reduce the potential lifetime negative effects from anxiety.⁸

Temperamental inhibition has been identified as a central risk factor for anxiety and internalizing problems. Inhibition is the tendency to avoid, withdraw, or respond fearfully to novelty and 10-15% of children are highly inhibited. Longitudinal studies have shown inhibition has a particularly strong relationship with risk of social anxiety disorder, with 43% of inhibited children developing social anxiety disorder compared to 13% of controls. Nevertheless, not all children with an inhibited temperament will develop an anxiety disorder, and other risks, such as parenting, may be influential. A child's inhibited temperament can elicit overprotective and controlling behaviors in parents, inadvertently reinforcing and maintaining anxiety by reducing the development of autonomy. Other parenting behaviors that may contribute include anxious modelling and harsh or negative interactions.

There is growing evidence that anxiety disorders can be prevented in children and adolescents. ^{12,13} The Cool Little Kids parenting group program aims to intervene early in life to prevent anxiety disorders in children who have an inhibited temperament. ¹⁴ The manualized program consists of 6 sessions delivered by trained psychologists to groups of parents with an inhibited preschool-aged child. The program focuses on strategies parents can implement with their child to manage their child's avoidant coping, reduce parental overprotection, and encourage child

independence. Two randomized controlled trials (RCTs) have demonstrated its efficacy. 14,15 In the first trial, children in the intervention group had significantly lower rates of anxiety disorders than children in the control group three years later (40% versus 69%). 16 A follow-up 11 years later showed that program benefits were maintained into adolescence for girls. 17 A second study with a higher-risk sample and slightly more intensive intervention also found lower rates of anxiety disorders in intervention children compared to controls at 6-month follow-up (53% versus 93%, p<.001). 15 The population cost-effectiveness of the program has also been evaluated and was found to represent very good value for money. 18 Overall, Cool Little Kids is ready for approaches to wider translational dissemination in the community. 19

Despite Cool Little Kids being a relatively brief program, there remain barriers to its wider dissemination. A scarcity of trained mental health professionals limits availability of the program. Parents with young families also face substantial barriers to attending group programs, including time demands and scheduling issues, as well as practical barriers such as transportation and arranging child care. Internet delivery can increase the reach of mental health interventions and may help reduce the burden of mental health problems. Online delivery of Cool Little Kids could potentially overcome some participation barriers and reach families who live in areas with limited access to child mental health services. An online adaptation of the group-based program, Cool Little Kids Online, was developed and piloted to assess acceptability and perceived utility. A sample of 51 Australian parents of an inhibited young child were provided access to the Cool Little Kids Online program and were invited to complete pre-post questionnaires. Pilot study results showed that online dissemination of Cool Little Kids was feasible and acceptable to parents. Parents reported high levels of satisfaction and there were significant improvements in child anxiety and related outcomes. The program was then improved and refined based on parent feedback.

The aim of this study was to evaluate the efficacy of Cool Little Kids Online in a larger randomized controlled trial. We hypothesized that compared to a waitlist control, the program would

lead to lower child anxiety and internalizing symptoms, fewer child anxiety disorders, lower life interference related to anxiety, and reduced overprotective parenting practices.

Method

Full details of the study method have been described in the trial protocol.²⁴ The trial was registered with the Australian New Zealand Clinical Trials Registry (12615000217505) and was approved by La Trobe University Human Ethics Committee (UHEC15-010).

Participants and recruitment

Inclusion criteria were Australian parents of a 3-6 year old child with an inhibited temperament. Exclusion criteria were child major developmental delay (i.e., cerebral palsy, an intellectual disability, or severe autism) reported by parents. Participants were enrolled in the study after completing an online screening questionnaire, giving informed consent, and completing the baseline questionnaire online. Participants were recruited via the Cool Little Kids Online website (www.coollittlekids.org.au), which contained information about the study and the online link to enroll. The study was promoted with paid advertisements on Facebook and Google targeted Australia-wide, and advertisements on parenting and mental health related websites. Flyers were also distributed to preschool services in three metropolitan and one non-metropolitan area in the state of Victoria, Australia. See Figure S1, available online, for examples of advertisements. Recruitment occurred between June and September 2015. The target sample size was 385 to allow detection of an effect size of 0.32 standard deviations between groups on the primary outcome measure, with 80% power at the two-sided significance level of 0.05 and allowing for 20% attrition. Table 1 presents the sociodemographic characteristics of the sample, which were well balanced between intervention and control groups. Parents living outside of major cities were represented at similar rates to population data (70.9%).25

Randomization

Parents were randomly allocated to intervention or waitlist-control groups in a 1:1 allocation.

Randomization occurred at the end of the baseline questionnaire with an automated computer script.

Parents were informed via email about their group allocation and received a welcome phone call within the first week. Intervention parents were emailed instructions on how to create an account with the online program immediately after randomization. Parents in the control group were emailed these instructions once they had completed the final questionnaire after a waiting period of 24 weeks. Parents were not restricted from seeking other assistance during the study.

Measures

Except where noted, all measures were completed at baseline, 12 weeks after baseline, and 24 weeks after baseline. All assessments were completed online by a parent or primary care giver.

Child inhibition

Potential participants completed the Approach subscale of the Short Temperament Scale for Children (STSC)²⁶ as a screen for child temperamental inhibition. This 7-item subscale measures social approach versus withdrawal behaviors. Scores range from 0-42 and higher scores indicate greater withdrawal. As in previous research on the Cool Little Kids program, a score over 30 was the cutpoint for study eligibility.^{14,19} This is approximately 1.15 standard deviations above the age-adjusted norm, and is consistent with meeting criteria for behavioral inhibition on a laboratory assessment.¹⁴

Child anxiety symptoms

The primary outcome measure was the Revised Preschool Anxiety Scale (PAS-R).²⁷ The PAS-R assesses parent-reported anxiety symptoms in young children and includes four subscales: generalized anxiety, social phobia, separation anxiety, and specific phobias. Total scores range from 0-112 and can differentiate between children with an anxiety disorder (M = 61) and without (M = 23).²⁷

Child anxiety disorders

The Online Assessment of Preschool Anxiety (OAPA) is a newly developed measure that assesses anxiety diagnoses in young children aged 6 years and below. It was adapted from the Youth Online Diagnostic Assessment²⁸ for children aged 7 to 17. Parents complete the OAPA online and are asked screening questions for each of the following child anxiety disorders: separation anxiety disorder, specific phobia, social phobia, and generalized anxiety disorder. Automated rules determine whether the rest of the symptom questions for that disorder are presented. Parents rate child anxiety symptoms and level of interference in closed questions, and also provide written descriptions of child thoughts and behaviors and examples of life interference. Initially, responses are automatically scored for the presence or absence of a disorder based on DSM-IV criteria. De-identified reports that include each parent's responses and provisional diagnoses are then reviewed by a psychologist to check whether parents' written descriptions are consistent with the disorder being assessed and whether the level of impairment described is clinically sufficient to warrant a diagnosis. Reports were reviewed by two postgraduate clinical psychology candidates who received ongoing supervision by two experienced clinical child psychologists. The OAPA was completed at the 24week follow-up assessment. Initial evidence of construct validity is supported by children with OAPA anxiety disorders scoring significantly higher on PAS-R anxiety symptoms than children without a diagnosis, *p*<.001 (unpublished data, January, 2017).

Child internalizing symptoms

Child internalizing symptoms (depression and anxiety) were assessed with the Emotional Symptoms subscale of the Strengths and Difficulties Questionnaire (parent version; SDQ-P).²⁹ The SDQ-P is a widely used screening tool for psychosocial problems in children aged 4 to 10 years. The Emotional Symptoms subscale (SDQ-ES) has five items and scores range between 0 and 10.

Life interference

Life interference from child anxiety was assessed with the preschool version of the Children's

Anxiety Life Interference Scale (CALIS).³⁰ Kennedy et al¹⁵ adapted the CALIS for use with younger, preschool age children (CALIS-PV). The preschool version is a 20-item parent-report questionnaire with two subscales: child life interference from anxiety and family interference due to child anxiety.

Over-involved/protective parenting

The Over-Involved/Protective parenting scale (OI/P)³¹ is an 8-item measure of overinvolved/protective parenting behaviors that discourage autonomy in young children. The mean of the items ranges between 1 and 4, with higher scores indicating greater over-involved/protective parenting practices. The OI/P was completed at baseline and the 24-week follow-up assessment.

Parent psychological distress

Psychological distress in the parent was assessed at baseline with the Kessler 10 Psychological Distress Scale (K10).³² According to Australian norms, scores from 10-15 indicate low, 16-21 moderate, 22-29 high, and 30-50 very high psychological distress.³³

Intervention

Cool Little Kids Online was adapted from the Cool Little Kids parenting group program into 8 online modules that include written information, videos, audio narration, interactive worksheets and activities, and parent stories. Modules include psychoeducation about the nature, development and risks for anxiety disorders and teach practical ways to reduce child anxiety through graded exposure, contingency management, reducing overprotective behaviors, and managing parents' own fears and worries (see Table S1for an overview of each module, available online). Further detail about the program's development is provided in the pilot study²³ and study protocol.²⁴ In the present trial, parents could access the program for 6 months after creating their account. A new module became available each week and parents were encouraged to complete one module per week, but could work at their own pace if they preferred. Parents received automated summary emails after completing each module, which reinforced activities to practice at home before the next module. Automated emails also announced the availability of each new module, which also served as reminders to use

the program. Participants in the intervention group were sent one SMS reminder after 2 weeks of website inactivity to check whether they were having technical problems and to encourage them to log in.

Parents in the intervention group could request telephone support during the 24-week study period by contacting the study team. Intervention participants were informed of the availability of the support call in the participant information sheet, welcome email, welcome phone call, and in the module 2 and module 5 summary email. The support was provided by a provisionally registered psychologist with prior experience delivering the Cool Little Kids parenting group program, who was supervised by an experienced clinical psychologist. The psychologist could examine parents' completed worksheets and their progress through the online program to help parents troubleshoot difficulties implementing intervention techniques.

Statistical analyses

Mixed-model repeated measures analyses of variance were conducted on all continuous outcomes to evaluate the effect of the intervention. These analyses are able to account for correlations among repeated measurements and can include participants with missing data. The mixed-models approach is consistent with intention-to-treat analytic approaches under the assumption that data are missing at random. For each outcome, the optimal within-subject covariance structure was chosen as the one that minimizes Bayesian Information Criterion calculated using Restricted Maximum Likelihood. Planned contrasts compared the amount of change from baseline to each follow-up point between groups, as well as change between the 12-week and 24-week follow-up. Effect sizes (Cohen's d) for difference in change over time were calculated by standardizing the differences in change over time (follow-up-baseline) between the two groups by the pooled standard deviation of the difference. Responders were identified as children who demonstrated a statistically reliable improvement in anxiety symptoms on the PAS-R between baseline and the 24-week follow-up, according to the procedures in Jacobson and Truax.³⁴ Response rates and relative risk (RR) were calculated and tested

for significance. Differences in the number of child anxiety disorders between groups were modelled with negative binomial regression. The incidence rate ratio (IRR) is the ratio of the number of anxiety disorders at the 24-week follow-up in the intervention and control groups. Statistical analyses were conducted using SPSS 22 and R and significance level was set at p < .05.

Results

Of 1053 families screened for eligibility, 433 were recruited to the trial, with 215 randomized to the intervention group and 218 to the control group. Study attrition was relatively low, with 86.4% of participants (84.2% intervention, 88.5% control, p=.187) providing primary outcome data on two or more occasions (see Figure 1 for the trial flow diagram). The two groups were similar on the PAS-R, SDQ-ES, CALIS-PV, and OI/P scales at baseline, indicating that randomization resulted in comparable groups (see Table 2). Average child anxiety scores were high at baseline and two-thirds of children were in the abnormal range of emotional symptoms on the SDQ, indicating that many children had clinical levels of anxiety or internalizing problems. One-quarter of parents (25.4%) reported previously seeking help for their child's shyness or anxiety from a health professional (e.g., doctor, psychologist, nurse, speech therapist). Reported rates of health professional visits at the 12-week follow-up were 41.2% and 29.5% (control vs intervention respectively, p=.025), and 33.9% and 27.1% (control vs intervention, p=.172) at the 24-week follow-up.

Program use and satisfaction

In the intervention group, 91.6% of participants accessed at least one module (6 parents did not create an account and 12 did not access any modules after creating their account). The mean number of modules accessed was 4.0 (SD=2.8) and the mean number of logins was 6.0 (SD=5.3). All 8 modules were accessed by 24.9% of parents who created an account. At the 12-week follow-up, the most common reason given by the remaining parents (n=109) for not completing all modules was lack of time (95.4%), followed by child improved and no longer needed help (54.1%), parent sought help for their child from a professional instead (23.8%), parent experienced website technical

problems (13.8%), and the program wasn't helping (6.4%). About a fifth (18.7%) of parents continued to access the online program after providing 12-week follow-up data. A majority of parents reported regularly practicing program skills with their children (22.5% everyday, 44.4% a few times a week, 19.2% once a week, 13.9% less than once a week). Few parents (5.1%) requested a support call from the Cool Little Kids clinician. The clinician provided 12 calls to 11 parents, which lasted an average of 35 minutes (range 14-53). Support calls primarily included psychoeducation, help with designing and implementing stepladders, and encouragement to practice skills and use the program.

Participants who provided 12-week assessment data were very satisfied with the online program. The program was rated by 93% as 'quite' to 'extremely' useful for understanding young children's shyness, inhibition and anxiety; 91% for knowing what leads to anxiety developing in young children; 91% for knowing how to encourage brave behavior in their child; 89% for knowing how to reduce anxious behavior in their child; and 84% for knowing how to change their own anxious and fearful thoughts. Most parents (95.4%) reported that they would probably or definitely recommend the program to others.

Primary outcomes

Baseline, 12-week, and 24-week scores on all child outcome measures are presented in Table 2. Table 3 presents the results from the planned contrasts estimating the mean difference in change over time between groups. There was significantly greater improvement in child anxiety symptoms (PAS-R total score) in the intervention group compared with the control group at the 24-week follow-up. This difference was small to moderate in size (d = 0.38). Greater improvement was also demonstrated for each anxiety subscale, with small to moderate effect sizes. The rates of reliable change on child anxiety symptoms are presented in Table 4. Responders, those who showed a reliable improvement, were significantly more likely in the intervention group, RR = 1.51 (95% CI:

1.20-1.89). The number needed to treat to achieve one response to the intervention compared to the control was 5.1 (95% CI: 3.4-11.1).

To explore whether help-seeking during the study accounted for observed effects, a post-hoc sensitivity analysis was conducted which excluded participants who reported seeking external support (see Table S2, available online). Estimates of intervention effects were similar to those using all participants.

Secondary outcomes

Rates of anxiety disorders assessed by the OAPA at the 24-week follow-up are presented in Table 4. Fewer children in the intervention group met criteria for any anxiety disorder than controls, RR = 0.74 (95% CI: 0.58-0.94). The number needed to treat to prevent one case of anxiety disorder was 7.2 (95% CI: 4.1-33.9). Results were similar for each type of anxiety disorder: separation anxiety disorder RR = 0.77 (95% CI: 0.50-1.18), specific phobia RR = 0.49 (95% CI: 0.31-0.79), social phobia RR = 0.76 (95% CI: 0.55-1.06), and generalized anxiety disorder RR = 0.54 (95% CI: 0.29-0.997). The mean number of anxiety disorders was also lower in the intervention group (M = 0.69, SD = 1.02) than the control group (M = 1.05, SD = 1.20), IRR = 0.66 (95% CI: 0.51-0.86).

Of the remaining secondary outcomes, child and family life interference from anxiety showed significantly greater improvement in the intervention group than the control group between baseline and 24-week follow-up (see Table 3). The intervention and control groups did not differ at follow-up on child internalizing symptoms (SDQ-ES) or overprotective parenting (OI/P). Both of these outcomes reduced substantially from baseline to follow-up across trial arms.

Discussion

This study aimed to evaluate an internet-delivered parenting program for early intervention of anxiety problems in young children. Results provide empirical support for the efficacy of online delivery of the Cool Little Kids program. As hypothesized, the intervention group showed significantly greater reductions in child anxiety symptoms and life interference from anxiety, along

with lower rates of anxiety disorders than the control group. Average improvements were small to moderate in size relative to controls, consistent with other anxiety prevention programs delivered to children at greater risk.¹² The number needed to treat to achieve a reliable response or to prevent an anxiety disorder was approximately 6-7. Parent satisfaction was high, even though the amount of program use was relatively low. The program however did not demonstrate improvements in broader child internalizing symptoms or overprotective parenting. Overall, these results suggest that offering online access to the program with minimal support could be an effective way of reducing anxiety in children with an inhibited temperament.

These results add to evidence of the efficacy of the Cool Little Kids program. This study found a difference of 14% in the rate of anxiety disorders between intervention and control groups, equivalent to the one year follow-up result in the first RCT of the group program. ¹⁴ Intervention group reductions in anxiety symptoms were also similar in size to those shown in the second RCT at 6-month follow-up, ¹⁵ but the effect on anxiety disorders was smaller in the present trial. Compared to the pilot evaluation of Cool Little Kids Online, this study found larger within-group effect sizes, even higher parent satisfaction, and more frequent homework practice. ²³ Online program usage was lower than the high attendance rates observed for the group parenting program when delivered through a university research clinic. ^{14,15} Adherence rates were closer to those found in translational research, where the group program was delivered in preschool services and only a third of parents attended most sessions (Bayer et al., in preparation). These differences in program adherence between clinical, community and internet-based populations may reflect different levels of parent commitment. Compared to the clinic-based evaluations of Cool Little Kids, parents could easily sign up to this internet-based study, as they were not required to commit to laboratory observations and in-person assessments, and hence motivation levels may have been lower.

Although the program was effective overall, there was variation in children's outcomes and an important minority (42%) did not demonstrate reliable improvement. There is therefore room to

further improve program effects and to identify those families who are least likely to benefit from this method of delivery and why. The lack of effect on internalizing symptoms was unexpected and the reason for this finding is unclear. The limited effect on overprotective parenting could be due to several reasons. One is that there may be natural improvement over time as children start school and are given more independence by parents. Alternatively, as much of the content targeting overprotection begins in the fourth module, some parents may not have received an adequate dose to realistically achieve change in parenting behavior. However, the lack of effect on overprotective parenting does raise important theoretical questions about program mechanisms, which could be investigated in further mediation research.¹⁴

A key area of future research is to explore which families are most likely to benefit from the program and under what conditions. Evidence of effectiveness despite limited use of the program may be a realistic reflection of the non-clinical sample, and some families may not need to learn all the skills and complete all 8 modules. Alternatively, changes to the program could be required to increase adherence or engagement with the material. More frequent assessments could identify when improvements occur and whether these are related to particular modules or skills. Changing the model of clinician support is another avenue of investigation, as the low take-up of this was surprising. Other research has found higher rates of 19%-48% when clinician support was offered on-demand to support self-guided treatment of anxiety. 35,36 However, the program was promoted as a resource to prevent anxiety and improve child confidence, and parent expectations about the need for clinician support may differ from online treatment programs for clinical anxiety. In-depth qualitative research could investigate adherence and the reasons for non-usage, and whether these barriers would be feasible to overcome through changes to the program or the provision of support. The value of changing the module structure (e.g., fewer modules), clinician support model, or program components could then be evaluated to optimize the design and delivery of the program.

This study has several strengths. It achieved a large sample representing a range of sociodemographic characteristics and a low attrition rate for an online study. The study design was quite pragmatic in that the intervention was delivered in a similar way to how it could be used in practice if disseminated. There were minimal inclusion/exclusion criteria, the online enrolment process presented few barriers to participation, and participants were not restricted from accessing other help or resources during the study. A limitation of the study was the use of single-informant self-report measures. Using other informants (e.g. teachers) would have reduced the risk of bias from parents being aware of their group allocation. However, this was not feasible to implement due to the Australia-wide geographic distribution of participants. The waitlist control also precluded investigating longer-term preventive effects, which may be particularly important given the young age of the children and the increased onset of anxiety in middle childhood. Thirdly, the assessment of child anxiety diagnoses used a new measure with limited established psychometric properties.

With these caveats in mind, offering an online adaptation of the Cool Little Kids parenting program appears to be effective in reducing anxiety in inhibited young children. Online dissemination has the potential to reach larger numbers of parents in the community with greater cost-efficiency than face-to-face delivery by trained professionals. That the program demonstrated benefits with minimal clinician support augurs well for the flexibility and cost-effectiveness of future dissemination efforts. Additional research could investigate how to optimize the program in order to maximize its positive impact on anxious children and their families.

References

Merikangas KR, He J-P, Burstein M, et al. Lifetime prevalence of mental disorders in U.S. adolescents: Results from the National Comorbidity Survey Replication-Adolescent Supplement (NCS-A). *J. Am. Acad. Child Adolesc. Psychiatry*. 2010;49(10):980-989.

- 2. Lawrence D, Johnson S, Hafekost J, et al. The Mental Health of Children and Adolescents.
 Report on the second Australian Child and Adolescent Survey of Mental Health and
 Wellbeing. Canberra, Australia: Department of Health;2015.
- 3. Egger HL, Angold A. Common emotional and behavioral disorders in preschool children: Presentation, nosology, and epidemiology. *J Child Psychol Psychiatry*. 2006;47(3-4):313-337.
- **4.** Wichstrøm L, Berg-Nielsen TS, Angold A, Egger HL, Solheim E, Sveen TH. Prevalence of psychiatric disorders in preschoolers. *J Child Psychol Psychiatry*. 2012;53(6):695-705.
- 5. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Arch. Gen. Psychiatry.* 2005;62(6):593-602.
- **6.** Ezpeleta L, Keeler G, Erkanli A, Costello EJ, Angold A. Epidemiology of psychiatric disability in childhood and adolescence. *J Child Psychol Psychiatry*. 2001;42(7):901-914.
- 7. Costello EJ, Mustillo S, Erkanli A, Keeler G, Angold A. Prevalence and development of psychiatric disorders in childhood and adolescence. *Arch. Gen. Psychiatry.* 2003;60(8):837-844.
- **8.** Hirshfeld-Becker DR, Biederman J. Rationale and principles for early intervention with young children at risk for anxiety disorders. *Clin. Child Fam. Psychol. Rev.* 2002;5(3):161-172.
- **9.** Rapee RM, Schniering CA, Hudson JL. Anxiety disorders during childhood and adolescence: Origins and treatment. *Annu. Rev. Clin. Psychol.* 2009;5(1):311-341.
- 10. Fox NA, Henderson HA, Marshall PJ, Nichols KE, Ghera MM. Behavioral inhibition: Linking biology and behavior within a developmental framework. *Annu. Rev. Psychol.* 2005;56(1):235-262.

- 11. Clauss JA, Blackford JU. Behavioral inhibition and risk for developing social anxiety disorder: A meta-analytic study. *J. Am. Acad. Child Adolesc. Psychiatry*. 2012;51(10):1066-1075.
- **12.** Teubert D, Pinquart M. A meta-analytic review on the prevention of symptoms of anxiety in children and adolescents. *J. Anxiety Disord.* 2011;25(8):1046-1059.
- 13. Yap MBH, Morgan AJ, Cairns K, Jorm AF, Hetrick SE, Merry SN. Parents in prevention: A meta-analysis of randomized controlled trials of parenting interventions to prevent internalizing problems in children from birth to age 18. *Clin. Psychol. Rev.* 2016;50:138-158.
- 14. Rapee RM, Kennedy S, Ingram M, Edwards S, Sweeney L. Prevention and early intervention of anxiety disorders in inhibited preschool children. *J. Consult. Clin. Psychol.* 2005;73(3):488-497.
- 15. Kennedy SJ, Rapee RM, Edwards SL. A selective intervention program for inhibited preschool-aged children of parents with an anxiety disorder: Effects on current anxiety disorders and temperament. *J. Am. Acad. Child Adolesc. Psychiatry.* 2009;48(6):602-609.
- **16.** Rapee RM, Kennedy SJ, Ingram M, Edwards SL, Sweeney L. Altering the trajectory of anxiety in at-risk young children. *Am. J. Psychiatry*. 2010;167(12):1518-1525.
- 17. Rapee RM. The preventative effects of a brief, early intervention for preschool-aged children at risk for internalising: Follow-up into middle adolescence. *J Child Psychol Psychiatry*. 2013;54:780-788.
- 18. Mihalopoulos C, Vos T, Rapee RM, et al. The population cost-effectiveness of a parenting intervention designed to prevent anxiety disorders in children. *J Child Psychol Psychiatry*. 2015;56(9):1026-1033.
- **19.** Bayer JK, Rapee R, Hiscock H, et al. The Cool Little Kids randomised controlled trial: Population-level early prevention for anxiety disorders. *BMC Public Health*. 2011;11(1):11.

- **20.** Axford N, Lehtonen M, Kaoukji D, Tobin K, Berry V. Engaging parents in parenting programs: Lessons from research and practice. *Child Youth Serv Rev.* 2012;34(10):2061-2071.
- 21. Comer JS, Barlow DH. The occasional case against broad dissemination and implementation: Retaining a role for specialty care in the delivery of psychological treatments. *Am. Psychol.*Jan 2014;69(1):1-18.
- **22.** Kazdin AE, Blase SL. Rebooting psychotherapy research and practice to reduce the burden of mental illness. *Perspect. Psychol. Sci.* Jan 2011;6(1):21-37.
- 23. Morgan AJ, Rapee RM, Bayer JK. Prevention and early intervention of anxiety problems in young children: A pilot evaluation of Cool Little Kids Online. *Internet Interv.* 2016;4:105-112.
- 24. Morgan AJ, Rapee RM, Tamir E, et al. Preventing anxiety problems in children with Cool Little Kids Online: Study protocol for a randomised controlled trial. *Trials*. 2015;16:art. no. 507.
- **25.** Australian Bureau of Statistics. *Regional population growth, Australia, 2014-15 (cat. no. 3218.0).* Canberra, Australia: ABS;2016.
- **26.** Prior MR, Sanson AV, Oberklaid F. The Australian Temperament Project. In: Kohnstamm GA, Bates JE, Rothbart MK, eds. *Temperament in childhood*. Chichester, England: John Wiley and Sons; 1989:537-554.
- 27. Edwards SL, Rapee RM, Kennedy SJ, Spence SH. The assessment of anxiety symptoms in preschool-aged children: The Revised Preschool Anxiety Scale. *J. Clin. Child Adolesc.**Psychol. 2010;39(3):400-409.
- 28. McLellan LF, Iverach L, Kangas M, et al. *Youth Online Diagnostic Assessment*. Sydney, Australia: Centre for Emotional Health, Macquarie University; 2016.

- **29.** Goodman R. The Strengths and Difficulties Questionnaire: A research note. *J Child Psychol Psychiatry*. 1997;38(5):581-586.
- 30. Lyneham HJ, Sburlati ES, Abbott MJ, et al. Psychometric properties of the Child Anxiety Life Interference Scale (CALIS). *J. Anxiety Disord*. 2013;27:711-719.
- **31.** Bayer JK, Sanson AV, Hemphill SA. Parent influences on early childhood internalizing difficulties. *J. Appl. Dev. Psychol.* 2006;27(6):542-559.
- **32.** Kessler RC, Barker PR, Colpe LJ, et al. Screening for serious mental illness in the general population. *Arch. Gen. Psychiatry.* 2003;60(2):184-189.
- 33. Slade T, Grove R, Burgess P. Kessler Psychological Distress Scale: Normative data from the 2007 Australian National Survey of Mental Health and Wellbeing. *Aust. N. Z. J. Psychiatry*. 2011;45(4):308-316.
- **34.** Jacobson NS, Truax P. Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *J. Consult. Clin. Psychol.* 1991;59(1):12-19.
- 35. Berger T, Caspar F, Richardson R, Kneubuhler B, Sutter D, Andersson G. Internet-based treatment of social phobia: a randomized controlled trial comparing unguided with two types of guided self-help. *Behav. Res. Ther.* 2011;49(3):158-169.
- **36.** Kleiboer A, Donker T, Seekles W, van Straten A, Riper H, Cuijpers P. A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety. *Behav. Res. Ther.* 2015;72:63-71.
- 37. Kelders SM, Bohlmeijer ET, Pots WTM, van Gemert-Pijnen JEWC. Comparing human and automated support for depression: Fractional factorial randomized controlled trial. *Behav. Res. Ther.* 2015;72:72-80.

TablesTable 1

Baseline Participant Characteristics in Intervention and Control Groups

	Intervention	Control		
	(n = 215)	(n = 218)		
Child age M (SD)	4.8 (1.0)	4.8 (1.0)		
Child gender (female) (%)	54.9	50.5		
Child inhibition M (SD)	35.6 (3.1)	35.4 (2.8)		
Parent age $M(SD)$	35.8 (5.0)	36.0 (5.2)		
Parent is child's birth mother (%)	94.9	94.0		
Parent relationship status (%)				
Married or defacto	92.6	90.8		
Single or widowed	2.3	4.1		
Separated or divorced	5.1	5.0		
Parent highest level of education (%)				
Postgraduate degree	24.7	31.5		
Tertiary degree	33.0	37.0		
Technical diploma/certificate	26.5	16.7		
Trade apprenticeship	1.9	1.4		
High school	14.0	13.4		
Speaks mainly English at home (%)	96.7	93.1		
Lives in major city (%)	74.4	68.8		
Household income (%)				
AUD 116,000 or more	38.6	40.8		
AUD 75,000 to 116,000	29.3	28.9		

AUD 44,000 to 75,000	13.0	14.2
Less than AUD 44,000	6.5	6.4
Don't know/missing	12.5	9.6
Financial difficulty ('Health care card') (%)	18.6	15.6
Weekly internet use (%)		
< 10 hours	47.9	45.9
10 hours or more	52.1	54.1
Parent psychological distress (K10) M (SD)	18.6 (6.4)	19.3 (6.3)

Note. AUD = Australian dollars. During the recruitment period 1AUD was equivalent to 0.70-0.78 USD.

Table 2. Observed Means and Standard Deviations for All Outcome Measures at Baseline and Follow-ups

	Baseline		We	ek 12	Week 24		
	Control Intervention		Control	Intervention	Control	Intervention	
	(n = 218)	(n =215)	(n = 187)	(n =156)	(n = 180)	(n =166)	
Child anxiety symptoms (total)							
M (SD)	69.1 (13.5)	69.7 (14.6)	58.9 (15.1)	55.7 (15.9)	55.7 (17.4)	50.0 (19.1)	
Separation anxiety	11.6 (4.0)	11.6 (4.1)	9.5 (4.1)	9.0 (3.9)	8.7 (4.3)	7.9 (4.2)	
Specific phobia	18.5 (6.8)	18.6 (7.1)	15.5 (6.5)	14.8 (6.2)	14.8 (7.2)	13.0 (6.9)	
Social phobia	20.6 (4.0)	20.7 (3.9)	17.7 (4.9)	16.6 (5.5)	16.9 (5.4)	15.1 (6.3)	
Generalized anxiety	18.4 (4.2)	18.8 (4.6)	16.1 (4.8)	15.3 (4.7)	15.3 (5.2)	14.0 (5.2)	
Child internalizing symptoms							
M (SD) ^a	5.5 (2.2)	5.6 (2.3)	4.5 (2.2)	4.1 (2.3)	4.1 (2.2)	4.0 (2.2)	
Normal %	21.6	19.1	36.6	47.4	43.9	47.6	
Borderline %	11.5	16.7	15.6	14.7	15.0	12.7	
Abnormal %	67.0	64.2	47.8	37.8	41.1	39.8	
Anxiety life interference ^b							
Child M (SD)	24.1 (6.5)	24.2 (6.8)	20.5 (7.6)	18.3 (7.5)	18.9 (8.4)	16.3 (8.6)	
Family M (SD)	15.5 (8.1)	15.4 (7.8)	13.4 (8.0)	11.7 (7.7)	12.3 (9.1)	10.1 (7.9)	
Over-involved/protective		•		•			
parenting M (SD) ^c	1.74 (0.44)	1.68 (0.39)			1.59 (0.38)	1.49 (0.33)	

a. control group n=186 at week 12 b. control group n=184 at week 12, intervention group n=165 at week 24 c. intervention group n=165 at week 24

Table 3.

Estimated Mean Difference in Change Over Time Between Intervention and Control Groups for all Outcome Measures

	Intervention vs control									
	Baseline to week 24		Baseline to week 12		Week 12 to 24					
Variable	Mean	95% CI	р	Mean	95% CI	р	Mean	95% CI	р	d [95% CI]
Child anxiety symptoms										
(total)	-6.47	[-10.02,-2.91]	<.001	-3.53	[-6.28,-0.78]	.012	-2.93	[-5.66,-0.21]	.035	0.38 [0.17,0.59]
Separation anxiety	-0.94	[-1.80,-0.08]	.031	-0.46	[-1.13,0.21]	.180	-0.48	[-1.18,0.21]	.172	0.23 [0.02,0.44
Specific phobia	-1.82	[-3.07,-0.57]	.004	-0.82	[-1.77,0.12]	.088	-0.99	[-1.98,-0.01]	.048	0.28 [0.07,0.49
Social phobia	-1.88	[-2.94,-0.81]	.001	-1.12	[-2.03,-0.21]	.016	-0.76	[-1.64,0.12]	.091	0.33 [0.12,0.55
Generalized anxiety	-1.79	[-2.78,-0.81]	<.001	-1.16	[-2.05,-0.28]	.010	-0.63	[-1.55,0.29]	.180	0.40 [0.18,0.61
Child internalizing symptoms	-0.23	[-0.74,0.28]	.370	-0.34	[-0.75,0.06]	.096	0.11	[-0.31,0.54]	.601	0.10 [-0.11,0.33
Anxiety life interference										
Child	-2.50	[-4.08,-0.93]	.002	-2.13	[-3.57,-0.68]	.004	-0.38	[-1.75,0.99]	.588	0.33 [0.12,0.55
Family	-2.26	[-3.66,-0.86]	.002	-1.75	[-2.94,-0.55]	.004	-0.52	[-1.77,0.73]	.417	0.35 [0.13,0.56
Over-involved/protective										
parenting	-0.04	[-0.11,0.03]	.217							0.15 [-0.06,0.37

Note. Negative values indicate a greater reduction in scores for the intervention group relative to the control group

Table 4

Rates of Reliable Change and Anxiety Disorders at 24-Week Follow-up

	Со	ntrol	Intervention			
Child anxiety symptom change	n	%	n	%		
Reliably improved	69	38.3	96	57.8		
No change	106	58.9	68	41.0		
Reliably deteriorated	5	2.8	2	1.2		
Online Assessment of Preschool						
Anxiety (n)	171		148			
Any anxiety disorder	92	53.8	59	39.9		
Separation anxiety disorder	42	24.6	28	18.9		
Specific phobia	47	27.5	20	13.5		
Social phobia	62	36.3	41	27.7		
Generalized anxiety disorder	28	16.4	13	8.8		

Figure 1. Flow of participants through the study