Cool Little Kids translational trial to prevent internalising: Two-year outcomes and prediction of parent engagement

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ABSTRACT

Background The aim was to determine outcomes in the first year of school of a population-delivered parenting program to prevent internalising problems in temperamentally inhibited preschool children and predictors of engagement in parenting groups.

Method *Design:* randomised controlled trial. *Setting:* 307 preschool services across eight socioeconomically diverse government areas in Melbourne, Australia. *Participants:* 545 parents of inhibited 4-year-old children; 469 (86%) retained at two-year follow-up. *Intervention:* Cool Little Kids program. *Primary outcomes:* child internalising symptoms and anxiety disorders. *Secondary outcomes:* parenting, parent wellbeing, and engagement. Trial registration ISRCTN30996662 http://www.isrctn.com/ISRCTN30996662

Results In the first year of school (M(SD) age 6.7 (0.4) years), child anxiety symptoms were reduced in the intervention versus control arm (PAS-R M(SD): total 36.2 (17.2) versus 39.4 (18.5); adjusted difference -3.26, 95% CI -6.46 to -0.05, p=0.047; specific fears 9.1 (6.2) versus 10.7 (6.8), adjusted difference -1.53; 95% CI -2.69 to -0.38, p=0.009). However, there was little difference in broader child internalising (CMFWQ

M(SD): 2.2 (0.5) versus 2.3 (0.6); adjusted difference -0.03, 95% CI -0.13 to 0.06, p=0.489) or anxiety disorders (37.6% versus 42.6%; adjusted OR 0.79, 95% CI 0.53 to 1.18, p=0.242). Lower income, younger mothers, less educated and more culturally diverse fathers engaged less with the intervention. Continued skills practice was less frequent for parents of girls and in advantaged neighbourhoods.

Conclusions There were population effects of Cool Little Kids in the first year of school for anxiety symptoms but not disorders. Considering motivation techniques to engage subgroups of families would be helpful in translation research.

Key practitioner message:

- Inhibited temperament is a key risk for anxiety disorders. In university efficacy trials, the Cool Little Kids parenting group program prevented anxiety disorders in inhibited young children
- This is the first translational trial, with a universal screen for inhibited preschoolers
- In children's first year of school (age 6) anxiety symptoms were reduced, but not anxiety disorders. Some disadvantaged families engaged less with the intervention
- Motivation techniques tailored to these subgroups could be helpful

Internalising problems encompass anxiety and depression and are a leading cause of global burden of disease (Murray et al., 2012; Waldman, Poore, van Hulle, et al., 2016). Internalising problems affect one in five children and frequently persist into adolescence and then adulthood (Bosquet & Egeland, 2006; Carter et al., 2010; Copeland, Angold, Shanahan, et al., 2014; Lawrence et al., 2015; Pine, Cohen, Gurley, et al., 1998; Reef, Diamantopoulou, van Meurs, et al., 2009). Young children with a shy/inhibited temperament are known to be at risk for internalising problems (Claus & Blackford, 2012; Muris, van Brakel, Arntz & Schouten, 2011; Rapee, Schneiring & Hudson, 2009).

Children's shy/inhibited behaviours at times elicit responses from parents (overprotective and/or harsh) that contribute to internalising problems developing over time (Bayer, Sanson & Hemphill, 2006a; Murray, Creswell & Cooper, 2009; Rubin, Nelson, Hastings, et al., 1999). The Cool Little Kids parenting group program addresses these risks early in life. Cool Little Kids has successfully reduced inhibited children's internalising problems in university-based efficacy trials. In the first of two randomised trials, Rapee and colleagues recruited 146 parents of inhibited 4-year-old children and reported significantly fewer anxiety disorders among intervention than control children at age 5 (50% *vs.* 64%) and 7 years (40% *vs.* 69%) (Rapee, Kennedy, Ingram, et al., 2005, 2010). In adolescence, intervention girls also had less depression (Rapee, 2013). Rapee's next randomised trial targeted a higher risk sample of 71 inhibited preschoolers whose parents had an anxiety disorder. At 6-month follow up, intervention children had substantially fewer anxiety disorders than controls (53% vs. 93%; Kennedy, Rapee & Edwards, 2009).

The efficacy trials led to a world first translational trial of Cool Little Kids (Bayer et al., 2011). Population design aspects were a brief parent-report screening tool for inhibition offered universally through preschool services in the year before school, followed by an invitation to parents of all inhibited children to attend the Cool Little Kids parenting group

program in their local community. The translational trial short-term outcomes show that population screening for inhibition was acceptable to parents and they reported the group program was useful for encouraging child brave behaviour and reducing anxiety (Beatson et al., 2014). The outcomes at school-entry (age 5) were a significant reduction in child internalising difficulties across the population (Strengths and Difficulties Questionnaire: abnormal cut-off 24.2% versus 33.0%, $p<.05$; symptoms M(SD) 2.5 (2.0) versus 2.9 (2.2), $p<0.05$). There was little impact on child anxiety disorders at age 5 (44.2% versus 50.2%, $p>0.05$). However, for children with anxious parents internalising symptoms and anxiety disorders were reduced (Bayer et al., 2018).

This study reports on outcomes after two years (in the first year of primary school) of the Cool Little Kids program offered at population level for temperamentally inhibited preschool children to prevent internalising problems. The study also explores predictors of parent engagement in the group program.

METHODS

Trial design and participants

Trial design was published in detail previously (Bayer et al., 2011) and is summarised briefly here. The trial ran in metropolitan Melbourne (population four million), Victoria, Australia (ISRCTN30996662, http://www.isrctn.com/ISRCTN 30996662). Melbourne's 31 local government areas were ranked by census-derived socioeconomic indexes of relative disadvantage (Australian Bureau of Statistics, 2006) and eight areas were selected to provide broad social circumstance. All preschool services offering a government-funded program for 4-year-old children in these districts were invited to participate. The participating preschools (n=307, 78% uptake) distributed an inhibition screening questionnaire to all parents of children enrolled in their year before school in 2011 and 2012 (17,661 enrolled). The research

team received 6,346 completed screening questionnaires from parents (36% response) and posted all a letter of their child's inhibition status and trial eligibility. Parents with an inhibited child (11%; Beatson et al., 2014) were telephoned to explain the trial and mailed the baseline questionnaire with written informed consent (Ethics in Human Research Committee of the Royal Children's Hospital Melbourne 30105A, La Trobe University Human Ethics Committee HEDC13-022). Parents with insufficient English to complete questionnaires were excluded along with children with major health/developmental problems who were considered unlikely to benefit from the intervention. After trial consent a concealed web-based computer-generated randomisation process was implemented (with allocation stratified by preschool) to determine trial arm status for each child.

The Cool Little Kids intervention comprises six, 90-minute manualised[i] parenting group sessions delivered over three months. Parenting groups provide information about the nature of child anxiety and principles of anxiety management, detailed instruction in exposing young children to specific triggers for emotional distress, and methods for parents to reduce overprotective and harsh parenting responses and manage their own worry. Parenting groups were delivered at participating preschools in the local community with after-hours timing (7-9pm) to facilitate attendance by working parents. The parenting groups were delivered by trained clinical psychologists and postgraduate clinical psychology interns[ii] (who were supervised by experienced clinical psychologists). Families in the control arm of the trial had 'usual care' access to available support services in the community. In Australia most young children with socioemotional problems do not receive any help from professional services (Oh, Mathers, Hiscock, et al., 2015; Lawrence et al., 2015). Families in the trial were followed up previously at school-entry age 5-years (Bayer et al., 2018). The present two-year follow up assessed outcomes in the first year of school (age 6). The figure presents the flowchart of participants.

[insert Figure here]

Measures

The child's primary caregiving parent[iii] completed the trial questionnaire at points of enrolment (child inhibition screening, baseline family demographics, parenting practices and parent wellbeing), postintervention (parenting group attendance), one-year follow up (parent skills practice in preparation for school), and two-year follow up (child internalising symptoms, parenting practices, parent wellbeing) together with structured telephone interviews by assessors blind to allocation (child anxiety diagnoses).[iv]

Child inhibition was measured at baseline by the Australian Temperament Project's 7-item approach/inhibition subscale that has sound psychometric properties (Sanson, Pedlow, Cann, et al., 1996; Sanson, Smart, Prior, et al., 1994). This screen mimicked what may be possible if early intervention were to be rolled out in the population.[v] Children scoring above 30 on this measure were considered inhibited (consistent with Rapee's prior trials) and eligible for the translational trial. Broader socioemotional functioning was measured by the Strengths and Difficulties Questionnaire (SDQ: Goodman, 2001). Family demographics at baseline were child sex, birth order, household composition, parent age, education, family income, main language at home, and a neighbourhood disadvantage score (by home postcode: Australia M(SD) 1000 (100); Australian Bureau of Statistics, 2011).

At post intervention parents reported on attendance at the Cool Little Kids group program (0-6 sessions). Engagement in terms of group attendance was categorised for the present study into 'no group sessions', 'introductory sessions only' (1-2 groups) and 'most of the program' (5-6 groups). At one-year follow up parents responded to a questionnaire item describing how frequently they had applied the Cool Little Kids parenting skills with their child in the year after the program (none, a little, about half, most, or all of the time, 1-5).

Engagement in terms of continued skills practice was defined as 'infrequent' (none or a little of the time) versus 'regular' (about half, most, or all of the time).

Child anxiety symptoms at two-year follow up were measured by the Revised Preschool Anxiety Scale (PAS-R: Edwards, Rapee, Kennedy et al., 2010). The PAS-R has 28 parent-report items that cover subscales of specific fears, separation anxiety, social anxiety, and generalised anxiety, combining to form the total score. The PAS-R has convergent validity with child anxiety diagnoses and internalising symptoms (Edwards et al., 2010). Children's broader internalising (anxious/depressive) symptoms were measured by the Children's Moods, Fears and Worries Questionnaire (CMFWQ: Bayer, Sanson & Hemphill, 2006b) that consists of 34 parent-report items and has demonstrated convergent validity with both internalising scales of the Child Behavior Checklist (CBCL) and Behaviour Assessment System for Children (BASC-2) (Andrijic, Bayer & Bretherton, 2013). Child anxiety diagnosis was measured by the Anxiety Disorders Interview Schedule for DSM-IV, Child Version, Parent Interview Schedule (ADIS-CP-IV: Silverman & Albano, 1996) covering separation anxiety disorder, specific phobia, social and generalised anxiety disorders.[vi] The ADIS has good to excellent test-retest reliability, fair to excellent interrater reliability (K = .45-.82), and telephone administration has demonstrated validity with face-to-face interviews (Lyneham & Rapee, 2005). Parenting was measured by the Parent Behavior Checklist (PBC: Brenner & Fox, 1998) nurturing and harsh discipline subscales. The PBC yields T-scores (M(SD) 50 (10)) derived from developmental norms with 6-month age bands. This was supplemented with an overinvolved/protective subscale scored by the mean of items (Bayer et al., 2006a, 2010). Finally, parent distress was measured by the Depression Anxiety Stress Scales (DASS-21: Lovibond & Lovibond, 1995).

Analyses

For the two-year follow up outcomes, trial arms were analysed using the intention to treat principle with participants analysed in the arm to which they were randomised. Continuous, count and binary outcomes were analysed using unadjusted and adjusted Generalised Estimating Equations (GEEs) assuming gaussian, poisson and binomial distributed outcomes respectively and with sandwich estimates of standard error. The GEEs allowed for correlation within preschool which was chosen as the cluster variable. As per protocol (Bayer et al., 2011) potential confounding variables at baseline were statistically adjusted including child sex, parent wellbeing, education and socioeconomic disadvantage.[vii] Means and standard deviations or percentages are presented for each trial arm, along with the mean difference between arms or odds ratio, 95% confidence interval, and *p*-value. We explored a priori interactions between the intervention and baseline parent mental health and child comorbid externalising problems on the child internalising outcomes. R version 3.0.2 (R Core Team, 2013) and package geepack (Hojsgaard, Halekoh & Yan, 2006) were used for the analysis. Missing data were not an issue. When looking at participants retained at two-year follow up, less than 4% of data were missing across outcome and baseline variables used in the adjusted analyses. Next, focusing on the intervention arm, multinomial logistic regression related intervention group attendance to baseline characteristics (demographics, child symptoms, parenting practices, parent distress). Logistic regression related parents' Cool Little Kids skills practice in the year after the program (regular versus infrequent) to the same set of baseline characteristics.

RESULTS

Of 703 inhibited children on the preschool screening questionnaire, parents of 545 (78%) completed the baseline questionnaire and were recruited to the trial (Figure); 265 in the intervention and 280 in the control arms. Table 1 describes the sample characteristics, which were well balanced between trial arms. At two-year follow up (child M(SD) age 6.7 (0.4)

years), 218 (82%) intervention and 245 (88%) control families returned questionnaires, while 213 (80%) intervention and 237 (85%) control families completed their telephone interview. There was no association between loss to follow-up and baseline child internalising symptoms.

[insert Table 1 here]

At two-year follow up (Table 2), children's total anxiety symptoms on the PAS-R were reliably reduced in the intervention versus control arm across the population, with a lower M(SD) total (36.2 (17.2) *vs* 39.4 (18.5), adjusted difference -3.26; 95% CI -6.46 to -0.05, p=0.047) as well as their specific fears subscale (9.1 (6.2) *vs* 10.7 (6.8), adjusted difference -1.53; 95% CI -2.69 to -0.38, p=0.009). There was little difference between the intervention and control arms on broader child internalising (anxious/depressive) symptoms (CMFWQ M(SD): 2.2 (0.5) *vs* 2.3 (0.6); adjusted difference -0.03, 95% CI -0.13 to 0.06, p=0.489) or presence of anxiety disorders (37.6 *vs* 42.6%; adjusted OR 0.8; 95% CI 0.5 to 1.2, p=0.242). Parenting practices and parent distress were also similar in the intervention and control arms in the first year of school. The a priori interaction tests did not significantly moderate children's outcomes at two-year follow up.

[insert Table 2]

Multinomial logistic regression related baseline sample characteristics to the degree of parenting group program attendance (Table 3). The families who were more likely not to attend any group sessions were as follows. Families with very low income (<$25,000) were more likely to attend no groups (80% *vs* 0%). Families with less educated fathers (≤ final year of high school) were more likely to attend no groups (37% *vs* 18%). Families with overseas born fathers were more likely to attend no groups (35% *vs* 24%). Families with younger mothers were more likely to attend no groups (age M(SD): 36.9 (4.8) *vs* 38.7 (4.1)). The families who were more likely to attend only an introductory amount of the intervention

(1-2 group sessions) had overseas born fathers (35% *vs* 23%) and family income in the second lowest bracket (39% $25,000-$51,900 *vs* 20% <$25,000, 25% $52,000-$88,400, 23% >$88,400).

[insert Table 3]

Logistic regression related baseline sample characteristics to intervention parents' degree of Cool Little Kids skills practice with their inhibited child following the program in the year before school (Table 4). Parents were less likely to continue skills practice with girls than boys (40% *vs* 55%), younger preschoolers (age M(SD): 4.6 (0.3) *vs* 4.7 (0.4)), and in more advantaged neighbourhoods (SEIFA M(SD): 1056.1 (41.4) *vs* 1043.4 (42.9)).

[insert Table 4]

DISCUSSION

At two-year follow up (inhibited children's first year of school) Cool Little Kids resulted in reliably lower child anxiety symptoms across the population but no widespread impact on broader internalising (anxious/depressive) symptoms or disorders, parenting practices or parent distress. Families with inhibited preschoolers in the population who were less engaged with the early intervention had younger mothers, less educated and more culturally diverse fathers, and lower household income. Ongoing parent skills practice after the program to prepare inhibited children for school was less frequent with girls and in more advantaged neighbourhoods.

Provision of parenting support is a feature of wealthier nations' health and social care services and studies have explored engagement. Whittaker and Cowley's (2012) review notes that engagement in parenting support programs (generally) by neediest parents can be poor. Barriers experienced by parents may include personal life factors (beliefs, lifestyles, limited resources) and program factors (delivery, content and support arrangements). The authors

state “for programs to stand a chance of working it is logical that at the very least parents need first to attend and second to engage with the sessions provided” (p.140). There is little knowledge in relation to preventing internalising problems from early childhood. A first efficacy trial of online (individual) Cool Little Kids parent education indicated that no consistent characteristics predicted program completion, although parents who engaged in more online modules and home practice were more likely to have girls (Morgan, Rapee, Salim et al., 2017). Comparability of findings is limited, given Morgan et al. was an efficacy waitlist-control study of online parent-education with 24-week follow up, whereas this translational study had population screening for inhibition, local community parenting groups and long-term follow up. The present findings are novel to focus engagement techniques when offering parenting groups in the population to prevent child internalising.

The translational trial has strengths of a) high uptake for population trials (78% of eligible parents), non-participants’ social disadvantage only marginally lower than participants’ (findings generalise to a wide socioeconomic spectrum), psychometric and developmentally sensitive child mental health measures (symptom and assessor-blind diagnosis; Bayer et al., 2018), along with high retention at two-year follow up (86%). The study also has limitations inherent to population-scale design (Bayer et al., 2018). Assessment was single source (primary caregivers) and while primary caregivers are widely recognised to be the most informed source on young children’s socioemotional functioning (Glascoe, 2005) the results could be open to bias as parents can’t be blinded to trial arm in parenting programs although diagnostic assessors were blind. Multisource measures (clinician observation, teacher report) might tap more aspects of child/family functioning, however direct observation is impractical in population studies. Tertiary educated parents were overrepresented in the trial sample, although many disadvantaged families were

recruited. There may have been elevated risk of a type-1 error with the number of analyses conducted and so the findings require replication.

In terms of practical implications and future research, Mian (2014) noted "the greatest challenges to dissemination and establishing effectiveness of early childhood anxiety interventions for high-risk children will likely be related to parents' interest, willingness, or ability to engage in these programs" (p.90). The challenge is similar for young children's externalising problems (Baker, Arnold & Meagher, 2011; Clarke et al., 2015; Shaw, Dishion, Supplee, et al., 2006; Ros, Hernandez, Graziano, et al., 2016). We could know more about why family characteristics predict practice and engagement. Perhaps programs are not sufficiently meaningful to men from diverse cultural backgrounds. If so, culturally relevant tailoring in delivery of parenting support may be helpful. If parents view inhibition as normal in girls ('she's just shy') they may be less likely to practice early intervention skills with girls, or more actively try to reduce inhibition with boys (Doey, Coplan & Kingsbury, 2014). Considering motivational techniques tailored to individual families may be beneficial in further translational research on the Cool Little Kids parenting group program.

CONCLUSION

Follow up of the Cool Little Kids translational trial in children's first year of school (age 6) found some population effects were sustained for anxiety symptoms. However, more significant child internalising problems were not reduced at two-year follow up. Families who were less engaged with the early intervention had younger mothers, less educated and more culturally diverse fathers and lower household income. Ongoing parent skills practice after the program was less frequent with girls and in advantaged neighbourhoods. It would be useful to know more about why particular family characteristics influence engagement in the parenting groups to prevent child internalising and how including motivation techniques that tailor to families in dissemination could be helpful.

FIGURE CAPTION

Flow chart of participants. *Take-up of intervention was voluntary (figures based on post-intervention questionnaire). †All loss to follow-up owing to failure to return questionnaire or complete interview.

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Table 1. Baseline Sample Characteristics by Trial Arm

Variable	Intervention (n=265)	Control (n=280)
Children		
Inhibition, M(SD)	34.0 (2.7)	34.4 (2.8)
Female, n(%)	116 (43.8)	147 (52.5)
Age in years, M(SD)	4.5 (0.4)	4.6 (0.4)
First born, n(%)	134 (50.6)	146 (52.1)
Socio-emotional functioning, M(SD)		
total difficulties	12.3 (6.1)	11.4 (5.3)
emotional	4.2 (2.2)	4.1 (2.2)
conduct	1.8 (1.7)	1.6 (1.4)
Primary caregiver		
Age, M(SD)	37.5 (4.4)	37.6 (4.4)
Relationship		
married/cohabiting, n(%)	242 (91.3)	260 (92.9)
separated/divorced, n(%)	18 (6.8)	16 (5.7)
single/widowed, n(%)	5 (1.9)	4 (1.4)
Born in Australia/New Zealand, n(%)	200 (75.5)	202 (72.1)
English home language, n(%)	238 (89.8)	245 (87.5)
Highest education		
didn't complete high school, n(%)	29 (11.1)	32 (11.6)
high school only, n(%)	63 (24.1)	63 (22.8)
tertiary degree, n(%)	169 (64.8)	181 (65.6)
Wellbeing, M(SD)		

depression	4.4 (5.8)	4.7 (5.8)
anxiety	2.9 (5.0)	2.9 (3.9)
stress	10.3 (7.0)	10.5 (7.5)
Parenting, M(SD)		
over-involved/protective	1.8 (0.3)	1.7 (0.4)
harsh discipline	40.1 (5.7)	40.6 (6.3)
nurturing	52.7 (10.3)	52.5 (9.2)
Family		
Income $AUS pa (optional)		
<$25,000, n(%)	10 (4.4)	11 (4.8)
$25,000 to $51,900, n(%)	36 (15.9)	23 (10.0)
$52,000 to $88,400, n(%)	43 (18.9)	61 (26.5)
>$88,400, n(%)	138 (60.8)	135 (58.7)
Socioeconomic disadvantage, M(SD)	1048 (41)	1044 (44)

Sample size was no lower than 261 in intervention and 276 in control arm (except optional income, 227 intervention and 230 control).

Table 2. Two-year Follow-up Outcomes by Prevention Trial Arm Status

Outcome	Intervention M(SD)/%	Control M(SD)/%	Unadjusted diff./OR	Adjusted diff./OR	95% CI	p-value
Anxiety symptoms (PAS-R)	36.24 (17.22)	39.41 (18.54)	-3.13	-3.26	-6.46, -0.05	0.047
specific fears	9.08 (6.16)	10.68 (6.84)	-1.55	-1.53	-2.69, -0.38	0.009
social	11.18 (5.47)	12.08 (5.75)	-1.01	-1.01	-2.06, 0.04	0.059
separation	4.97 (4.03)	5.34 (4.19)	-0.38	-0.44	-1.18, 0.30	0.246
generalised	11.04 (5.18)	11.24 (5.35)	-0.14	-0.24	-1.17, 0.70	0.619
Internalising symptoms (CMFWQ)	2.24 (0.54)	2.29 (0.59)	-0.03	-0.03	-0.13, 0.06	0.489
>clinical cut-point	16.1	13.9	1.23	1.25	0.74, 2.13	0.408
Any anxiety disorder	37.6	42.6	0.80	0.79	0.53, 1.18	0.242
specific phobia	16.0	20.3	1.36	1.31	0.80, 2.16	0.289
social	25.4	26.2	1.05	1.06	0.68, 1.65	0.806
separation	15.0	11.0	0.70	0.64	0.36, 1.15	0.134
generalised	10.8	8.4	0.72	0.72	0.36, 1.41	0.334
number of diagnoses	0.54	0.55	0.96	0.99	0.74, 1.31	0.915

Parenting						
over-involved/protective	1.58 (0.32)	1.59 (0.32)	-0.01	-0.01	-0.06, 0.05	0.866
harsh discipline	39.70 (5.32)	39.08 (5.17)	0.69	0.64	-0.31, 1.59	0.188
nurturing	49.45 (10.00)	50.50 (9.45)	-0.97	-0.92	-2.67, 0.83	0.302
Parent wellbeing						
anxiety	2.58 (4.01)	2.61 (4.22)	-0.03	0.00	-0.75, 0.75	0.995
stress	9.05 (7.00)	9.80 (8.39)	-0.73	-0.75	-2.22, 0.71	0.312
depression	3.93 (5.32)	4.46 (6.79)	-0.43	-0.43	-1.55, 0.68	0.447

Table 3 Baseline Characteristics in Relation to Parenting Program Attendance

Predictor	**0 *vs* 5-6 sessions**			**1-2 *vs* 5-6 sessions**		
	RRR	**95% CI**	**p-value**	**RRR**	**95% CI**	**p-value**
Demographics						
Child						
age	1.25	0.51-3.06	0.627	1.44	0.59-3.53	0.423
sex	1.41	0.68-2.93	0.355	1.12	0.53-2.36	0.774
birth order	0.48	0.23-1.01	0.052	0.52	0.25-1.10	0.088
Mother						
age	0.91	0.83-0.99	0.029	0.95	0.87-1.03	0.229
education	1.73	0.80-3.72	0.163	1.15	0.51-2.56	0.741
country of birth	0.75	0.33-1.69	0.486	0.57	0.26-1.28	0.175
Father						
age	0.95	0.88-1.03	0.225	0.94	0.86-1.02	0.113
education	2.72	1.24-5.97	0.013	1.07	0.49-2.34	0.863
country of birth	0.39	0.17-0.93	0.034	0.38	0.16-0.90	0.028
Family						
marital status	1.76	0.42-7.41	0.440	0.89	0.16-5.02	0.886
English home language	0.81	0.24-2.71	0.731	0.44	0.15-1.32	0.144
income	0.48	0.30-0.77	0.003	0.56	0.34-0.92	0.020
area disadvantage	1.00	0.99-1.00	0.189	1.00	0.99-1.01	0.621
Child wellbeing						
inhibition	0.86	0.73-1.01	0.060	0.93	0.80-1.07	0.303
internalising	0.84	0.71-1.00	0.055	1.03	0.87-1.21	0.760

externalising	0.88	0.69-1.11	0.279	0.80	0.62-1.04	0.094
Parent wellbeing						
anxiety	0.98	0.91-1.06	0.567	1.00	0.94-1.07	0.941
stress	0.98	0.93-1.03	0.396	0.97	0.92-1.02	0.200
depression	0.97	0.91-1.03	0.291	0.95	0.88-1.02	0.134
Parenting						
over-involved/protective	1.17	0.39-3.47	0.781	2.26	0.78-6.51	0.132
harsh discipline	1.01	0.95-1.08	0.704	1.02	0.96-1.09	0.535
nurturing	0.99	0.95-1.03	0.503	1.00	0.96-1.03	0.808

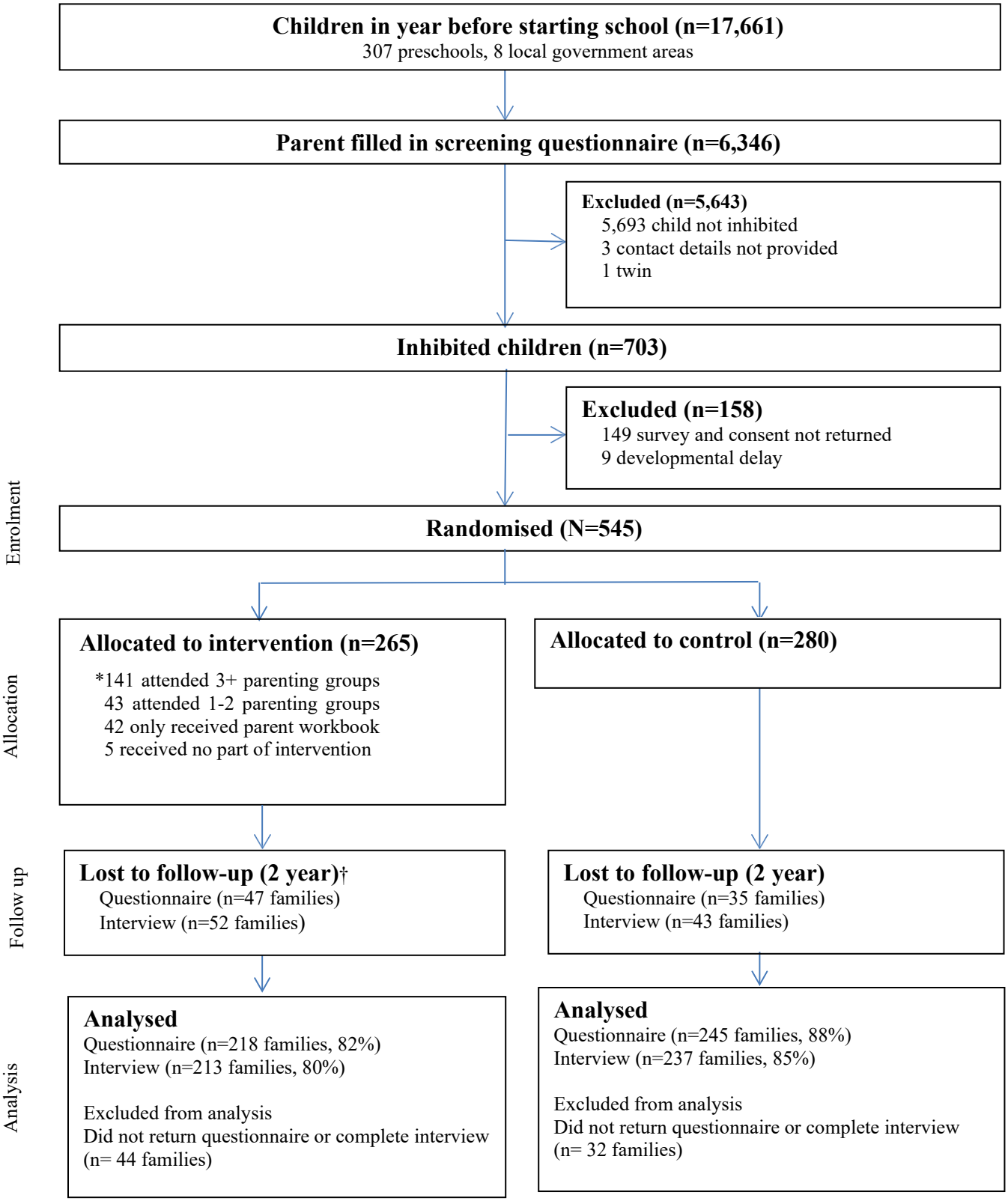
Note: Relative risk ratio (RRR) indicates probability of being in comparison group (none or introductory groups only) compared to the reference group (most of the program). RRR>1 comparison group more likely, RRR<1 reference group more likely.

Table 4 Baseline Characteristics in Relation to Skills Practice Following Program

Predictor	OR	95% CI	p-value
Demographics			
Child			
age	2.48	1.13-5.44	0.024
sex	0.55	0.32-0.96	0.037
birth order	0.81	0.47-1.41	0.459
Mother			
age	1.04	0.97-1.11	0.299
education	0.76	0.42-1.37	0.365
country of birth	0.94	0.50-1.76	0.839
Father			
age	1.02	0.96-1.09	0.475
education	0.93	0.52-1.65	0.795
country of birth	0.98	0.52-1.86	0.983
Family			
marital status	0.95	0.35-2.56	0.914
English home language	0.76	0.31-1.84	0.537
income	0.98	0.69-1.39	0.914
area disadvantage	0.99	0.99-1.00	0.033
Child wellbeing			
inhibition	1.04	0.94-1.16	0.430
internalising	0.95	0.84-1.08	0.453
externalising	1.01	0.86-1.19	0.913

Parent wellbeing			
anxiety	1.04	0.98-1.10	0.187
stress	1.04	1.00-1.08	0.061
depression	1.04	0.99-1.09	0.146
Parenting			
over-involved/protective	0.61	0.27-1.40	0.243
harsh discipline	0.99	0.94-1.04	0.695
nurturing	0.99	0.97-1.02	0.540

Note: Odds ratio (OR)>1 indicates regular practice more likely (regular practice= half the time or more *vs* infrequent practice= none or a little of the time).


Children in year before starting school (n=17,661)
307 preschools, 8 local government areas
Parent filled in screening questionnaire (n=6,346)
Excluded (n=5,643)
5,693 child not inhibited
3 contact details not provided
1 twin
Inhibited children (n=703)
Excluded (n=158)
149 survey and consent not returned
9 developmental delay
Randomised (N=545)
Enrolment
Allocated to intervention (n=265)
*141 attended 3+ parenting groups
43 attended 1-2 parenting groups
42 only received parent workbook
5 received no part of intervention
Allocated to control (n=280)
Allocation
Lost to follow-up (2 year)†
Questionnaire (n=47 families)
Interview (n=52 families)
Lost to follow-up (2 year)
Questionnaire (n=35 families)
Interview (n=43 families)
Follow up
Analysed
Questionnaire (n=218 families, 82%)
Interview (n=213 families, 80%)
Excluded from analysis
Did not return questionnaire or complete interview
(n= 44 families)
Analysed
Questionnaire (n=245 families, 88%)
Interview (n=237 families, 85%)
Excluded from analysis
Did not return questionnaire or complete interview
(n= 32 families)
Analysis

Endnotes

[i] Manual can be obtained from ******, Centre for Emotional Health, Macquarie University, Sydney, Australia.

[ii] National health practitioner provisional registration psychologists completing postgraduate clinical training.

[iii] The child's primary caregiver provided data (not both parents), even if some parents chose to participate in the Cool Little Kids groups as a couple.

[iv] Child anxiety diagnoses were not assessed at baseline. As this was a translational trial, we did not want to over-burden families and wanted delivery as it would typically be in the real world (where formal diagnoses would not be made).

[v] As inhibition is considered a constitutional (biologically based) aspect of temperament (Calkins, Fox & Marshall, 1996) the measure was not repeated as a trial outcome.

[vi] Diagnostic outcome assessors were blind to allocation status via password protected access to randomisation sections of the study database.

[vii] As in other public health trials (Hiscock et al., 2007, 2008) and the 1-year follow up (Bayer et al., 2018) we do not control for 'usual care' (other services received) as the aim is to test intervention effects over and above usual care.