

Preventing preschool mental health problems: Population-based cluster randomized controlled trial

Running head: Preventing child mental health problems: a population trial.

ABSTRACT

Objective

Prevention of child behavior problems may reduce later mental health problems. We compared the effectiveness, at the population level, of an efficacious targeted prevention program alone or following a universal parenting program.

Method

Three arm, cluster randomized controlled trial. 1353 primary caregivers and healthy eight-month-old babies recruited July 2010 to January 2011 from well-child centers (randomization unit). Primary outcome: Child Behavior Checklist (CBCL) externalizing and internalizing scales* at child age three and 4.5 years. Secondary outcomes: Parenting Behavior Checklist* and over-involved/protective parenting (primary caregiver report). Secondary caregivers completed starred measures at age three.

Results

Retention was 76% and 77% at ages three and 4.5 years, respectively. At three years, intention-to-treat analyses found no [statistically](#) significant differences (adjusted mean difference (95% CI; p-value)) for externalizing (Targeted versus Usual Care -0.2 (-1.7 to 1.2; p= 0.76); Combined versus Usual Care 0.4 (-1.1 to 1.9; p=0.60)) or internalizing behavior problems (Targeted versus Usual Care 0.2 (-1.2 to 1.6; p= 0.76); Combined versus Usual Care 0.4 (-1.1 to 2.0; p=0.58)). Primary outcomes were similar at 4.5 years. At three years, primary and secondary caregivers reported less over-involved/protective parenting in both the Combined and Targeted versus Usual Care arm; secondary caregivers also reported less harsh discipline in the Combined and Targeted versus Usual Care arm. Mean program costs per family were \$A218 (Targeted arm) and A\$682 (Combined arm).

Conclusion

When translated to the population level by existing staff, pre-existing programs appeared ineffective in improving child behavior, alone or in combination, but improved parenting.

Abbreviations: CBCL: Child Behavior Checklist; CI: Confidence Interval; LGA: Local Government Areas; MCH: Maternal and Child Health; PBC: Parenting Behavior Checklist; SD: Standard Deviation; SEIFA: Socio-Economic Indexes for Areas.

INTRODUCTION

Mental health problems are common and often preceded by early behavior problems including externalizing (e.g. aggression) and internalizing (e.g. anxiety) problems.¹⁻⁴ Youth mental health problems incur substantial costs across health, educational and justice services.⁴⁻⁷ While prevention of childhood behavior problems is therefore a public health priority, the most effective and cost-effective approach to prevention has not been established.

Prevention can be universal i.e. offered to all, selected i.e. targeted towards those with an above average risk of developing a problem, or indicated i.e. targeted towards those with pre-clinical symptoms of a problem.⁸ Universal prevention has a wider reach and may be less stigmatizing but by its nature will be offered to many who do not need it, and its typical brevity may render it insufficient for those who do. Targeted prevention may be more effective but may stigmatize, miss individuals in need, and is typically more cost and time intensive.⁹

Preventive programs for early child behavior problems typically focus on enhancing adverse parenting practices,⁹ with programs that aim to increase warmth and nurturing and decrease harsh discipline and over-involved/protective parenting being the most effective^{10,11}

However, these programs are usually intensive (up to 10 sessions), have been largely tested in children with parent-reported behavioral concerns (i.e. self-selecting) and not evaluated at a whole of population level. Furthermore, most employed waitlist control designs precluding estimates of longer term effects.

The *Family Check-Up* is a brief, targeted program with substantial evidence for longer term efficacy.⁹ This one-on-one family support program involves in-home sessions delivered by a parent consultant.¹² The consultant focuses primarily on parenting and factors that compromise optimal caregiving quality (e.g. parental wellbeing). They can provide direct skill training (e.g. for parenting) or facilitate referrals to community supports (e.g. for housing difficulties), based on parent goals.

We previously designed and trialed a universal parenting program - *Toddlers Without Tears* - delivered in the first two years of life. While associated with small improvements in parenting, it did not change child behavior at age two years.¹³ Despite this lack of stand-alone efficacy, it remains possible that targeted programs could be enhanced by leveraging off a universal anticipatory guidance platform such as *Toddlers Without Tears*, that might avoid stigma, increase acceptability, enhance reach, and facilitate uptake ([i.e. increase enrolment into a program when eligible](#)) of a more intensive intervention for families in need. However, this stepped approach has not been rigorously tested across a population sample against either a targeted program alone or usual care in the community.

We therefore conducted a three-arm, population-based translational trial to compare, in a community sample of healthy children, the effectiveness, uptake and costs of two population-based approaches to prevention of early behavioral problems, compared to usual care.

We hypothesized that families offered the targeted *Family Check-Up* program, alone or in combination with the universal *Toddlers Without Tears* preventive program, would have better child behavior (primary outcome), parenting, caregiver mental health and caregiver and child quality of life (secondary outcomes) at child ages three and 4.5 years than those who

were not offered any preventive intervention. We further hypothesized that uptake of the targeted program would be greater for the combined group, where the targeted program followed the universal parenting program, than for the targeted program alone.

METHODS

Design and setting

The methodology of this trial has previously been published.¹⁴ Briefly, *Families in Mind* was a three-arm cluster randomized controlled trial conducted in partnership with health and government agencies. Thus, the interventions were largely delivered by staff already employed by the relevant sectors. Ethics approval was obtained from The XX (#29144) and XX (#2010-156) Human Research Ethics Committees.

Eligibility and recruitment

Research staff recruited families from well-child Maternal and Child Health (MCH) centers in nine local government areas (LGA) of XX[U01], Australia. We ranked XX[U02]'s 31 LGA by Socio-Economic Indexes for Areas (SEIFA) index of relative disadvantage and selected three LGAs from each of the low, middle and high tertiles of SEIFA.

MCH nurses (well child nurses) invited all families attending their free eight-month visit from July 2010 to January 2011 to participate. More than 85% of XX families attend these visits.¹⁵ Research staff sent eligible and interested families an enrolment pack. Enrolment occurred when caregivers returned the completed survey and signed consent form. To ensure the study was universal, mail 'mop-up' procedures were conducted for families who did not attend their well-child eight-month visit, i.e. we invited eligible families to hear more about

the study via a letter posted to the family home. We excluded children with a major medical condition and primary caregivers with insufficient English to complete surveys.

Randomization and masking

The 133 MCH centers were grouped into 85 clusters before randomization, to avoid contamination for nurses working across multiple centers. Randomization of clusters was stratified by LGA. Clusters were rank-ordered within each LGA according to the number of participants recruited. An independent statistician used computer-generated block randomization with fixed block sizes of three to minimize the imbalance in the number of participants in each of the trial arms. Randomization [of clusters](#) was performed after recruitment [of families](#), thus ensuring allocation concealment. Once randomized to the Combined, Targeted, or Usual Care trial arms, families and nurses were notified of their group allocation in writing, precluding subsequent blinding to allocation status.

Interventions

Toddlers Without Tears: Families in the Combined arm only were invited to attend the universal *Toddlers Without Tears* parenting group sessions when their child was 15, 18 and 24 months of age. Details of this intervention are published elsewhere.^{16,17} Briefly, sessions included anticipatory guidance on normal development, how to respond to early signs of externalizing and internalizing behaviors and encourage positive behaviors. Strategies to encourage desirable behaviors included praise and rewards whilst strategies to manage problematic behaviors included ignoring, logical consequences, distraction, quiet time and anxiety desensitization. Sessions were led by a nurse and co-facilitated by a parenting expert.

Family Check-Up: At child age two years, primary caregivers completed the Child Behavior Checklist (CBCL), Parenting Behavior Checklist (PBC) and Rothbart's Children's Behavior Questionnaire. As this is a targeted intervention, only caregivers of children deemed 'at risk' of developing future behavior problems were invited to take part. Children were deemed 'at risk' if they scored one standard deviation or more (1) above the normative mean for externalizing behaviors on the CBCL, and/or (2) above the normative mean for harsh discipline parenting on the PBC, and/or (3) below the normative mean for low inhibitory control on Rothbart's scale. These criteria were chosen to replicate those used in previous Family Check Up trials.^{9,12}

Families of at risk children in both the Targeted and Combined trial arms were invited to receive the *Family Check-Up*. Seven parent consultants (provisional psychologists i.e. those completing supervised practice and general registration psychologists, i.e. those who have completed accredited postgraduate training to be a general psychologist) were trained in the *Family Check-Up* program over an initial five day, face-to-face workshop conducted by the program's US authors followed by ongoing, fortnightly supervision by a trained psychologist and a general registration psychologist.

The intervention included an initial "Get-to-know-you" assessment session with the parent consultant meeting families to assess child and family risk and protective factors and learn about the family's current concerns, goals, strengths and challenges. Parents completed questionnaires and the consultant videotaped interactions of parents and children during age-appropriate tasks (e.g. clean-up task). In a second "feedback" session, the consultant relayed information to the families from the first session, including selected video-clips of primarily positive parent-child interaction to highlight parents' strengths and promote motivation for

change.^{18,19} Additional intervention sessions (up to four) were offered to families to work on their goals and concerns.

Usual Care: Families randomized to Usual Care trial arm (controls) were offered no trial intervention but, like both the other arms, could attend the MCH program of up to 10 scheduled well-child visits between birth and five years. Visits can include brief (5-10 minutes) anticipatory guidance on child health, behavior, development and parenting with written parent education materials.

Measures

Table 1 summarizes trial measures. The primary caregiver completed mailed surveys at child age eight months, 12 months, three years and 4.5 years. The eight and 12 month surveys were aggregated to form the baseline survey. The child's MCH center's postcode provided a census-derived index for relative social disadvantage (national mean 1000, standard deviation 100).²⁰ Lower scores represent greater disadvantage.

The primary outcomes were primary caregiver-reported child externalizing and internalizing behaviors at child ages three and 4.5 years. Secondary outcomes included primary caregiver parenting behaviors, caregiver mental health, and caregiver and child quality of life.

At age three years, we asked primary caregivers to pass a survey to the secondary caregiver (where applicable), measuring their views on child behavior, parenting behaviors, over-involved/protective parenting, their own mental health, and age, education and relationship to child. The secondary carer pack was enclosed in a separate envelope and placed in the primary carer pack. At the end of the primary carer survey, we asked the primary carer if there was a secondary carer and if yes, had they passed on the secondary carer pack

Program costs

Costs were estimated in 2014 Australian dollars using project team and provider records. Costs of delivering the *Toddlers Without Tears* program comprised MCH nurses training costs; booking, rescheduling, preparing, and facilitating parent sessions at each time point; and related travel and intervention material costs. Costs of delivering the *Family Check-Up* comprised consultant training costs; booking, preparing and facilitating family consultations; reporting and consulting with supervisors. Program costs were assigned to families who received the relevant component of the intervention. Programs were funded by the project grant and were free to participants.

Sample size

The sample size was based on detecting a reduction of 0.25 of a standard deviation in the mean scores for externalizing and internalizing behaviors on the CBCL at age 4.5 years with 80% power and two-sided significance level of 0.05. With nine LGAs, we anticipated from our previous trial¹⁷ that 60 MCH clusters would be recruited with 20 allocated to each trial arm. In order to allow for correlation between the responses of children from the same cluster, we needed to inflate this figure using a formula that is appropriate when the number of clusters is fixed and known in advance, but the number of participants required per cluster needs to be calculated.²¹ Assuming an intra-MCH center correlation coefficient of 0.03¹⁷ for the primary outcomes, 393 subjects were required in each trial arm, increasing to 492 (total 1476) to allow for 20% attrition by age 4.5 years.

Statistical methods

We conducted an intention-to-treat analysis, with families analyzed according to the trial arm to which their MCH center was randomized. Each of the Combined and Targeted only trial

arms were compared to the Usual Care arm. Analyses of quantitative outcomes and intervention costs (unadjusted and adjusted for potential prognostic factors including trial arm status, child gender, LGA, socioeconomic status and MCH center measured at baseline) were implemented using linear regression with information sandwich (“robust”) standard errors, ~~specifying an exchangeable correlation structure~~ to allow for correlation between responses from the same cluster. Where available, we also adjusted for the baseline value of the outcome variable.

The main reported comparisons of outcomes between the trial arms are based on the analyses of 20 multiply imputed datasets in which missing values were filled in, with the assumption that data were missing at random. Data were imputed using the multivariate normal imputation method with all study variables (trial arm status, outcomes, potential confounders, measures of dose for the *Toddlers Without Tears* and *Family Check-Up* program elements) included in the imputation model. In addition, complete case analyses were carried out to assess how sensitive the findings were to treatment of missing values.

-In a post hoc analysis, we conducted tests of interaction for our primary outcomes at child age three and 4.5 years for subgroups of primary caregiver education (completed high school yes/no) and symptoms of severe depression at baseline (DASS depression scale cut point > 9 (yes/no)).

The proportion of toddlers defined ‘at risk’ whose caregiver took up the *Family Check-Up* program was compared between the Combined and Targeted arms. The economic evaluation comprised a cost-consequences analysis,²² allowing for comparison of the incremental costs against all outcomes of interest (e.g. child behavior).

-All analyses were conducted with STATA version 13.

RESULTS

Figure 1 displays the flow of participants through the study. Of the 1439 families approached by nurses and the 696 identified by the mail mop-up, 1353 (63%) were recruited. Compared with families who chose to take part, those that did not were more likely to attend a center in a lower socioeconomic area (mean SEIFA 1040.3 (SD 40.9) vs 1033.6 (43.8), respectively). Table 2 describes participant baseline characteristics.

1034 (76%) and 1048 (77%) of recruited primary caregivers completed follow-up surveys at child age three and 4.5 years, respectively. At both time points, primary caregivers who were followed-up were more likely to have completed high school than non-responders (92.9% vs 84.9% at three and 92.6% vs 85.8% at 4.5 years, respectively). At three years, primary caregivers who completed surveys the three year follow-up were more likely to come from a higher socioeconomic area than those that did not (Mmean (SD):= 1041.7 (-SD-39.7) vs M=1035.8 (-SD=44.3), p=0.02). Socioeconomic status was similar between the two groups amongst those completing the 4.5 year follow-up than non-responders (completed: Mmean (SD): =1041.1 (-SD-40.3) vs. not completed: M=1037.7 (-SD=42.9, p=0.19)). At three years, 928 primary caregivers reported passing on a pack to a secondary caregiver, of which 774 were completed.

The main reported results are based on the full sample of 1353 families, by imputing missing data for primary and secondary caregivers at three and 4.5 years who would otherwise have been excluded from the analysis.

Child behavior (primary outcome), parenting, quality of life, and parent mental health

Table 3 describes the outcomes at three and 4.5 years, by trial arm. At child age three years, no significant differences were observed between arms for primary caregiver report of externalizing (adjusted mean difference (95% CI; p-value): Targeted versus Usual Care = -0.2 (-1.7 to 1.2; p=0.76); Combined versus Usual Care = 0.4 (-1.1 to 1.9; p=0.60)) or internalizing behavior problems (adjusted mean difference (95% CI; p-value) Targeted versus Usual Care = 0.2 (-1.2 to 1.6; p=0.76); Combined versus Usual Care = 0.4 (-1.1 to 2.0; p=0.58)). There was little evidence of interaction effects based on subgroups defined by primary caregiver education and depression (all $p > 0.05$ the smallest p-value was 0.30, data not shown).

Almost all secondary outcomes were also similar between arms, with some exceptions. At age three years, both primary and secondary caregivers reported less over-involved/protective parenting in both the Combined and Targeted versus Usual Care arm; secondary caregivers also reported less harsh discipline in the Combined and Targeted versus Usual Care arm. At age 4.5 years, primary caregivers reported less harsh discipline in the Targeted arm and less over-involved/protective parenting in the Combined arm, compared with Usual Care.

The results for the complete case analyses were essentially the same as for the main analyses based on imputed datasets. Findings from the complete case analysis of the CBCL internalizing behavior score indicated that Ffor families where both caregivers returned measures, ~~the CBCL internalizing behavior score suggested that~~ the interventions had a more positive effect. However, the analyses of the imputed data did not show this effect for the overall sample and we consider the analyses of imputed data to be more valid here.

The intra-cluster (intra-MCH center) correlation coefficients ~~was zero for all analyses except primary caregiver reported over involved/ protective parenting score and DASS depression score (both 0.005) at 4.5 years and secondary caregiver reported PBC harsh discipline (0.002) at three years~~ (are reported in see Tables 3 and 4^[U03]).

Uptake of the *Family Check-Up* program was similar i.e. 69% (47/68) and 71% (47/66) of eligible families in the Targeted and Combined arms, respectively. Attendance by primary caregivers was also broadly similar (e.g., 69% vs 71% for the first two sessions in the Targeted versus Combined arms, respectively). Twenty six percent of secondary caregivers attended the “Get to know you” session and 20% attended the “feedback” session. Thereafter, between 18-27% of secondary caregivers attended subsequent sessions. For the *Toddlers Without Tears* sessions, around a quarter of families had a secondary carer present at the all three sessions (28%, 23%, 21%, respectively).

Program fidelity

All seven parent consultants completed the initial five-day *Family Check-Up* training workshop and were offered fortnightly group supervision, averaging 28 supervision hours per consultant over the 7-month trial period. In US-based studies, initial training is followed by weekly cross-site case supervision and certification involving review of videotaped consultation feedback and follow up interventions. However, this latter process could be only partially implemented within our service partnerships, funding, and time constraints. Therefore, only two parent consultants achieved full certification by the program’s US authors in delivering the program.

Program costs

The mean costs of the trial intervention program were \$A218 per family in the Targeted arm (\$A208 costs to government and A\$10 costs to family) and A\$682 per family in the Combined arm (\$A516 costs to government and A\$166 costs to family). Cost-consequences analysis is presented in Table 3.

DISCUSSION

In this large translational trial, primary caregivers reported that neither a targeted nor a combined universal-plus-targeted approach to prevention was effective in reducing child behavior problems by age three and 4.5 years. Secondary outcomes were also similar across arms, other than small reductions in over-involved/protective parenting in both intervention arms at three years. Offering both a universal and a subsequent targeted program improved neither reach nor uptake. The mean program delivery costs were quite modest given the intensity and duration of the intervention.

In contrast to our trial, two independent^{23,24} randomized controlled efficacy trials of the *Family Check-Up* conducted in the US found positive outcomes for child behavior, parenting and maternal depression, by primary caregiver report. These differences may reflect several reasons. In our trial, only a relatively small proportion of families in each arm were eligible for and received the *Family Check-Up*. We measured intervention effects at the population level, which would substantially dilute any true effects. Nonetheless, this approach to prevention may reflect the needs of policy makers to see reductions in population prevalence of disorders and represents the outcome of a program that screens children at a whole of population level for risk of behavioral problems. Second, this was a pragmatic translational trial conducted under real-life conditions. Due to budget and time difference restraints, only

two parent consultants achieved certification in delivering the *Family Check-Up* program. Fidelity of treatment has repeatedly been linked to effectiveness with the *Family Check-Up*.²⁵ Third, families in our trial appear better educated and more economically secure than those in the US trials who were recruited through food stamp programs. As such, Australian families may have had less to gain from the program. Fourth, recent analyses of the *Family Check Up* trials have shown greatest improvements in children whose mothers had a history of depression (although we found no evidence for this) or whose parents reported involvement with child welfare or criminality. Triaging children into the program based on these risk factors may have increased program effectiveness.²⁶ Finally, the Australian health system is built on free, universal health care platforms not found in the US. These platforms offer support and advice around parenting and child behavior, thus the impacts of parenting programs in Australia may not be as profound.

The study had a number of strengths. We recruited a large, population-based sample from a broad sociodemographic range and had reasonable retention. We used validated outcome measures and multi-informant measures of the primary outcomes. However, most parents were married, spoke English, had finished formal schooling, and were not experiencing severe disadvantage. Our results may not generalize to single parents, those from non-English backgrounds or those with less education. While caregivers reported subjective outcomes, the small differences between trial arms suggests that response bias was minimal.

CONCLUSIONS

At the whole of population level, neither a combined universal and targeted approach nor a targeted only approach based on the *Family Check-Up* and *Toddlers Without Tears* programs

is effective in reducing child behavior problems. Both may reduce overprotective parenting.

The non-significant effect of these programs on child behavior and parenting in Australia suggest that efficacious strategies for promoting child and family well-being and development may depend on policies that promote social equity through the provision of high quality, affordable and universal education, health care and family support as standard practice. Future research is required at a population level to establish whether similarly

promising parenting programs can prevent child behavior problems. Policy makers must be able to rely on rigorous trials such as this, which include an economic analysis and long term outcomes, to avoid waste and to underscore the need for better prevention of childhood mental health problems.

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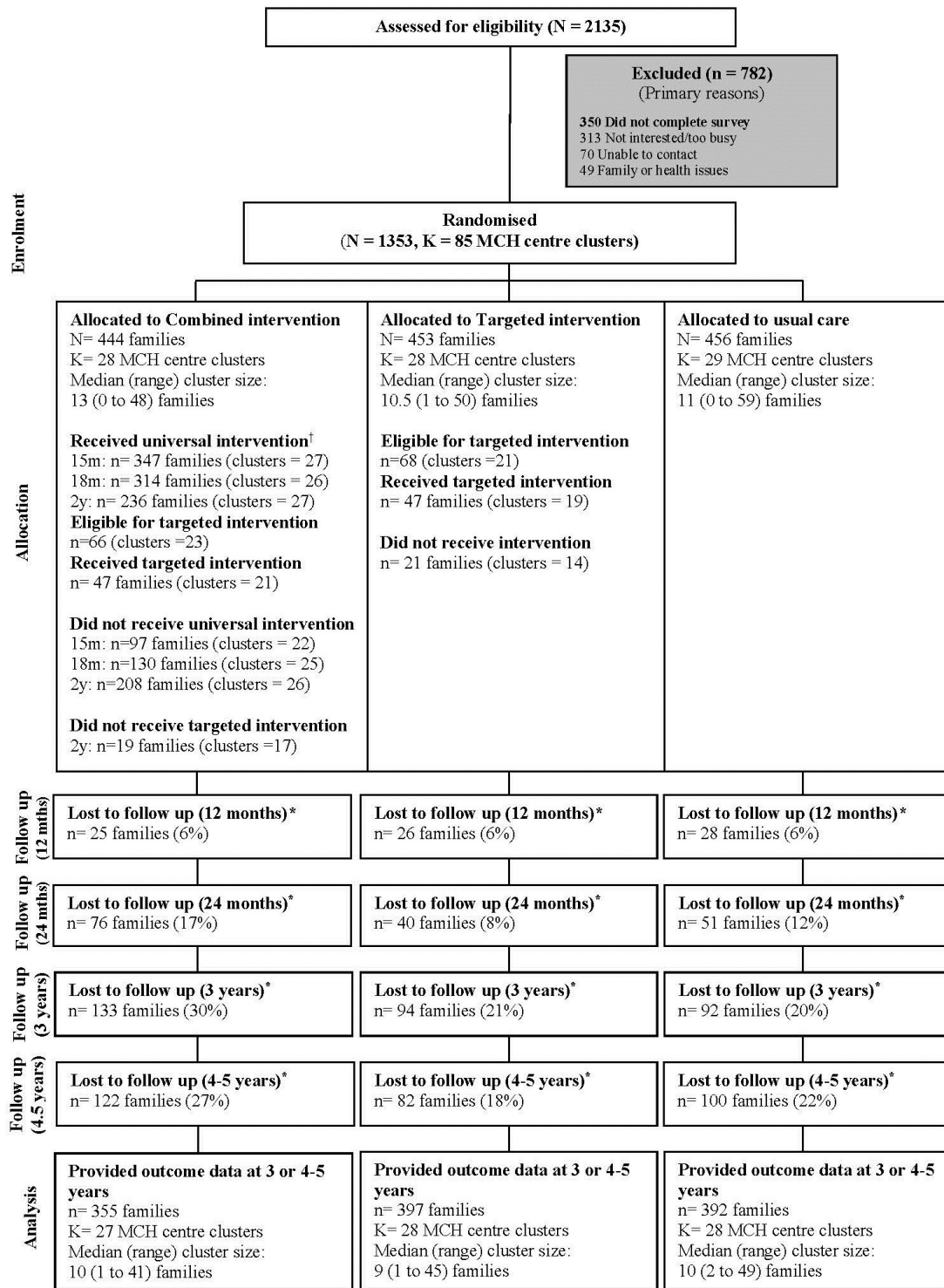
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Figure 1. Flow chart of participants



[†] Take-up of the intervention was voluntary.

* All lost to follow up due to failure to return questionnaires.

Analyses included all recruited participants as these were based on imputed datasets

Table 1: Study Measures

Construct	Description	Baseline	2 years	3 years	4.5 years
Child behavior (primary outcome)	Child Behavior Checklist (CBCL) ²⁷ 1½-5 years old - validated 99-item measure. Responders rate their child’s behavior over the past 2 months as "Not true" (0); “Somewhat or Sometimes true” (1) to "Very true or often true" (2). Subscales of externalizing (24 items) and internalizing (36 items) are averaged with a possible range of 0 to 48 and 0 to 72, respectively. Raw scores converted to standardized T-scores (mean 50, SD 10); T-scores scores ≥ 60 considered to be borderline/clinical.		●	● ▲	●
Parenting Practices	Parenting Behavior Checklist (PBC) ²⁸ - validated 21-item measure; each item has a 4-point scale from “almost never/never” (0) to “almost always/always” (3). Three subscales: harsh discipline (10 items), nurturing (10 items) and expectations (12 items); means generated for each subscale, possible range 0 to 30, 0 to 30 and 0 to 36, respectively, converted to standardized T-Scores (mean 50, SD 10). Higher scores indicate harsher discipline, lower nurturing and inappropriate expectations.	●	●	● ▲	●
Over-involved/ protective parenting	Over-involved/protective parenting scale ¹⁴ - 17 items at child age 2 and 3 years and 8 items at child age 4.5 years. Responders endorse their answers on a 4-point scale from “almost never/never” (1) to “almost always/always” (4). Items were averaged to create a total score with a possible range of 17 to 68 at ages 2-3 years and 8 to 32 at age 4.5 years. Higher scores indicate more over/involved parenting.	●	●	● ▲	●
Relationship satisfaction	Partner Relationship Scale ¹⁴ - Abbreviated to 1 item; respondents describe the degree of happiness of their relationship” on a 7-point scale from “extremely unhappy” (1) to “perfect” (7).	●			
Primary caregiver	Depression, Anxiety, Stress Scale (DASS) ²⁹ - 21-item scale measuring depression, anxiety, and stress	●	●	●	●

mental health	over the past week. Responders endorse statements on a 4-point scale from “Not at all” (0) to “Most of the time” (3). Depression (7 items), anxiety (7 items) and stress (7 items) subscales summed, each with a possible range of 0 to 21.				
Secondary caregiver psychological distress	The Kessler-6 ³⁰ - 6-item measure of psychological distress over a 4-week period. Responders indicate their responses on a 5-point scale from “None of the time” (1) to “All of the time” (5). Total scores are generated by summing responses with a possible range from 6 to 30. Higher scores indicating higher levels of psychological distress.			▲	
Parent quality of life	Assessment of Quality of Life 6D (AQoL-6D) ³¹ - 20-item scale of adult quality of life. Six subscales of independent living (4 items), mental health (4 items), coping (3 items), relationships (3 items), pain (3 items), and senses (3 items). Reported as a single weighted utility score from 1 (full health) or 0 (death equivalent-health related quality of life).	●	●	●	●
Child quality of life	PedsQL ³² - 21-item scale on domains of physical, emotional, social and school functioning. Each item comprises a 5-point scale from “never” (0) to “almost always” (5), generating summary scores of physical (8 items), psychosocial (13 items) and total health (21 items). Scores are transformed with a possible range of 0 – 100. Higher scores indicate better quality of life.			●	●
Family risk factors	Family Psychosocial Screening Instrument ¹⁴ - 12-item public health screen of domestic violence, parent substance abuse, social isolation.	●			
Socioeconomic status	SEIFA Index of Relative Disadvantage ²⁰ , in which each family was assigned a score based on the postcode of the recruiting Maternal and Child Health center (mean = 1000, SD = 100). Higher scores indicate greater advantage.				●

Child inhibitory control	Child Behavior Questionnaire (CBQ) ³³ - 13-item measure of child temperament in early to middle childhood. Participants endorse responses on an 8-point Likert scale from 'Extremely True' (1) to 'Extremely Untrue' (7) or Not applicable (0). Total scores range from 0 to 91 with higher scores indicating lower inhibitory control.		●		
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● = Primary carer ▲ = Secondary carer

Table 2: Baseline characteristics of the intention-to-treat population

Characteristic	Trial arm		
	Usual Care (N=456)	Targeted (N=453)	Combined (N=444)
Child			
Female, %	47.4	47.7	51.4
Age in months, mean (SD)	9.1 (1.1)	9.0 (1.0)	9.0 (1.0)
‘Difficult’ temperament, %	6.5	5.8	6.9
Primary caregiver			
Married/de-facto, %	96.3	96.7	97.3
Age in years, mean (SD)	33.9 (4.8)	33.5 (4.6)	34.2 (4.5)
Anglo Australian, %	81.7	85.7	78.6
Education			
Did not complete school, %	7.0	9.5	9.9
Completed school, %	24.0	31.6	23.1
Degree/postgraduate, %	69.0	58.9	67.0
English main language spoken at home, %	93.4	96.5	93.2
Domestic violence, %	5.8	6.3	3.8
Drinking problem, %	0.7	0.9	0.5
Ever had a drug problem, %	2.2	2.6	1.8
Used drugs in the last 24 hours, %	3.3	3.8	2.7
Social support problems, %	16.2	16.0	17.3
Parenting Behavior Checklist			
Harsh discipline t-score, mean (SD)	44.0 (6.7)	43.6 (6.2)	43.0 (5.9)
Nurturing t-score, mean (SD)	54.7 (8.9)	55.5 (8.1)	54.4 (8.5)
Inappropriate expectations t-score, mean (SD)	44.7 (9.6)	44.6 (9.6)	43.9 (9.1)
Over involved/ protective parenting score, mean (SD)	2.4 (0.4)	2.5 (0.4)	2.5 (0.4)
Depression (mild to extreme), %	10.1	11.3	10.8

Anxiety (mild to extreme), %	7.5	6.8	8.1
Stress (mild to extreme), %	13.2	12.1	13.3
Secondary caregiver			
Age in years, mean (SD)	35.8 (5.2)	35.6 (5.2)	36.6 (5.8)
Education			
Did not complete school, %	20.2	22.6	22.6
Completed school, %	19.9	30.5	26.1
Degree/postgraduate, %	59.8	46.9	51.4
Anglo Australian, %	76.6	78.5	78.3
SEIFA (MCH nurse center), mean (SD)	1043.2 (31.1)	1032.5 (47.1)	1045.4 (41.9)

Table 3: Outcomes by trial arm status for primary carers (imputed data)

Outcome	Usual Care	Targeted vs Usual Care			Combined vs Usual Care			
	Mean (SD)	Mean (SD)	Mean diff* (95% CI)	p	Mean (SD)	Mean diff* (95% CI)	p	ICC[†]
<i>3 years</i>								
<u>CBCL T-score (primary outcome)</u>								
<u>Externalizing</u>	<u>46.5 (9.0)</u>	<u>46.3 (9.5)</u>	<u>-0.2 (-1.7 to 1.2)</u>	<u>0.76</u>	<u>46.9 (9.0)</u>	<u>0.4 (-1.1 to 1.9)</u>	<u>0.60</u>	<u>0.021</u>
<u>Internalizing</u>	<u>44.6 (9.8)</u>	<u>44.8 (10.0)</u>	<u>0.2 (-1.2 to 1.6)</u>	<u>0.76</u>	<u>45.0 (10.0)</u>	<u>0.4 (-1.1 to 2.0)</u>	<u>0.58</u>	<u>0.004</u>
<u>Parenting Behavior Checklist T-score</u>								
<u>Harsh discipline</u>	<u>43.3 (8.0)</u>	<u>42.8 (7.6)</u>	<u>-0.4 (-1.4 to 0.6)</u>	<u>0.44</u>	<u>41.8 (7.6)</u>	<u>-0.6 (-1.7 to 0.5)</u>	<u>0.26</u>	<u>0.048</u>
<u>Nurturing</u>	<u>53.0 (10.6)</u>	<u>53.0 (10.9)</u>	<u>-0.4 (-1.6 to 0.9)</u>	<u>0.55</u>	<u>51.8 (10.9)</u>	<u>-1.0 (-2.3 to 0.3)</u>	<u>0.13</u>	<u>0.044</u>
<u>Inappropriate expectations</u>	<u>58.2 (9.0)</u>	<u>58.3 (8.5)</u>	<u>0.4 (-0.7 to 1.5)</u>	<u>0.46</u>	<u>57.4 (9.1)</u>	<u>-0.5 (-1.7 to 0.7)</u>	<u>0.44</u>	<u>0</u>
<u>Over-involved/ protective parenting</u>	<u>2.4 (0.4)</u>	<u>2.4 (0.4)</u>	<u>-0.05 (-0.10 to -0.01)</u>	<u>0.02</u>	<u>2.3 (0.4)</u>	<u>-0.09 (-0.13 to -0.04)</u>	<u><0.001</u>	<u>0.008</u>
<u>DASS Mental Health score</u>								
<u>Depression</u>	<u>3.7 (4.8)</u>	<u>3.3 (4.6)</u>	<u>-0.4 (-1.0 to 0.2)</u>	<u>0.20</u>	<u>3.2 (4.8)</u>	<u>-0.5 (-1.3 to 0.3)</u>	<u>0.21</u>	<u>0.005</u>
<u>Anxiety</u>	<u>2.4 (3.8)</u>	<u>2.1 (3.8)</u>	<u>-0.2 (-0.8 to 0.3)</u>	<u>0.37</u>	<u>2.1 (3.6)</u>	<u>-0.3 (-0.9 to 0.2)</u>	<u>0.26</u>	<u>0</u>
<u>Stress</u>	<u>9.4 (6.6)</u>	<u>9.3 (6.8)</u>	<u>0.03 (-0.6 to 0.7)</u>	<u>0.93</u>	<u>8.6 (6.2)</u>	<u>-0.8 (-1.6 to 0.1)</u>	<u>0.08</u>	<u>0</u>
<u>Parent quality of life score</u>	<u>0.8 (0.1)</u>	<u>0.9 (0.1)</u>	<u>0.008 (-0.008 to 0.02)</u>	<u>0.32</u>	<u>0.8 (0.1)</u>	<u>0.006 (-0.01 to 0.02)</u>	<u>0.45</u>	<u>0</u>
<u>Child quality of life score</u>	<u>89.4 (8.0)</u>	<u>90.1 (7.7)</u>	<u>0.4 (-0.8 to 1.6)</u>	<u>0.52</u>	<u>89.1 (9.3)</u>	<u>-0.2 (-1.6 to 1.1)</u>	<u>0.72</u>	<u>0.015</u>

4.5 year outcomes

<u>CBCL T-score (primary outcome)</u>									
<u>Externalizing</u>	<u>43.8 (9.1)</u>	<u>44.4 (9.8)</u>	<u>0.3 (-1.1 to 1.7)</u>	<u>0.66</u>	<u>43.8 (9.8)</u>	<u>0.2 (-1.2 to 1.7)</u>	<u>0.78</u>	<u>0.014</u>	
<u>Internalizing</u>	<u>44.4 (10.4)</u>	<u>44.9 (10.6)</u>	<u>0.004 (-1.3 to 1.3)</u>	<u>1.00</u>	<u>44.5 (10.4)</u>	<u>0.2 (-1.4 to 1.7)</u>	<u>0.84</u>	<u>0.003</u>	
<u>Parenting Behavior Checklist T-score</u>									
<u>Harsh discipline</u>	<u>40.1 (5.8)</u>	<u>39.5 (5.0)</u>	<u>-0.8 (-1.5 to -0.1)</u>	<u>0.03</u>	<u>39.4 (5.3)</u>	<u>-0.6 (-1.4 to 0.2)</u>	<u>0.14</u>	<u>0.051</u>	
<u>Nurturing</u>	<u>54.4 (10.2)</u>	<u>54.3 (10.1)</u>	<u>-0.4 (-1.7 to 0.9)</u>	<u>0.53</u>	<u>53.4 (10.5)</u>	<u>-0.7 (-1.9 to 0.5)</u>	<u>0.24</u>	<u>0.038</u>	
<u>Inappropriate expectations</u>	<u>40.9 (10.7)</u>	<u>41.3 (10.2)</u>	<u>0.3 (-1.0 to 1.7)</u>	<u>0.62</u>	<u>39.4 (10.9)</u>	<u>-1.3 (-2.7 to 0.2)</u>	<u>0.08</u>	<u>0</u>	
<u>Over-involved/ protective parenting</u>	<u>1.7 (0.3)</u>	<u>1.7 (0.3)</u>	<u>-0.04 (-0.09 to 0.01)</u>	<u>0.10</u>	<u>1.6 (0.3)</u>	<u>-0.07 (-0.12 to -0.03)</u>	<u>0.002</u>	<u>0.001</u>	
<u>DASS Mental Health</u>									
<u>Depression score</u>	<u>3.6 (5.1)</u>	<u>3.8 (5.6)</u>	<u>-0.1 (-0.9 to 0.7)</u>	<u>0.80</u>	<u>3.1 (4.7)</u>	<u>-0.6 (-1.4 to 0.3)</u>	<u>0.18</u>	<u>0.004</u>	
<u>Anxiety score</u>	<u>2.3 (3.9)</u>	<u>2.7 (4.3)</u>	<u>0.2 (-0.3 to 0.7)</u>	<u>0.42</u>	<u>1.9 (3.2)</u>	<u>-0.4 (-1.0 to 0.1)</u>	<u>0.15</u>	<u>0</u>	
<u>Stress score</u>	<u>9.3 (6.8)</u>	<u>9.2 (7.2)</u>	<u>-0.002 (-0.8 to 0.8)</u>	<u>1.00</u>	<u>8.6 (6.2)</u>	<u>-0.6 (-1.5 to 0.2)</u>	<u>0.15</u>	<u>0</u>	
<u>Parent quality of life score</u>	<u>0.8 (0.1)</u>	<u>0.9 (0.1)</u>	<u>0.007 (-0.009 to 0.02)</u>	<u>0.36</u>	<u>0.8 (0.1)</u>	<u>0.008 (-0.009 to 0.03)</u>	<u>0.33</u>	<u>0.011</u>	
<u>Child quality of life score</u>	<u>88.2 (9.1)</u>	<u>88.4 (10.0)</u>	<u>-0.05 (-1.4 to 1.3)</u>	<u>0.95</u>	<u>87.5 (10.2)</u>	<u>-0.9 (-2.3 to 0.5)</u>	<u>0.20</u>	<u>0.003</u>	
<u>Intervention costs (A\$)</u>	<u>0</u>	<u>218 (717)</u>	<u>223 (138 to 308)</u>	<u><0.001</u>	<u>682 (777)</u>	<u>685 (599 to 771)</u>	<u><0.001</u>	<u>n.a</u>	

†ICC= Intra-cluster correlation from adjusted analysis

*Adjusted for child gender, LGA, SEIFA of MCH center and baseline outcome score where measured and reported. Mean differences are Targeted minus Usual Care and Combined minus Usual Care. N = 1353 for analyses of imputed data.

Table 3: Outcomes by trial arm status for primary carers (imputed data)

Outcome	ICC [‡]	Usual Care	Targeted vs Usual Care			Combined vs Usual Care		
		Mean (SD)	Mean (SD)	Mean diff* (95% CI)	p	Mean (SD)	Mean diff* (95% CI)	p
<i>3 years</i>								
CBCL T score (primary outcome)								
Externalizing	0.021	46.5 (9.0)	46.3 (9.5)	-0.2 (-1.7 to 1.2)	0.76	46.9 (9.0)	0.4 (-1.1 to 1.9)	0.60
Internalizing	0.004	44.6 (9.8)	44.8 (10.0)	0.2 (-1.2 to 1.6)	0.76	45.0 (10.0)	0.4 (-1.1 to 2.0)	0.58
Parenting Behavior Checklist T score								
Harsh discipline	0.048	43.3 (8.0)	42.8 (7.6)	-0.4 (-1.4 to 0.6)	0.44	41.8 (7.6)	-0.6 (-1.7 to 0.5)	0.26
Nurturing	0.044	53.0 (10.6)	53.0 (10.9)	-0.4 (-1.6 to 0.9)	0.55	51.8 (10.9)	-1.0 (-2.3 to 0.3)	0.13
Inappropriate expectations	0	58.2 (9.0)	58.3 (8.5)	0.4 (-0.7 to 1.5)	0.46	57.4 (9.1)	-0.5 (-1.7 to 0.7)	0.44
Over-involved/protective parenting	0.008	2.4 (0.4)	2.4 (0.4)	-0.05 (-0.10 to 0.01)	0.02	2.3 (0.4)	-0.09 (-0.13 to 0.04)	<0.001
DASS Mental Health score								
Depression	0.005	3.7 (4.8)	3.3 (4.6)	-0.4 (-1.0 to 0.2)	0.20	3.2 (4.8)	-0.5 (-1.3 to 0.3)	0.21
Anxiety	0	2.4 (3.8)	2.1 (3.8)	-0.2 (-0.8 to 0.3)	0.37	2.1 (3.6)	-0.3 (-0.9 to 0.2)	0.26
Stress	0	9.4 (6.6)	9.3 (6.8)	0.03 (-0.6 to 0.7)	0.93	8.6 (6.2)	-0.8 (-1.6 to 0.1)	0.08
Parent quality of life score	0	0.8 (0.1)	0.9 (0.1)	0.008 (-0.008 to 0.02)	0.32	0.8 (0.1)	0.006 (-0.01 to 0.02)	0.45
Child quality of life score	0.015	89.4 (8.0)	90.1 (7.7)	0.4 (-0.8 to 1.6)	0.52	89.1 (9.3)	-0.2 (-1.6 to 1.1)	0.72

4-5 year outcomes

CBCL T score (primary outcome)								
—Externalizing	0.014	43.8 (9.1)	44.4 (9.8)	0.3 (-1.1 to 1.7)	0.66	43.8 (9.8)	0.2 (-1.2 to 1.7)	0.78
—Internalizing	0.003	44.4 (10.4)	44.9 (10.6)	0.004 (-1.3 to 1.3)	1.00	44.5 (10.4)	0.2 (-1.4 to 1.7)	0.84
Parenting Behavior Checklist T score								
—Harsh discipline	0.051	40.1 (5.8)	39.5 (5.0)	-0.8 (-1.5 to -0.1)	0.03	39.4 (5.3)	-0.6 (-1.4 to 0.2)	0.14
—Nurturing	0.038	54.4 (10.2)	54.3 (10.1)	-0.4 (-1.7 to 0.9)	0.53	53.4 (10.5)	-0.7 (-1.9 to 0.5)	0.24
—Inappropriate expectations	0	40.9 (10.7)	41.3 (10.2)	0.3 (-1.0 to 1.7)	0.62	39.4 (10.9)	-1.3 (-2.7 to 0.2)	0.08
Over-involved/ protective parenting	0.001	1.7 (0.3)	1.7 (0.3)	-0.04 (-0.09 to 0.01)	0.10	1.6 (0.3)	-0.07 (-0.12 to -0.03)	0.002
DASS Mental Health								
Depression score	0.004	3.6 (5.1)	3.8 (5.6)	-0.1 (-0.9 to 0.7)	0.80	3.1 (4.7)	-0.6 (-1.4 to 0.3)	0.18
Anxiety score	0	2.3 (3.9)	2.7 (4.3)	0.2 (-0.3 to 0.7)	0.42	1.9 (3.2)	-0.4 (-1.0 to 0.1)	0.15
Stress score	0	9.3 (6.8)	9.2 (7.2)	-0.002 (-0.8 to 0.8)	1.00	8.6 (6.2)	-0.6 (-1.5 to 0.2)	0.15
Parent quality of life score	0.011	0.8 (0.1)	0.9 (0.1)	0.007 (-0.009 to 0.02)	0.36	0.8 (0.1)	0.008 (-0.009 to 0.03)	0.33
Child quality of life score	0.003	88.2 (9.1)	88.4 (10.0)	-0.05 (-1.4 to 1.3)	0.95	87.5 (10.2)	-0.9 (-2.3 to 0.5)	0.20
Intervention costs (A\$)	n.a	0	218 (717)	223 (138 to 308)	<0.001	682 (777)	685 (599 to 771)	<0.001

†ICC= Intra cluster correlation

*Adjusted for child gender, LGA, SEIFA of MCH center and baseline outcome score where measured and reported. Mean differences are Targeted minus Usual Care and Combined minus Usual Care. N = 1353 for analyses of imputed data.

Table 4: Outcomes by trial arm for secondary carers

<u>Outcome</u>	<u>Usual Care</u>	<u>Targeted vs Usual Care</u>			<u>Combined vs Usual Care</u>			
	<u>Mean (SD)</u>	<u>Mean (SD)</u>	<u>Mean diff* (95% CI)</u>	<u>p</u>	<u>Mean (SD)</u>	<u>Mean diff* (95% CI)</u>	<u>p</u>	<u>ICC[†]</u>
<u>3 years</u>								
<u>CBCL T-score</u>								
<u>Externalizing</u>	<u>47.5 (8.7)</u>	<u>45.9 (9.9)</u>	<u>-1.1 (-2.7 to 0.5)</u>	<u>0.16</u>	<u>45.8 (9.3)</u>	<u>-1.1 (-2.9 to 0.6)</u>	<u>0.20</u>	<u>0</u>
<u>Internalizing</u>	<u>45.5 (9.6)</u>	<u>44.1 (9.9)</u>	<u>-0.8 (-2.4 to 0.8)</u>	<u>0.32</u>	<u>44.4 (10.2)</u>	<u>-0.9 (-2.5 to 0.7)</u>	<u>0.26</u>	<u>0.008</u>
<u>Parent Behavior Checklist T-score</u>								
<u>Harsh discipline</u>	<u>38.6 (9.4)</u>	<u>37.4 (8.7)</u>	<u>-1.7 (-3.2 to -0.2)</u>	<u>0.03</u>	<u>36.5 (8.6)</u>	<u>-1.6 (-3.2 to -0.05)</u>	<u>0.04</u>	<u>0.064</u>
<u>Nurturing</u>	<u>48.0 (10.6)</u>	<u>46.7 (10.5)</u>	<u>-1.0 (-2.6 to 0.6)</u>	<u>0.21</u>	<u>47.4 (10.4)</u>	<u>-0.5 (-2.5 to 1.6)</u>	<u>0.63</u>	<u>0.058</u>
<u>Inappropriate expectations</u>	<u>36.0 (9.9)</u>	<u>35.0 (9.5)</u>	<u>-0.8 (-2.4 to 0.8)</u>	<u>0.32</u>	<u>34.0 (9.0)</u>	<u>-1.8 (-3.8 to 0.3)</u>	<u>0.09</u>	<u>0.011</u>
<u>Over-involved/ protective parenting score</u>	<u>2.5 (0.4)</u>	<u>2.4 (0.4)</u>	<u>-0.11 (-0.17 to -0.05)</u>	<u>0.001</u>	<u>2.4 (0.4)</u>	<u>-0.14 (-0.22 to -0.06)</u>	<u>0.002</u>	<u>0</u>
<u>K6 psychological distress score</u>	<u>8.7 (3.3)</u>	<u>8.4 (3.1)</u>	<u>-0.3 (-0.9 to 0.2)</u>	<u>0.22</u>	<u>8.6 (3.1)</u>	<u>-0.3 (-0.8 to 0.3)</u>	<u>0.36</u>	<u>0.012</u>

[†]ICC= Intra-cluster correlation from adjusted analysis

*Adjusted for child gender, LGA, SEIFA of MCH center and primary caregiver baseline outcome score where measured and available. Mean differences are Targeted minus Usual Care and Combined minus Usual Care. N = 1353 for analyses of imputed data

Table 4: Outcomes by trial arm for secondary carers

<u>Outcome</u>	<u>Usual Care</u>	<u>Targeted vs Usual Care</u>	<u>Combined vs Usual Care</u>
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	ICC [†]	Mean (SD)	Mean (SD)	Mean diff* (95% CI)	p	Mean (SD)	Mean diff* (95% CI)	p
<i>3 years</i>								
CBCL T score								
Externalizing	0	47.5 (8.7)	45.9 (9.9)	-1.1 (-2.7 to 0.5)	0.16	45.8 (9.3)	-1.1 (-2.9 to 0.6)	0.20
Internalizing	0.008	45.5 (9.6)	44.1 (9.9)	-0.8 (-2.4 to 0.8)	0.32	44.4 (10.2)	-0.9 (-2.5 to 0.7)	0.26
Parent Behavior Checklist T score								
Harsh discipline	0.064	38.6 (9.4)	37.4 (8.7)	-1.7 (-3.2 to -0.2)	0.03	36.5 (8.6)	-1.6 (-3.2 to -0.05)	0.04
Nurturing	0.058	48.0 (10.6)	46.7 (10.5)	-1.0 (-2.6 to 0.6)	0.21	47.4 (10.4)	-0.5 (-2.5 to 1.6)	0.63
Inappropriate expectations	0.011	36.0 (9.9)	35.0 (9.5)	-0.8 (-2.4 to 0.8)	0.32	34.0 (9.0)	-1.8 (-3.8 to 0.3)	0.09
Over-involved/protective parenting score	0	2.5 (0.4)	2.4 (0.4)	-0.11 (-0.17 to -0.05)	0.001	2.4 (0.4)	-0.14 (-0.22 to -0.06)	0.002
K6 psychological distress score	0.012	8.7 (3.3)	8.4 (3.1)	-0.3 (-0.9 to 0.2)	0.22	8.6 (3.1)	-0.3 (-0.8 to 0.3)	0.36

[†]ICC= Intra-cluster correlation

*Adjusted for child gender, LGA, SEIFA of MCH center and primary caregiver baseline outcome score where measured and available. Mean differences are Targeted minus Usual Care and Combined minus Usual Care. N= 1353 for analyses of imputed data

