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Universal parenting programme to prevent early childhood behavioural problems: cluster randomised trial

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ABSTRACT

Objective To determine whether a parenting programme, offered universally in primary care, can prevent behavioural problems in children and improve parenting and maternal mental health.

Design Cluster randomised trial.

Setting 40 primary care nursing centres (clusters) in Victoria, Australia.

Participants 733 English speaking mothers of 8 month old children sequentially recruited from well child appointments; 656 retained at 24 months.

Intervention Structured three session programme at age 18-24 months, co-led by well child providers and a parenting expert. The programme covered normal development and behaviour, strategies to increase desired behaviour, and strategies to reduce unwanted behaviour.

Main outcome measures Maternal report of child externalising behaviour (child behavior checklist 1½ -5 year old), parenting (parent behavior checklist), and maternal mental health (depression anxiety stress scales) at 18 and 24 months.

Results At 18 months, child behaviour and parenting scores were similar in the two groups. At 24 months, externalising scores in the intervention and control groups were similar (mean 11.9 (SD 7.2) v 12.9 (7.4)); however, on the parent behavior checklist subscale scores, intervention group parents were less likely to report harsh/abusive parenting (mean 38.9 (SD 7.7) v 40.5 (8.8); adjusted mean difference −1.83, 95% confidence interval −3.12 to −0.55) and unreasonable expectations of child development (40.9 (9.9) v 42.7 (9.6); −2.18, −3.74 to −0.62). Mean scores for nurturing parenting and maternal mental health were similar in the two groups at both times.

Conclusions A universal parenting programme resulted in modest improvement in parenting factors that predict behavioural problems in children but did not reduce externalising behavioural problems or affect maternal mental health at 2 years.

Trial registration ISRCTN 77531789.
problems: 0.3-0.7 for reductions in parenting risks and 0.3-0.9 for reductions in behavioural problems.\textsuperscript{11,13} Approaches targeting children with family or social risk factors also seem to be effective but have targeted very restricted populations (very disadvantaged young mothers, families eligible for food assistance, and socioeconomically disadvantaged areas).\textsuperscript{11,14-18}

However, all targeted approaches share five possible limitations: misclassification of children on the basis of early risk factors, as at most half of the children who later develop mental health problems have identifiable risk factors and are therefore likely to be targeted by such programmes\textsuperscript{10,19}; stigmatisation, which can lead to poor uptake rates\textsuperscript{20}; delivery to only the minority at highest risk, when most children with subsequent mental health problems come from the numerically much larger “low risk” population\textsuperscript{10}; lack of denominator figures in published studies that are critical to enable estimation of population risk reduction and thus determination of impact at the population level; and a tendency to offer targeted programmes to children of preschool or primary school age, by which time their behaviour may already have had substantial and lasting negative effects.

Universal prevention offered to all families lacks these limitations.\textsuperscript{3} However, no high quality evidence showing the effectiveness of universal prevention has been published.\textsuperscript{24} Here, we report intermediate trial outcomes of the first truly universal parenting programme aiming to prevent early childhood externalising behaviours before onset. As previously reported,\textsuperscript{21} programme content was informed by a review of the literature on intervention (social learning and attachment theoretical perspectives) and developed in partnership with parenting experts and well-child providers. We designed the programme to be suitable for all parents and to be delivered by trained health professionals working in the primary care setting. We hypothesised that families receiving the intervention would report fewer childhood externalising behavioural problems; less harsh discipline, more nurturing parenting, and more reasonable expectations of normal child development; and fewer symptoms of maternal depression or anxiety. We powered the study to be able to detect much smaller effect sizes than those reported for targeted approaches, given that the entire population is the denominator.

\section*{METHODS}
\subsection*{Setting and participants}

We ran the trial in greater Melbourne (population 3.4 million), Victoria, Australia. We ranked Melbourne’s 31 local government areas by the census derived socioeconomic indexes for areas index of relative disadvantage\textsuperscript{25}; we then divided them into thirds representing low, middle, and high socioeconomic status. From each third, we selected two local government areas to provide a broad spread of social circumstance; all maternal and child health nurses in these six local government areas participated. In Victoria, free health visits are scheduled at 1, 2, 4, 6-8, 12, 18, 24, and 42 months of age, and more than 90\% of all parents attend visits during the first six months.\textsuperscript{23} To access a key developmental transition associated with an abrupt rise in parenting challenges (that is, the point at which infants become mobile), maternal and child health nurses consecutively invited mothers of 6-7 month old infants attending in August/September 2004 to take part in the toddlers without tears study. Mothers with insufficient English to complete questionnaires were excluded. The research team telephoned interested mothers and mailed the baseline questionnaire to be returned with written informed consent.

\subsection*{Universal intervention}

The intervention consisted of three sessions targeting key modifiable parenting risk factors for childhood behavioural problems: unreasonable expectations, harsh parenting, and lack of nurturing parenting.\textsuperscript{27,9} At the routine 8 month visit, mothers received four handouts discussing normal child behavioural, motor, and social development over the ensuing 12 months and ways to encourage language development. At 12 months, parents attended a two hour group session discussing ways to develop a warm and sensitive relationship with their toddler and to plan for and encourage desirable behaviour in toddlers. The session introduced the need to plan ahead for “difficult” situations in which toddlers are likely to misbehave and offered alternatives to common “irrational beliefs” by parents that can lead to harsh parenting. At 15 months, parents attended another two hour group session discussing ways to manage unwanted behaviour in children. Rather than smacking and yelling, parents were encouraged to identify “low priority” problem behaviours (for which strategies such as planned ignoring, distraction, and logical choices were discussed) and “high priority” behaviours (for which “quiet time” was discussed). All sessions took place at a local maternal and child health centre and were delivered by a nurse and a co-facilitator expert in running parenting groups. Programme content drew on attachment theory (warm, sensitive parent-child interactions) and social learning theory (reinforcing desired behaviours and extinguishing undesirable behaviours).

Intervention nurses attended a half hour training session (for the 8 month session) and two 2.5 hour training sessions (for the 12 and 15 month sessions) led by HH (paediatrician) and JB (child psychologist) and underpinned by a programme manual and written handouts for parents. Training incorporated didactic teaching, written information, role play, and video vignettes of appropriate parenting responses to common childhood behaviours. The standardised programme manual and training encouraged fidelity to the programme, and nurses completed a checklist at the end of each group session to record components of the intervention delivered.
Usual care
Families in the control arm received usual care from their maternal and child health centre, which may include advice on children’s behaviour but does not include a structured, evidence based parenting programme for early childhood behaviour.

Measures
Mothers completed written questionnaires at 7 months (baseline sociodemographic details, maternal mental health, and family stress), 12 months (baseline parenting style and partner relationship), and 18 and 24 months (outcomes). The primary outcome was externalising behavioural problems measured with the 99 item validated child behavior checklist 1½-5 year old. The checklist also quantifies internalising behavioural problems and yields both raw scores (used in this report to compare groups as our primary outcome) and T scores with a clinical cut point derived from the combined norming sample of children aged 1-5 years (used in this report to describe our sample relative to international norms). Another validated outcome measure was the parent behavior checklist, a 32 item measure of three parenting styles known to contribute to childhood behavioural problems (harsh discipline, nurturing parenting, and expectations of normal development) for parents of preschool (1-5 years) children. The parent behavior checklist yields T scores (mean 50, SD 10) derived from norms with 6 month age bands but no clinical cut points. We measured maternal mental health with the depression anxiety stress scales, a 21 item measure that, as well as mean scores for each subscale, has cut points to indicate risk of depression (score >9), anxiety (score >7), and stress (score >14). We measured children’s temperament, a potential confounder of the effect of the parenting programme, with a parent rated global temperament item (1=“much easier than average” to 5=“much more difficult than average”). Sociodemographic factors included infants’ sex and birth order, maternal age, marital status, education, and language mainly spoken at home. We assigned each family an Australian index of disadvantage score based on the postal code of their home address (72 separate postcodes in the six local government areas, index of disadvantage mean 1044.5, SD 68.9, range 825-1140).

Randomisation
We ran the trial in accordance with the CONSORT statement for cluster randomised trials. We randomised maternal and child health centres (clusters) in the study to minimise the contamination that could occur when participants attending the same centre are randomised to different groups. After recruitment was complete, an independent statistician randomly allocated maternal and child health centres (and therefore their families), stratified by local government area, to intervention or control arms. Within each of the local government areas, a list of participating centres was created. As we considered balance on socioeconomic status to be important, randomisation was done with a computer generated allocation sequence by matching pairs of centres according to the closeness of their average socioeconomic disadvantage scores and then randomising one centre from each pair to the intervention arm. Masking occurred at randomisation, with group allocation concealed from researchers and participants until allocation was complete.

Sample size
To detect a reduction of 0.3 standard deviation units in the mean score for the primary outcomes with 80% power at the two sided significance level of 0.05, 175 children would be needed for each of the intervention and control groups. We inflated this sample size by a design effect of 1.18 to 210 infants per trial arm to allow for correlation between responses within the same cluster (that is, maternal and child health centre), assuming an average cluster size of seven (the number

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Flow chart of participants. *Take-up of intervention was voluntary: 246 families reported receiving intervention. †All lost to follow-up owing to failure to return questionnaires.
of eligible mothers attending each centre) and an intracluster correlation coefficient of 0.03. Assuming a 30% dropout rate, the study needed a final sample size of 300 infants in each trial arm.

Analyses
We analysed the trial arms as randomised at the level of the individual, applying the intention to treat principle. We implemented unadjusted and adjusted analyses (potential prognostic factors listed in table 2) of the outcomes (all quantitative) by using random effects linear regression models fitted by maximum likelihood estimation to allow for the correlation between the responses of participants from the same maternal and child health centre.29 We present means and standard deviations for each trial arm, along with the mean difference between arms, 95% confidence intervals, and P values. We calculated effect sizes by dividing the mean difference between the trial arms by the pooled standard deviation. We used the bootstrap method to validate analyses of all skewed outcomes.30 We used Stata 9.2 for the analyses.

RESULTS
Of the 1069 eligible families, 840 expressed interest and 733 (69%) completed the baseline questionnaire (figure). Non-participating families were more likely than participating families to have low index of disadvantage scores (mean 1033.7 (SD 74.6), range 823-1132, P=0.03), but sex of child was similar in participating and non-participating families. Table 1 describes characteristics of the sample. At 18 months, 299 (91%) intervention families and 373 (92%) control families returned their questionnaires; this fell to 293 (89%) and 363 (90%) at 24 months. All families returned at least one questionnaire. Families who completed the follow-up questionnaires were representative of the baseline sample with respect to sex and temperament of children, maternal education and mental health, and household income and index of disadvantage score.

Programme fidelity
Content checklists completed by nurses indicated that the full programme was delivered for 95% of group sessions. In the intervention arm, 307 (93%) families attended the 8 month visit, 222 (67%) families attended a 12 month group, 185 (56%) attended a 15 month group, and 160 (49%) attended both groups. Primary reasons offered when parents missed group sessions were “family member sick” (52 families), “too busy” (28 families), and “no childcare” (27 families). On average, the number of parents at each group session was seven (range 2-12). The research team mailed the written handouts to all intervention families who missed groups at the maternal and child health centres, 98% of whom subsequently reported receiving the handouts.

Childhood behaviour
Compared with US externalising T score norms for 1-5 year olds (mean 50 (SD 10); 10% above clinical cut point), our sample of toddlers had slightly lower externalising problems at 18 months (mean 49.0 (SD 8.9); 4.5% above clinical cut point) and 24 months (49.5 (9.4); 6%). Internalising problems were also lower.

The mean (raw) externalising behaviour scores were similar in the intervention and control groups at 18 months [mean 12.1 (SD 6.9) v 11.9 (6.8); adjusted mean difference 0.16, 95% confidence interval 0.005 to 0.30] and at 24 months [mean 11.9 (SD 7.2) v 12.9 (7.4); adjusted mean difference −0.79, −2.27 to 0.69; P=0.30]. Mean internalising scores were also similar in the two groups at both 18 and 24 months (table 2).

Parenting
At 18 months, mean harsh discipline and unreasonable developmental expectations scores were similar in intervention families and control families. By 24 months, intervention mothers reported less harsh discipline and unreasonable expectations with their toddlers than did control mothers. For the harsh discipline subscale, the adjusted mean difference of −1.83 (95% confidence interval −3.12 to −0.55; P=0.005) corresponds to an effect size of −0.22 (95% confidence interval −0.38 to −0.07). For the

Table 1 | Baseline characteristics by trial arm. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group (n=329)</th>
<th>Control group (n=404)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Girls</td>
<td>164 (49.8)</td>
<td>193 (47.8)</td>
</tr>
<tr>
<td>First born</td>
<td>184/328 (56.1)</td>
<td>206/403 (51.1)</td>
</tr>
<tr>
<td>'Difficult’ temperament*</td>
<td>17/322 (5.3)</td>
<td>27/395 (6.8)</td>
</tr>
<tr>
<td><strong>Mothers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) age (years)</td>
<td>33.0 (4.8) (n=328)</td>
<td>33.3 (4.7) (n=401)</td>
</tr>
<tr>
<td>Married or cohabitating</td>
<td>318 (96.7)</td>
<td>390 (96.5)</td>
</tr>
<tr>
<td>Currently working</td>
<td>82/328 (25.0)</td>
<td>120 (29.7)</td>
</tr>
<tr>
<td>English spoken at home</td>
<td>317 (96.4)</td>
<td>387 (95.8)</td>
</tr>
<tr>
<td>Highest level of education:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed high school</td>
<td>113 (34.5)</td>
<td>130 (32.2)</td>
</tr>
<tr>
<td>Completed tertiary/postgraduate degree</td>
<td>150 (45.7)</td>
<td>189 (46.8)</td>
</tr>
<tr>
<td><strong>Mental health:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) depression score</td>
<td>4.1 (5.4) (n=328)</td>
<td>3.5 (4.5) (n=403)</td>
</tr>
<tr>
<td>Depressed</td>
<td>46 (14.0)</td>
<td>37/403 (9.2)</td>
</tr>
<tr>
<td>Mean (SD) anxiety score</td>
<td>2.2 (3.6) (n=328)</td>
<td>1.9 (3.1) (n=402)</td>
</tr>
<tr>
<td>Anxious</td>
<td>32/328 (9.8)</td>
<td>27/402 (6.7)</td>
</tr>
<tr>
<td>Mean (SD) stress score</td>
<td>9.0 (6.5) (n=328)</td>
<td>8.8 (6.3) (n=403)</td>
</tr>
<tr>
<td>Stressed</td>
<td>46 (14.0)</td>
<td>50/403 (12.4)</td>
</tr>
<tr>
<td><strong>Family</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household income per annum ($AUS):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 000</td>
<td>27 (9.1)</td>
<td>41 (10.5)</td>
</tr>
<tr>
<td>30 000-60 000</td>
<td>95 (32.0)</td>
<td>129 (33.2)</td>
</tr>
<tr>
<td>&gt;60 000</td>
<td>175 (58.9)</td>
<td>219 (56.3)</td>
</tr>
<tr>
<td>Mean (SD) socioeconomic disadvantage score</td>
<td>1066 (67) (n=325)</td>
<td>1043 (70) (n=401)</td>
</tr>
</tbody>
</table>

*Parent rated child as more difficult than average.
Sample size for adjusted analyses at 18 months ranged from 258 to 261 in intervention arm and was 350 in control arm. Sample size for adjusted analyses at 24 months was 256 in intervention arm and ranged from 340 to 341 in control arm.

Potential baseline confounders included child’s temperament status, and whether mother was depressed, anxious, or stressed.

### Table 2 | Main outcome comparisons

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention arm (I)</th>
<th>Control arm (C)</th>
<th>Unadjusted mean difference</th>
<th>Adjusted mean difference (I minus C)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>18 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Childhood behaviour:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Externalising score</td>
<td>12.1 (6.9)</td>
<td>11.9 (6.8)</td>
<td>0.21</td>
<td>0.16 (−1.01 to 1.33) 0.79</td>
</tr>
<tr>
<td>Internalising score</td>
<td>6.0 (4.2)</td>
<td>5.6 (4.3)</td>
<td>0.40</td>
<td>0.49 (−0.20 to 1.18) 0.16</td>
</tr>
</tbody>
</table>

**Parenting:**

| Unreasonable expectations  | 41.6 (10.4)          | 43.0 (10.3)     | −1.43                       | −1.58 (−3.21 to 0.05) 0.06         |
| Warm nurturing             | 55.4 (9.3)           | 54.8 (9.8)      | 0.43                        | 0.42 (−1.22 to 2.06) 0.62          |
| Harsh discipline           | 42.4 (5.3)           | 42.9 (5.4)      | −0.50                       | −0.72 (−1.54 to 0.10) 0.08         |

**Maternal mental health:**

| Depression                 | 3.4 (4.3)            | 2.9 (4.3)       | 0.43                        | 0.34 (−0.31 to 0.99) 0.30          |
| Anxiety                    | 1.9 (3.4)            | 1.8 (3.1)       | 0.11                        | 0.12 (−0.37 to 0.61) 0.64          |
| Stress                     | 8.2 (5.7)            | 7.7 (6.1)       | 0.47                        | 0.26 (−0.63 to 1.14) 0.57         |

| **24 months**               |                      |                 |                             |                                     |
| Childhood behaviour:        |                      |                 |                             |                                     |
| Externalising score         | 11.9 (7.2)           | 12.9 (7.4)      | −0.97                       | −0.79 (−2.27 to 0.69) 0.30          |
| Internalising score         | 6.4 (6.1)            | 6.4 (6.0)       | −0.02                       | 0.19 (−0.77 to 1.15) 0.70          |

**Parenting:**

| Unreasonable expectations  | 40.9 (9.9)           | 42.7 (9.6)      | −2.03                       | −2.18 (−3.74 to −0.62) 0.006       |
| Warm nurturing             | 53.5 (11.3)          | 53.7 (11.2)     | −0.54                       | −0.67 (−2.75 to 1.41) 0.53         |
| Harsh discipline           | 38.9 (7.7)           | 40.5 (8.8)      | −1.66                       | −1.83 (−3.12 to −0.55) 0.005       |

**Maternal mental health:**

| Depression                 | 3.5 (5.2)            | 2.9 (4.0)       | 0.64                        | 0.67 (−0.11 to 1.45) 0.09          |
| Anxiety                    | 2.0 (3.9)            | 1.9 (3.4)       | 0.06                        | 0.08 (−0.58 to 0.73) 0.82         |
| Stress                     | 8.6 (6.3)            | 8.3 (5.9)       | 0.26                        | 0.09 (−1.04 to 1.23) 0.87         |

Sample size for adjusted analyses at 18 months ranged from 258 to 261 in intervention arm and was 350 in control arm. Sample size for adjusted analyses at 24 months was 256 in intervention arm and ranged from 340 to 341 in control arm. Potential baseline confounders included child’s education level, household income, socioeconomic disadvantage score, child’s temperament status, and whether mother was depressed, anxious, or stressed.

Unreasonable developmental expectations subscale, the adjusted mean difference of −2.18 (−3.74 to −0.62; P=0.006) corresponds to an effect size of −0.22 (−0.38 to −0.06). Mean scores for nurturing parenting were similar in the two groups at both 18 and 24 months (table 2).

**Maternal mental health**

The mean maternal depression, anxiety, and stress subscale scores were not markedly different between the two groups at either 18 or 24 months (table 2).

**DISCUSSION**

A universal parenting programme, designed to prevent early childhood behavioural problems, resulted in modest reductions in maternal report at 24 months of parenting risk factors known to predict such problems.26 27 29 Although the intervention reduced harsh parental discipline and inappropriate developmental expectations, it did not lead to more nurturing parenting (which was high in both groups). The programme was acceptable to parents, was feasible in a routine primary care setting, and achieved greater reach than other reported programmes. However, we showed no significant impact on externalising behavioural problems in 2 year olds or on maternal mental health.

**Strengths**

The study had several strengths. Firstly, a 69% uptake on the basis of eligible birth records is high for population trials.3 Non-participants’ index of disadvantage scores were only marginally lower than those of participants, indicating that our results could be generalised to a wide socioeconomic spectrum, although perhaps not the lowest end. Secondly, we used well validated parent reported outcome measures appropriate to this age group. Thirdly, all clusters and more than 85% of all families remained in the trial, strongly supporting both the validity of the findings and the acceptability of the approach.

**Limitations**

We included single source (maternal report) rather than multi-source assessment, and the results could thus be open to bias as mothers could not be blinded to their group membership. Although primary caregiver report is recognised as the most useful measure of early childhood behaviour,31 multi-source assessment, including maternal report, could assess the family environment and childhood behavioural outcomes more extensively. However, direct observational measures are generally impractical for population based studies of this size,32 and, because many children are not yet attending out of home care on a regular
WHAT IS ALREADY KNOWN ON THIS TOPIC

Behavioural problems affect up to 20% of children and have cumulative personal, societal, and economic ramifications.

Prevention targeted to high risk families can be effective but has limited population reach and may stigmatise recipients.

WHAT THIS STUDY ADDS

By age 24 months, a brief, universally offered parenting programme led to modest improvements in parenting risks known to contribute to child behavioural problems but did not improve maternal distress or toddlers’ behaviour.

Longer term follow-up is needed to determine effectiveness in preventing preschool behavioural problems.

Meaning of the study

This is the first trial to evaluate a parenting programme delivered with a truly universal, as opposed to high risk, sample involving the full spectrum of social advantage through disadvantage. Previous prevention trials targeting existing behavioural problems reported parenting effect sizes ranging from 0.3 to 0.7. Our effect size on parenting behaviours of 0.2, although modest, is therefore promising, given the brevity of this universal prevention programme that started in infancy before the onset of any behavioural difficulties. However, this would only be of value if flow-on effects were shown at a population level at 3 years or beyond.

In conclusion, the outcomes at 2 years are insufficient to support widespread introduction of a very early universal programme to prevent behavioural problems in toddlers. If additional, longer term benefits emerge by preschool age, such universal prevention could be considered as a component of population childhood mental health strategies, in conjunction with effective targeted prevention and clinical treatment programmes.

We thank maternal and child health nurses and families of the Melbourne cities of Glen Eira, Greater Geelong, Kingston, Maribyrnong, Nillumbik, and Stonnington who took part in this research and the co-facilitators from the Parenting Research Centre.

Contributors: HH, JKB, and MW were involved in the conception and design of the study and obtained funding. HH, JKB, SR, and AP were involved with acquisition of study data and, together with OCU and MW, were responsible for analysis and interpretation of the data. OCU did the statistical analysis with assistance from AP. HH and JKB drafted the manuscript with critical revision from OCU, MW, AP, and SR. HH is the guarantor.

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Competing interests: None declared.

Ethical approval: Ethics in Human Research Committee of the Royal Children’s Hospital, Melbourne, Australia (project approval 24020A).


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