APPENDIX 12E: CLINICAL EVIDENCE –STUDY CHARACTERISTICS TABLES: INTERVENTIONS AIMED AT IMPROVING THE IMPACT OF AUTISM ON THE FAMILY

1.1 CHARACTERISTICS OF INCLUDED PSYCHOSOCIAL INTERVENTION STUDIES

1.1.1 TONGE2006

Study ID	TONGE2006
Bibliographic reference	Tonge B, Brereton A, Kiomall M, Mackinnon A, King N, Rinehart N. Effects on parental mental health of an education and skills training program for parents of young children with autism: a randomized controlled trial. Journal of the American Academy of Child and Adolescent Psychiatry. 2006;45:561-569. Tonge B, Brereton A, Kiomall M, Mackinnon A, Rinehart NJ. A randomised group comparison controlled trial of 'preschoolers with autism': a parent education and skills training intervention for young children with autistic disorder. Autism. In press, 2012. Available from: http://aut.sagepub.com/content/early/2012/09/11/1362361312458186.abstract..
Methods	**Allocation:** Randomised **Matching:** Initial allocation between one of two geographically separate metropolitan regions and one of two rural regions was made by computer-generated random numbers to either a treatment intervention region or a control region. Intervention subjects were then randomly allocated to either of the two active intervention conditions. **Blindness:** The inclusion of an attention-placebo control condition means that for comparisons between the two active intervention arms the participants were blinded. However, active intervention versus no intervention control comparisons were non-blind and intervention administrators were non-blind for all conditions. For follow-up clinician-rated outcome measurements the outcome assessor was blinded. **Setting:** Not reported **Raters:** Parent-rated and clinician-rated **Country:** Australia
Participants	**Diagnosis:** DSM-IV Autistic disorder **Coexisting conditions:** None reported **Qualifying Diagnostic Assessment:** The DSM-IV diagnosis was based on a multidisciplinary assessment including a medical review, a speech and language assessment, developmental and cognitive assessment, a family and developmental history, the Autism Diagnostic Interview-Revised (ADI-R), Childhood Autism Rating Scale (CARS), observation of the child in the company of other children at preschool or school, and a standardized clinical interview with the parents and child. **N:** 105 (N=105 were randomised but demographic and efficacy data was only reported for the completers, N=103) **Age:** Child age: 2.5-5.7 years (mean: 3.9 years); Principal caregiver age: 25-43 years (mean: 33.9 years) **Sex:** 16% female **Ethnicity:** Not reported **IQ:** 12-127 (mean: 59.2; as measured by the Psychoeducation Profile-Revised [PEP-R] - Developmental quotient) **Inclusion criteria:** Parents were included if they had: children who were aged 2.5-5 years who had received a DSM-IV diagnosis of autistic disorder within the

	last month (recruited via consecutive referrals to two metropolitan and two rural regional assessment services for young children suspected of having autism); adequate English language skills to complete questionnaires and participate in the intervention programs **Exclusion criteria:** Parents were excluded if their children had: a diagnosis of PDD-NOS or Asperger's disorder; previously participated in an intensive ABA programme
Interventions	**Experimental Intervention: Parent education and behaviour management (PEBM) training intervention versus parent education and counselling (PEC) intervention:** This study included two active intervention arms, the PEBM as the experimental intervention and the PEC as an attention-placebo condition to control for non-specific effects of the intervention. Both interventions were manual-based (Brereton & Tonge, 2005). Intervention consisted of both small group parent training sessions and individual family sessions. Group sessions (for both PEBM and PEC) included: education about autism; features of communication, social, play, and behavioural impairments; principles of managing behaviour and change; teaching new skills; improving social interaction and communication; services available; managing parental stress, grief and mental health problems; and sibling, family and community responses to autism. The key 'active' ingredient which differed between PEBM and PEC intervention arms was that in the PEBM individual family sessions the parents were provided with workbooks, modelling, videos, rehearsal (with child when present), homework tasks and feedback, while for the PEC intervention although the educational material in the manual was the same no skills training or homework tasks were set for the individual sessions and the emphasis was on nondirective interactive discussion and counselling. Both of these interventions were also compared against a no-treatment control group. **Delivery of intervention:** Intervention was delivered by special educators or psychologists who had experience working with children with autism and their parents, and group size for the group component was 4-5 **Format or method of administration:** Individual and group-based **Intensity:** Paper reports that planned intensity was achieved. Intensity was 25 hours (alternate 1.5 hour/week group sessions and 1 hour/week individual family sessions) **Duration of intervention:** 20 weeks **Total duration of follow-up:** 46 weeks (including follow-up at 6-months after the completion of intervention)
Outcomes	**Direct outcome:** **Impact on the family** (as measured by the General Health Questionnaire [GHQ-28] - Total score and Somatic symptoms, Anxiety and insomnia, Social dysfunction, and Severe depression subscales; Parenting Stress Thermometer - visual analogue rating of general stress level; and McMaster Family Assessment Device [FAD] - general family function) **Indirect outcomes:** **Core autism feature: Overall autistic behaviours** (as measured by the Developmental Behaviour Checklist [DBC] - Autism Screening Algorithm [ASA]; and the Childhood Autism Rating Scale [CARS] - Total score) **Behaviour that challenges** (as measured by the Developmental Behaviour Checklist [DBC] - Total Behaviour Problem Score [TBPS]) **Coexisting problems or disorders: Adaptive behaviour** (as measured by the Vineland Adaptive Behaviour Scale [VABS] - Communication, Daily Living

	Skills, and Socialization subscales); **IQ** (as measured by the Psychoeducational Profile-Revised [PEP-R] - Developmental Quotient [DQ]); **Fine and gross motor skills** (as measured by the VABS - Motor skills subscale); **Speech and language** (as measured by Reynell Developmental Language Scale - Comprehension and Expressive Language subscales)
Study Design	RCT
Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to insufficient detail reported with regards to allocation concealment and significant pre-intervention group differences (Children in the control group were significantly older than either of the experimental groups [p=0.005], and had a higher PEP-R DQ [p=0.026], and Reynell expressive [p=0.002] and comprehension [p=0.006] language scales. The PEAC group also had significantly more autism symptoms on the CARS [p=0.009] and the DBC-ASA [p=0.039] than the control group. Controls also had significantly lower scores on the VABS daily living [p=0.004] and socialization [p=0.008] domains than the PEBM group. Finally, the PEBM group had significantly higher scores than the PEAC group on the VABS communication [p=0.004], socialization [p=0.007], and motor [p=0.049] domains) 2. High risk of performance bias as intervention administrators were non-blind 3. High risk of response bias (for the comparison with treatment-as-usual) as participants were non-blind 4. Risk of detection bias is different for different outcomes and outcome measures and depending on comparison 5. Risk of selective reporting bias is unclear/unknown as the trial protocol was not registered on ClinicalTrials.gov or ISRCTN 6. High risk of other bias due to potential conflict of interest as the manuals used in this study have been published by Jessica Kingsley Publishers, and the authors receive royalties (5%) from sales
Notes	Some discrepancy between inclusion criteria and demographics as the youngest age range (as reported in participant demographics) falls below the age range defined in the inclusion criteria. The two active intervention arms were initially compared and where there were no significant differences the groups were combined and entered into meta-analysis. Where there was a significant difference between active intervention arms the data from each active intervention arm (relative to treatment-as-usual) was entered into the meta-analysis as subgroups (with the subtotal function disabled).

1.2 EXCLUDED PSYCHOSOCIAL INTERVENTION STUDIES

Study	Reason for exclusion
Dillenburger K, Keenan M, Gallagher S, McElhinney M. Parent education and home-based behaviour analytic intervention: an examination of parents' perceptions of outcome. Journal of Intellectual and Developmental Disability. 2004;29:119-130.	Non-randomised group assignment
Erguner-Tekinalp B, Akkok F. The effects of a coping skills training program on the coping skills, hopelessness, and stress levels of mothers of children with autism. International Journal for the Advancement of Counselling. 2004;26:257-269.	Non-randomised group assignment
Giarelli E, Souders M, Pinto-Martin J, Bloch J, Levy SE. Intervention pilot for parents of children with autistic spectrum disorder. Pediatric Nursing. 2005;31:389-399.	Sample size was less than ten participants per arm (N<10/arm)
Keen D, Couzens D, Muspratt S, Rodger S. The effects of a parent-focused intervention for children with a recent diagnosis of autism spectrum disorder on parenting stress and competence. Research in Autism Spectrum Disorders. 2010;4:229-241.	Non-randomised group assignment
Samadi SA, McConkey R, Kelly G. Enhancing parental well-being and coping through a family-centred short course for Iranian parents of children with an autism spectrum disorder. Autism. 2013;17:27-43.	Non-randomised group assignment
Schreibman L, Kaneko WM, Koegel RL. Positive affect of parents of autistic children: a comparison across two teaching techniques. Behavior Therapy. 1991;22:479-490.	Sample size was less than ten participants per arm (N<10/arm)
Shields J, Simpson A. The NAS EarlyBird programme: preschool support for parents of children with autistic spectrum disorder. Good Autism Practice. 2004;5:49-60.	Non-randomised group assignment
Zingale M, Belfiore G, Monegelli V, Trubia G, Buono S. Organization of a family training service pertaining to intellectual disabilities. Journal of Policy and Practice in Intellectual Disabilities. 2008;5:69-72.	Non-randomised group assignment