Baby Triple P for Preterm Infants

A randomised controlled trial

Child outcomes at 24 months corrected age

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Background

- Infants born very preterm (VPT) (<32 weeks) at higher risk for:
  - Motor and cognitive abnormalities (Bhutta et al 2002, Spittle et al 2014)
  - Language, behavioural and emotional problems (Spittle et al 2009)

- Previous interventions: high-cost, post-discharge (home-visits)
  - Accessed by few VPT infants
  - Improvements not sustained at school age

- Parents – depression, anxiety, post-traumatic stress

Background cont.

- A need for an early intervention that:
  - Focuses on sustained environmental enrichment via enhanced parenting practices
  - Cost effective
  - Addresses sustainability

Baby Triple P for Preterm Infants

RCT aim and hypotheses

Aim: to determine the efficacy of Baby Triple P for Preterm Infants in enhancing child development at 24 months ca

Hypotheses: Intervention group children

- lower levels of problematic behaviour (primary outcome)
- higher cognitive, language and motor skills (secondary outcome)

Funded by NHMRC

Method

Participants:

Infants (<32 weeks) and parents, with no major congenital anomalies

Recruited at Royal Brisbane and Women's Hospital (RBWH) and Mater Mothers' Hospital (MMH)

- February 2012 to April 2015

Design:

Randomised, controlled trial, 2 conditions: intervention, CAU

Procedure:

Parents completed baseline questionnaires

Family units randomised (stratified for site, risk of brain injury: high/low)

The Intervention

Slightly modified version of Baby Triple P

Group sessions (in hospital)

- Session 1: Survival skills
- Session 2: Partner support
- Session 3: Positive parenting
- Session 4: Responding to your baby

Telephone sessions

(at home beginning at 2 weeks corrected age)

- Session 5-8: Using positive parenting strategies 1-4

Key Differences

Flexible delivery format DVD of sessions with phone support for those back-transferred before session completion

The Intervention cont.

- At 6 weeks ca – linked with local Triple P community support
- Fortnightly text message reiterating content – 2 years

Examples:

"Triple P tip: Taking care of yourself by resting will ensure you are taking care of your baby's greatest asset - you. P76"

"Triple P Tip: To assist your toddler's language be available to listen, encourage questions & attempts at speech, talk about what you are doing-lang. tip sheet"

- Triple P tip sheets every 3 months

Measures

24 months ca

Child Behaviour

- Infant Toddler Social Emotional Assessment (ITSEA) Carter, Briggs-McGowan (2006)
  - mother reported
  - problem scales
  - 3 domains: behavioural dysregulation, externalising and internalising behaviour

- Observed chid aversive/non-aversive behaviour
  - Mother-toddler 15-minute video recorded observations
    - Clinical setting, coded with Family Observation Schedule – Revised (Sanders et al 1996)

Measures cont.

Cognitive, Language and motor skills

- Bayley Scales of Infant & Toddler Development (Bayley-III; Bayley 2005)
  - Conducted in clinical setting by trained psychologists and physiotherapists

Communication and Symbolic Behavior Scales Developmental Profile (CSBS DP; Morgan et al 2013)

Completed during 'parent busy' task
24-item screening tool for early identification of communication impairment
Communication (use of communication, eye-gaze, gestures), expressive speech (words & sounds), symbolic composite (understanding words and using objects)

Results

- 1067 families assessed for eligibility
- 287 back-transferred before approach
- 323 declined
- 33 excluded due to congenital abnormality
- 34 insufficient English
- 19 placed into Departmental care

Results

323 families of 384 infants randomised

n = 162 intervention n = 161 CAU

Infants: 41% female mean ga 28.5 weeks (SD=2.1)
57 twins, 2 triplets

Mothers: Mean age 30.6 years (SD=5.8)
No previous children 60%
Speak only English at home 90%
Planned pregnancy 71%
Married or living with partner 89%
University degree or post grad 40%, high school or less 26.5%
High financial stress 12%
Accessed mental health services in previous 12 months 27%

Results cont.

Intervention (n=162)

Received all 8 sessions (n=108)

Received 7 sessions (n=6)

Received 6 sessions (n=4)

Received 5 sessions (n=5)

Received 4 sessions (n=6)

Received 3 sessions (n=2)

Received 2 sessions (n=7)

Received 1 session (n=10)

Received 0 sessions (n=14, including 1 died and 1 removed to Department care)

N = 114 successfully completion (7 or 8 sessions)

Of those who completed the first 4 sessions (n=129)

67% all face-to-face

30% combination of face-to-face and DVD

3% DVD only.

Mode of delivery unrelated to successful completion

More likely to complete if infant ELBW, university or trade education, no financial stress

More intervention mothers accessed Triple P community services than CAU mothers (17% v 10%, $p = 0.046$)

Results cont. – Outcome Measures

Child behaviour – Parent report

Measure	Intervention (N = 171) Mean (95% CI)	CAU (N = 163) Mean (95% CI)	Adjusted Difference (95% CI)	P value
ITSEA[a]				
External	45.4 (44.1 – 46.8)	45.1 (43.7 - 46.5)	0.3 (-1.6 – 2.2)	0.8
Internal	43.8 (41.8 – 45.7)	45.2 (43.1 – 47.3)	-1.4 (-4.3 – 1.3)	0.3
Dysregulation	45.1 (43.2 – 47.1)	44.9 (42.9 – 46.9)	0.2 (-2.5 – 3.0)	0.9

	Intervention n(%)	CAU n(%)	OR (95% CI)	P value
Categories of concern*				
External	9(5.3)	2(1.2)		
Internal	10(5.8)	15(9.2)		
Dysregulation	12(7.0)	15(9.2)		
Any of Concern	22 (12.9)	23(14.1)	0.9 (0.4 – 1.68)	0.7

Child behaviour – observed

- No group differences on observed aversive ($p = 0.9$) or non-aversive ($p = 0.7$) child behaviour

Results cont.

Cognition, language and motor skill

Domain	Intervention		CAU		P value
	n	Mean (95% CI)	n	Mean (95% CI)	
Bayley-III					
Cognition	160	98.5 (96.2 – 100.8)	155	95.0 (92.5 – 97.4)	0.04
Language	156	96.0 (93.1 – 98.8)	148	92.2 (89.2 – 95.2)	0.07
Motor skill	150	99.6 (97.5 – 101.7)	148	94.1 (91.9 – 96.3)	<0.001

Motor skill - 0.36 (SD) Cognition - 0.23 (SD)

	Intervention		CAU		P value
	n	Mean (95% CI)	n	Mean (95% CI)	
CSBS DP	161		150		
Total score		47.1 (45.8 – 48.4)		45.7 (44.3 – 47.1)	0.16
Communication composite		20.6 (20.0 – 21.2)		20.3 (19.7 – 21.0)	0.50
Expressive speech composite		11.6 (11.1 – 12.0)		11.3 (10.8 – 11.2)	0.33
Symbolic composite		14.8 (14.4 – 15.3)		14.1 (13.7 – 14.6)	0.03

Discussion

Baby Triple P for Preterm Infants – better cognitive, motor and symbolic communication skills at 24 months CA for children in the intervention group, however there were no condition differences for child behaviour.

Effect for motor skill (0.36 SD) is larger than in Cochrane review (0.10 SD) (Spittle et al 2015)

Child behaviour?

- Floor effects
- Strategies not able to be implemented immediately
- On average 58% of tip sheet support phone calls participated in

Discussion cont.

Strengths:
Hospital-based intervention continuing into existing community-based support

Flexible mode of delivery

- 33% of families completed intervention via some DVD

Where to from here?

Conflict of interest statement

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