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Effectiveness and Cost-Consequences of FNP in England in Reducing Maltreatment and Improving Child Health and Development by Age Seven Years

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Randomized Clinical Trials of Nurse-Family Partnership Seminar Series 17th Feb 2021

My talk

- FNP in England
- Our original trial
- Moving on to BB:2-6
- Cohort study design
- Our results
- Questions



Contribution to BB:2-6 cohort study



- I declare no conflicts of interests
- I acknowledge all teams and families who have contributed to these studies
- Acknowledge funding from NIHR PRP, NIHR PHR programmes

The need?

Children of teenage mums ...

- Lower birthweight
- Not be breast fed
- Greater risk of accidents and early death
- Do worse educationally
- More emotional & behavioural problems
- Become teenage parents themselves



Policy response in England

- Specialist community public health nurses: support new mothers and children
 - Healthy Child Programme
- 2006 Reaching Out: an Action Plan on Social Exclusion
 - HMG: initial testing of Family Nurse Partnership (FNP)
 - 10 sites, one per region/SHA from 2007



Reaching Out: An Action Plan on Social Exclusion

HM Government



Adaptation, feasiblity testing and roll-out

Maternal age: proxy for low income, easily measurable, associated with long-term clinical outcomes

Linguistic adaptation of programme materials

Specialist psychological support: *nurse supervision, safeguarding supervision and systems, FNP within local clinical governance*

Motivational Interviewing: as core training, focus on guiding

Implementation evaluation reported by phase: feasibility and acceptability of FNP in England (e.g. Barnes et al 2008)

National management via consortium: Tavistock and Portman NHS Foundation Trust, Impetus Trust, Social Research Unit at Dartington

Programme expanded to 16,000 places at 135 sites in England



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Building Blocks trial



Design

- Pragmatic, open, individually randomised controlled trial
- FNP + normally provided care vs normal care alone

Participants (1600 women)

- *Included:* Nulliparous, aged 19 or under, recruited by 24 weeks, in FNP catchment area, able to consent
- *Excluded:* planning to adopt, leave study area (3+months), required interpreter for FNP delivery

Randomisation (2009-2010)

- Following baseline assessment automated remote allocation
- Allocation 50% FNP : 50% Usual Care
- Stratification by site, minimised by gestation, smoking status and language of data collection
- Intention to treat analysis

Data model

• Individual consent, self-reported and routine EHRs, identifiable data linked & held at CTR





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Primary, select secondary outcomes



We found ...

No evidence of difference

- For 1°outcomes
- Initiation and duration of breastfeeding
- Cognitive delay at 12 & 18 months
- Injuries and Ingestions: GP, A&E, attendances, admissions

Evidence of a difference

- Breastfeeding intention (higher FNP)
- Cognitive delay at 24mths (lower FNP)
- Language delay 12 & 18mths (lower FNP)
- Language (ELM) 24mths (higher FNP)
- Safeguarding procedure in GP notes (higher in FNP)



Context, Comparator, Population



	Emira (n=400) 1977	Memphis (n=1138) 1987	Denver (n=735) 1994	England (n=1618) 2009
Setting:	Single semi-rural site 5 nurses	1 regional PH centre 12 nurses	21 clinics, one metropol. area 10 nurses	18 LAs across England 131 nurses
Control:	Developmental screening & referral, taxis	Developmental screening & referral, taxis	Developmental screening & referral, taxis	See next
Eligible	 At least one of: Age<19 yo Single Lower SES 	 At least two of: Unmarried <12 yrs educ Unemployed 	One of: • Medicaid qualified • No health insurance	• Age <20

... hence rationale for a trial in England

What was the comparator in England of 2009-13, and for BB:2-6?



Midwifery contacts n(SD)*:

• UC 10.69 (5.34), FNP 10.68 (5.25)

Specialist community public health nurse contacts n(SD)**:

- clinic: UC 6.31 (7.07), FNP 0.70 (2.92)
- home: UC 5.01 (5.5), FNP 4.70 (7.81)

Surveyed 161 non-/statutory services (18 sites)

* Late pregnancy, ** By 18 months

Robling M, et al. BMJ Open 2018;8:e020152. doi:10.1136/bmjopen-2017-020152

Delivery of FNP in BB:0-2 trial





	Phase		20 4
Indicators of FNP client visit experience	Pregnancy	Infancy	Toddlerhood
Women randomised to and enrolled in the FNP (n)	697	697	697
Women not receiving any valid visits, n (%)	6 (0.7)	40 (5.7)	98 (14.1)
Women receiving at least one valid visit, n (%)	691 (99.3)	657 (94.3)	599 (85.9)
Number of valid visits received			
Median (25th to 75th centile)	10 (8 to 12)	19 (15 to 22)	13 (10 to 16)
Mean (SD)	9.74 (3.42)	18.7 (5.97)	13.28 (5.46)
Reaching fidelity goal of, n/N (%)			
≥80%	401/697 (57.5)		
≥65%		364/697 (52.2)	1 St. C. 14
≥60%			297/697 (42.6)

Programme content:

- Visits reflect variation in developmental needs by programme phase (within specific ranges).
- Mostly on target, greater emphasis on Environmental health by phase, lower coverage of Personal health (Pregnancy) and Lifecourse (Toddlerhood)

At that stage ...

- Delivered as intended and to representative client group
- <u>Short-term</u>evidence so far
- Additional cost of £1993 per participant
- Long-term evaluation determine: value of secondary outcomes
- Considerations of differing: service context, client group, programme





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NIHR Commissioning Call



PHR programme Jan 2011

11/3002 Parenting support programmes

 Research Question(s)
 Which targeted parental support programmes are most effective and costeffective in reducing the prevalence of maltreatment of pre-school aged children; and what are the effective components within targeted parental support programmes?

> National Institute for Health Research



Trials Research

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Building Blocks: 2-6

Study aim

Determine effectiveness of FNP in reducing objectively measured medium-term maltreatment outcomes when compared to usually provided health and social care alone using routine data.

> National Institute for Health Research







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Trial cohort design



Study design:	Data linkage study with an additional 4+ years follow up – to age 7 yrs
Participants:	N=1,562 eligible mothers/children exiting BB:0-2 trial
Outcomes:	Objective and associated measures of maltreatment (e.g. child in need), Intermediate FNP programme outcomes (e.g. subsequent pregnancies), Child health, developmental & educational outcomes

Data Sources:





Outcomes assessed in BB:2-6



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Domains	Outcomes	Maternal	Child	HES	ONS	NPD
Primary	and the second second second			-		
CIN status recorded at any time during the follow-up period	CIN status as of 31 March each year		1			1
Secondary						
Objective measures of	Referral to social services		1			1
maltreatment	Child protection registration		1			1
	Category of child protection plan		1			1
	CIN categorisation		1			1
	CIN duration		1			1
	Looked-after status		1			1
	CLA period of care		1			1
	Legal status of CLA		1			1
	Cause of death		1		1	
Associated measures of	DNA appointments		1	1		
maltreatment	Injuries and ingestions		1	1		
Maternal outcomes	Subsequent pregnancies	1		1		
Costs	Health and social care resource use	1	1	1		1
Child health, developmental	SEN		1			1
and educational outcomes	Disability		1	1		1
	Day-care attendance		1			1
	Early-years assessment		1			1
	School attendance		1			1
	KS1 attainment		1			1



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Main analysis strategy



- Modified Intention To Treat, emphasis on confidence intervals
- Three-level multilevel modelling clustering of effect within site and family nurse fitted as random effects
- Trial site included as random effect in all models
- Adjusted for variables used in trial minimization: smoking status, gestational age, language
- Outcomes pre-specified for comparative analysis, exploratory / descriptive assessment
- A priori sub-groups analyses for selected outcome







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FIGURE 1 Final model of data flow, storage and access used in BB:2-6. a, De-identification and standardisation applied (e.g. date of birth to week of birth). b, Data providers confirm matching of BB/NHS Digital/ONS/DfE/DHSC IDs. ID, identifier.



Establishing feasibility

- Developing an adequate participant dissent model
- Establishing acceptable levels of record linkage
- Establishing adequate data quality





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Participant dissent model







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Levels of record linkage



Match¹ rates for NHS Digital and NPD - feasibility study

	Participants Sent (n)	Participants Matched (n)	Proportion matched
NHS Digital			
Mother Child	1434 1419	1407 1397	98.1% 98.4% ^{(98.3%)*}
NPD			
Mother Child	1428 1412	99 1272	6.9% 90% ^{(97.4%)*}

1 Any type of match, * in main study



FIGURE 5 The CONSORT flow diagram. C, child; EW, elective withdrawals; M, mother; MW, mandatory withdrawals.

Comparability: BB:0-2 and BB:2-6



Characteristics of mothers Values are N(%) unless otherwise stated

	BB:0-2 sample N=1618	BB:2-6 cohort N=1537
Trial arm		
FNP	808 (49.9)	766 (49.8)
Usual Care	810 (50.1)	771 (50.2)
Minimisation variables:		
Gestational age at baseline		
16 weeks or more	658 (40.7)	636 (41.4)
Less than 16 weeks	959 (59.3)	900 (58.6)
Missing	1 (0.1)	1 (0.1)
Smoking status		
No	860 (53.2)	822 (53.5)
Yes	758 (46.8)	715 (46.5)
Language		
English	1611 (99.6)	1530 (99.5)
Other	6 (0.4)	6 (0.4)
Missing	1 (0.1)	1 (0.1)

Comparability: BB:0-2 and BB:2-6



Characteristics of children *Values are N(%) unless otherwise stated*

	BB:0-2 sample N=1510	BB:2-6 sample N=1547
Trial arm		
FNP	742 (49.1)	773 (50.0)
Usual Care	768 (50.9)	774 (50.0)
Sex		
Male	777 (51.5)	787 (50.9)
Female	732 (48.5)	758 (49.1)
Missing	1	1

BB:2-6 cohort: trial baseline demographics



	Trial arm		
Characteristic	FNP	Usual care	
Mothers	N = 766	N = 771	
Maternal age at recruitment (years), median (25th to 75th centile)	17.9 (17.0 to 18.8)	17.9 (16.9 to 18.8)	
Ethnicity, n (%)			
White	675 (88.1)	680 (88.2)	
Mixed	44 (5.7)	38 (4.9)	
Asian (excluding Chinese)	15 (2.0)	10 (1.3)	
Black	29 (3.8)	40 (5.2)	
Chinese or other	< 5	< 5	
Relationship status with baby's father, n (%)			
Married	6 (0.8)	10 (1.3)	
Separated	72 (9.4)	78 (10.1)	
Closely involved/boyfriend	582 (76.0)	586 (76.0)	
Just friends	106 (13.8)	97 (12.6)	
NEET status, ^a n (%)			
Yes (i.e. NEET)	315 (41.1)	319 (41.4)	
No (i.e. in EET)	345 (45.0)	333 (43.2)	
Participant academic age of < 16 years at interview	104 (13.6)	117 (15.2)	
Missing	2 (0.3)	2 (0.3)	
IMD overall score, ^b median (25th to 75th centile)	38.1 (24.6 to 52.6); <i>n</i> = 760	38.1 (25.5 to 51.6); n = 765	

BB:2-6 cohort: trial baseline descriptives



	Trial arm		
Characteristic	FNP	Usual care	
Mothers	N = 766	N = 771	
Generalised self-efficacy scale (score 10–40), ^c median (25th to 75th centile)	30.0 (28.0 to 33.0); <i>n</i> = 764	30.0 (27.0 to 32.0); n = 769	
Adaptive functioning: difficulty in at least one basic	skill, n (%)		
Yes	213 (27.8)	184 (23.9)	
No	552 (72.2)	586 (76.1)	
Missing	1 (0.1)	1 (0.1)	
Adaptive functioning: had three or fewer life skills (out of five), n (%)		
Yes	185 (24.2)	218 (28.3)	
No	578 (75.8)	551 (71.7)	
Missing	3 (0.4)	2 (0.3)	
Adaptive functioning: at least one burden, n (%)			
Yes	214 (28.2)	237 (30.9)	
No	545 (71.8)	530 (69.1)	
Missing	7 (0.9)	4 (0.5)	
Cigarette smoking, participant self-reported, n (%)			
Ever smoked			
Yes	615 (80.3)	612 (79.4)	
No	151 (19.7)	159 (20.6)	

BB:2-6 cohort: trial baseline descriptives



	Trial arm	
Characteristic	FNP	Usual care
Children	N = 773	N = 774
Sex		
Male, n (%)	381 (49.3)	406 (52.5)
Female, n (%)	392 (50.7)	367 (47.5)
Missing (n)	0	1
Birthweight (g), mean (SD)	3223.81 (606.0)	3215.52 (555.56)
Missing (n)	49	22
Neonatal unit admission (direct or subse	equent)	
Yes, n (%)	76 (10.6)	66 (8.8)
No, n (%)	640 (89.4)	683 (91.2)
Missing (n)	57	25

EET, employment, education or training; IMD, Index of Multiple Deprivation; SD, standard deviation.

a Applicable only to those whose age at the end of the previous academic year at time of baseline interview was > 16 years.

b Higher IMD score indicated more deprivation. Mean IMD score for England in 2010 was 21.67.69

c Higher score indicates higher level of self-efficacy.



Maltreatment outcomes

Analysis: Maltreatment outcomes



Referrals to Social Services: Ever referred*, Age at first referral

Child in Need (CIN) Status: *Ever CIN*, Duration In need, Primary need*

Child protection plan (CPP): *Ever subject to CPP, Category of abuse*

Care experience: *Ever experienced care, Duration of care*

Death

Healthcare: DNAs, Inj/Ing: ER attendance, Admission, LOS

* Planned sub-group analyses

'Referral to Social Services'



Source : Child in Need Census dataset

Who is in the CIN census?

- All children referred to English LA children's services for social care assessment even if later assessed as 'not in need'
- Includes pre-birth referrals

What is a 'referral'?

- When a child is referred to Children's Services event is recorded as a 'contact'. Contacts not submitted to CIN Census.
- Contacts undergo a pre-referral assessment.
- If case provisionally meets threshold for support (s47 or s17), then passed to assessment team as 'referral'.
- These cases appear in the CIN dataset

Referral to Social Services



Outcome	FNP arm (N = 760)	Usual-care arm (N = 746)	Adjusted ^a parameter estimate (95% CI)	p-value
Referred to CSC services, n (%)	a second second	6	and there a	1.5
No	554 (72.9)	538 (72.1)		
Yes	206 (27.1)	208 (27.9)	0.97 ^b (0.74 to 1.28)	0.829
Total referrals made (n)	339	354		
Ratio of referrals to children	1.65	1.70		
Referrals made per child, n (%)				
1	159 (77.2)	140 (67.3)	Not tested, descriptive only	
2	34 (16.5)	51 (24.5)		
3-5	13 (6.3)	27 (8.2)		
Age (days) at first referral, median (25th to 75th centiles)	1541.5 (1272.75 to 1975.75)	1631.0 (1190.50 to 1984.75)	0.96 ^c (0.79 to 1.17)	0.694

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Referrals to Social Services



Outcome	FNP arm (N = 760)	Usual-care arm (N = 746)	Adjusted ^a parameter estimate (95% CI)	p-value
Source of referral	5.1.5			
Individual, n (%)	29 (8.8)	34 (10.0)	Not tested, descriptive only	
School/education, n (%)	150 (45.7)	136 (40.0)		
Health services, n (%)	114 (34.8)	132 (38.8)		
Local authority services, n (%)	35 (10.7)	38 (11.2)		
Missing (n)	11	14		
Primary need for referral				
Abuse or neglect, n (%)	198 (58.9)	205 (57.9)	Not tested, descriptive only	
Family dysfunction, n (%)	72 (21.4)	88 (24.9)		
Family in acute stress, n (%)	19 (5.7)	21 (5.9)		
Low income/absent parenting/ socially unacceptable behaviour, n (%)	11 (3.3)	7 (2.0)		
Parental/child's disability illness, n (%)	14 (4.2)	11 (3.1)		
Cases other than CIN, n (%)	11 (2.3)	12 (3.4)		
Not stated, n (%)	11 (3.3)	9 (2.5)		
Missing (n)	3	1		

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Referrals to Social Services Subgroups



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Child in Need outcomes



'Children in need' - legally defined (UK Children Act 1989, s 17) - require additional support from local authorities (Children's Services) to maintain or achieve a 'reasonable standard of health or development'

'Child in need': all children referred to social services, excluding cases where:

- the referral is flagged as being a referral resulting in no further action (n=72) or
- the only activity recorded is an assessment (no s47 enquiry or CPP) and the reason for the closure was no further action (n=197)

Of the 903 referrals, 634 referrals remained associated with a CIN from 323 children.

Outcome	FNP arm (N = 760)	Usual-care arm (N = 746)	Adjusted ^a parameter estimate (95% CI)	p-value	Absolute risk difference (95% CI)
Child ever in need, n (%)					
No	599 (78.8)	584 (78.3)			
Yes	161 (21.2)	162 (21.7)	0.98 ^b (0.74 to 1.31)	0.902	-0.53 (-0.47 to 0.36)

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Child in need:

Duration and primary need



Outcome	FNP arm (<i>N</i> = 760)	Usual-care arm (N = 746)	Adjusted ^a parameter estimate (95% CI)	p-value
Duration of time in need (days), median (25th to 75th centile)	210 (70.5 to 571.25)	216 (72.75 to 503.25)	1.20 ^e (0.90 to 1.59)	0.216
Primary need for first CIN case, n (%)				
Abuse or neglect	92 (57.1)	102 (63.0)	Reference	
Family dysfunction	29 (18.0)	34 (21.0)	0.95 (0.54 to 1.69) ^f	0.868
Family in acute stress	13 (8.1)	10 (6.2)	1.47 (0.61 to 3.54) ^f	0.389
Low income, absent parenting, socially unacceptable behaviour, not stated	13 (8.1)	7 (3.7)	2.38 (0.86 to 6.57) ^f	0.093
Child/parent disability	7 (4.3)	5 (3.1)	1.47 (0.45 to 4.84) ^f	0.525
Cases other than CIN	7 (4.3)	5 (3.1)	1.64 (0.50 to 5.37) ^f	0.417

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Referrals to CIN: Subgroups

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ljusted odds ratios

College of Biomedical and Life Sciences

Maltreatment outcomes



Child protection plan, Looked after, death

Outcome	FNP arm (N = 760)	Usual-care arm (N = 746)	Adjusted ^ª parameter estimate (95% CI)	p-value	Absolute difference (95% CI)
CPP, n (%)	1000	250.00		2	
No	708 (93.2)	697 (93.4)			
Yes	52 (6.8)	49 (6.6)	1.04 ^b (0.69 to 1.57)	0.846	0.27 (-0.23 to 0.28)
Initial category of abuse	n = 52	n = 49			
Neglect, n (%)	17 (32.7)	22 (44.9)	Reference		
Emotional, n (%)	22 (42.3)	12 (24.5)	2.77 ^c (1.02 to 7.56)	0.046	
Physical, n (%)	6 (11.5)	6 (12.2)	1.25 ^c (0.32 to 4.88)	0.743	
Sexual and multiple, ^{d} n (%)	7 (13.5)	9 (18.4)	1.13 ^c (0.33 to 3.86)	0.848	
CLA, n (%)					
No	735 (96.7)	719 (96.4)			
Yes	25 (3.3)	27 (3.6)	0.90 ^b (0.52 to 1.57)	0.712	-0.3 (-0.2 to 0.2)
Total duration of care (months), values medians (25th to 75th centiles)	10.0 (4.5 to 37.5)	12.0 (6.0 to 33.0)	0.75 ^e (0.65 to 0.86)	< 0.001	
Legal status of CLA					
Interim care order, n (%)	6 (35.3)	8 (34.8)	Not tested, descriptive only		
Full care order, n (%)	5 (29.4)	6 (26.1)			
Placement order granted	< 5	< 5			
Single period of accommodation under section 20	< 5	< 5			
Death	< 10 (combining both	arms)	Not tested, descriptive only		

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Associated measures of maltreatment:

Healthcare DNAs, Attendances and admissions for inj/ingestions



Outcome	FNP (N = 580)	Usual care (N = 577)	Adjusted ^a parameter estimate (95% CI)	Absolute risk difference (95% CI)
DNA, n (%)		2. 32 -		
Attended all appointments	290 (50.0)	289 (50.1)		
DNA at least once	290 (50.0)	288 (49.9)	1.00 ^b (0.79 to 1.26)	0.09 (-5.6 to 5.8)
Injuries and ingestions	FNP (N = 760)	Usual care (N = 759)		
Emergency attendance ^c				
None, n (%)	317 (41.7)	344 (45.3)		
At least one, n (%)	443 (58.3)	415 (54.7)	1.17 ^a (0.95 to 1.45)	3.6 (-1.4 to 8.6)
Number of attendances per child, median (25th to 75th centile)	2 (1 to 2)	2 (1 to 3)	1.09 ^d (0.93 to 1.28)	
Admission to hospital				
None, n (%)	671 (88.3)	660 (87.0)		
At least one, n (%)	89 (11.7)	99 (13.0)	0.87 ^b (0.63 to 1.20)	-1.3 (-4.7 to 2.0)
Unique admissions (n)	109	119		
Ratio of admissions to children	1.22	1.20		
Number of admissions per child, median (25th to 75th centile)	1 (1 to 1)	1 (1 to 1)	0.93 ^d (0.67 to 1.29)	÷.
Length of stay (days)	N = 106	N = 119		
Median (25th to 75th centile) days	0.5° (0.5 to 1.0)	0.5 (0.5 to 1.0)		



Child health, developmental and educational outcomes

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Child Health, developmental and educational outcomes



Early Years Foundation Stage Profile -

• GLD: in all 5 areas, All 17 LGs, Total Point Score*

Key Stage 1 (KS1) -

• Reading*, Writing*, Science*, Mathematics*

.... Sensitivity analyses

* Planned sub-groups

Early Years Assessments



- EYFS Profile (EYFSP): teacher completed, statutory assessment of child's development and learning achievements, at end of academic year in which they turn 5.
- 17 early learning goals in seven areas of learning covering children's: physical, intellectual, emotional and social development

Area of learning		Early learning goal	Part of the good level of development measure	
+		1: Listening and attention	Yes	
	Communication and	2: Understanding	Yes	
	language	3: Speaking	Yes	
Prime areas of learning Physical development Personal, social and	4: Moving and handling	Yes		
	5: Health and self-care	Yes		
		6: Self-confidence and self- awareness	Yes	
	Personal, social and	7: Managing feelings and behaviour	Yes	
	emotional development	8: Making relationships	Yes	
Specific <u>Mathematics</u> areas of Understanding the <u>world</u> Expressive arts,		9: Reading	Yes	
	Literacy	10: Writing	Yes	
		11: Numbers	Yes	
	Mathematics	12: Shape, space and measures	Yes	
	Understanding the	13: People and communities	No	
		14: The World	No	
	world	15: Technology	No	
	Expressive arts,	16: Exploring and using media and materials	No	
designing and making		17: Being imaginative	No	

Early Years Assessments



- % of children achieving a Good Level of Development at least the expected level (2+) within all of the following areas of learning:
 - Communication and language
 - Physical development
 - Personal, social and emotional development
 - Literacy
 - Mathematics
- % of children achieving at least the expected level in ALL 17 early learning goals (score of 2+).
- Average total point score across all 17 early learning goals (Range 17 to 51)

Early Years Assessments



Achieving GLD: All five areas, All 17 ELGs; Total Point Score

	FNP arm (N = 743), n (%)	Usual-care arm (N = 728), n (%)	Total (N = 1471), n (%)	Adjusted ^a parameter estimate (95% Cl)	p-value	Absolute difference ^b (95% CI)
Achieving a GLD						
Achieving a GLD in all five areas of learning ^c	431 (58.0)	380 (52.2)	811 (55.1)	1.26 ^d (1.03 to 1.55)	0.026	5.8 (0.7 to 10.9)
Prime areas						
Communication and language	642 (86.4)	613 (84.2)	1255 (85.3)	Not tested, descriptive only	100	2.2 (-1.4 to 5.8)
Physical development	676 (91.0)	643 (88.3)	1319 (89.7)	Not tested, descriptive only		2.7 (-0.5 to 5.8)
Personal, social and emotional development	668 (89.9)	634 (87.1)	1302 (88.5)	Not tested, descriptive only		2.8 (-0.4 to 6.1)
Specific areas						
Literacy	493 (66.4)	458 (62.9)	951 (64.6)	Not tested, descriptive only	-	3.4 (-1.4 to 8.3)
Mathematics	545 (73.4)	516 (70.9)	1061 (72.1)	Not tested, descriptive only	÷	2.5 (-2.1 to 7.0)
Achieving a GLD in all 17 early-learning goals	412 (55.5)	365 (50.1)	777 (52.8)	1.24 (1.01 to 1.52)	0.043	5.3 (0.2 to 10.4)
Total point score						
Mean (SD) ^e	32.22 (7.25)	31.59 (7.62)		0.65 ^f (-0.11 to 1.41)	0.094	
Score of < 34	325 (43.8)	345 (47.4)				
Score = 34	187 (25.2)	183 (25.1)				
Score of > 34	231 (31.1)	200 (27.5)				

National Pupil Database, The Department for Education

EYFSP Total Point Score:

Forest plot of estimates from sub-group analysis





Vertical solid line represents no effect (mean difference = 0) vertical dashed line indicates the overall treatment effect for EYFS total score (adjusted mean difference = 0.65).

National Pupil Database, The Department for Education

Key Stage 1: 5-6 years of age *Reading, Mathematics*



FNP arm (N = 740)	Usual-care arm (N = 732)	Total (N = 1472)	Adjusted ^a parameter estimate (95% CI)	p-value	Absolute difference (95% Cl)
257 (34.7)	289 (39.5)	546 (37.1)	Reference		
483 (65.3)	443 (60.5)	926 (62.9)	1.23 (0.99 to 1.53)	0.051	4.8 (-0.2 to 9.7)
371 (50.1 <mark>)</mark>	337 (46.0)	708 (48.1)	1.24 (0.99 to 1.56)	0.056	4.1 (-1.0 to 9.2)
112 (15.1)	106 (14.5)	218 (14.8)	1.20 (0.88 to 1.65)	0.250	0.7 (-3.0 to 4.3)
281 (38.0)	283 (38.7)	564 (383.)	Reference		
459 (62.0)	449 (61.3)	908 (61.7)	1.04 (0.84 to 1.28)	0.731	0.7 (-4.3 to 5.6)
392 (53.0)	376 (51.4)	768 (52.2)	1.06 (0.85 to 1.32)	0.611	1.6 (-3.5 to 6.7)
67 (9.1)	73 (10.0)	140 (9.5)	0.93 (0.64 to 1.35)	0.711	-0.9 (-3.9 to 2.1)
	(N = 740) 257 (34.7) 483 (65.3) 371 (50.1) 112 (15.1) 281 (38.0) 459 (62.0) 392 (53.0)	FNP arm (N = 740) arm (N = 732) 257 (34.7) 289 (39.5) 483 (65.3) 443 (60.5) 371 (50.1) 337 (46.0) 112 (15.1) 106 (14.5) 281 (38.0) 283 (38.7) 459 (62.0) 449 (61.3) 392 (53.0) 376 (51.4)	FNP arm (N = 740)arm (N = 732)Total (N = 1472)257 (34.7)289 (39.5)546 (37.1)483 (65.3)443 (60.5)926 (62.9)371 (50.1)337 (46.0)708 (48.1)112 (15.1)106 (14.5)218 (14.8)281 (38.0)283 (38.7)564 (383.)459 (62.0)449 (61.3)908 (61.7)392 (53.0)376 (51.4)768 (52.2)	FNP arm (N = 740)arm (N = 732)Total (N = 1472)Adjusted a parameter estimate (95% Cl)257 (34.7)289 (39.5)546 (37.1)Reference483 (65.3)443 (60.5)926 (62.9)1.23 (0.99 to 1.53)371 (50.1)337 (46.0)708 (48.1)1.24 (0.99 to 1.56)112 (15.1)106 (14.5)218 (14.8)1.20 (0.88 to 1.65)281 (38.0)283 (38.7)564 (383.)Reference459 (62.0)449 (61.3)908 (61.7)1.04 (0.84 to 1.28)392 (53.0)376 (51.4)768 (52.2)1.06 (0.85 to 1.32)	FNP arm (N = 740)arm (N = 732)Total (N = 1472)Adjusted° parameter estimate (95% Cl) p -value257 (34.7)289 (39.5)546 (37.1)Reference $123 (0.99 \text{ to } 1.53)$ 0.051483 (65.3)443 (60.5)926 (62.9)1.23 (0.99 \text{ to } 1.53)0.051371 (50.1)337 (46.0)708 (48.1)1.24 (0.99 \text{ to } 1.56)0.056112 (15.1)106 (14.5)218 (14.8)1.20 (0.88 \text{ to } 1.65)0.250281 (38.0)283 (38.7)564 (383.)Reference124459 (62.0)449 (61.3)908 (61.7)1.04 (0.84 \text{ to } 1.28)0.731392 (53.0)376 (51.4)768 (52.2)1.06 (0.85 \text{ to } 1.32)0.611

Key Stage 1 Science, Writing (2016/17, 2017/18)



KS1 assessment	FNP arm (N = 740)	Usual-care arm (N = 732)	Total (N = 1472)	Adjusted ^a parameter estimate (95% CI)	p-value	Absolute difference (95% Cl)
Science level, n (%)						
Lower than expected	203 (27.4)	219 (29.9)	422 (28.7)	Reference		
Reaching at least the expected standard ^b	537 (72.6)	513 (70.1)	1050 (71.3)	1.14 (0.91 to 1.43)	0.254	2.5 (-2.1 to 7.1)
Writing level, academic year 2016/17, n (%)	N = 498	N = 487	N = 985			
Lower than expected	257 (51.6)	278 (57.1)	535 (54.3)	Reference		
Reaching at least the expected standard ^c	241 (48.4)	209 (42.9)	450 (45.7)	1.24 (0.97 to 1.60)	0.090	5.5 (-0.7 to 11.6)
Expected standard	218 (43.8)	182 (37.4)	400 (40.6)	1.29 (1.00 to 1.68)	0.054	6.4 (0.3 to 12.5)
Higher standard	23 (4.6)	27 (5.5)	50 (5.1)	0.92 (0.51 to 1.64)	0.769	-0.9 (-3.8 to 1.9)
Writing level, academic year 2017/18, n (%)	N = 242	N = 245	N = 487			
Lower than expected	82 (33.9)	81 (33.1)	163 (33.5)			
Reaching at least the expected standard ^b	160 (66.1)	164 (66.9)	324 (66.5)	Not tested, descriptive only	NT	-0.8 (-9.2 to 7.5)
Expected standard	140 (57.9)	132 (53.9)	272 (55.8)	Not tested, descriptive only	NT	4.0 (-4.8 to 12.7)
Higher standard	20 (8.3)	32 (13.1)	52 (10.7)	Not tested, descriptive only	NT	-4.8 (-10.4 to 0.7)

(National Pupil Database, The Department for Education)

Sensitivity analysis: child's month of birth



National differences at KS1 by month of birth eg 17% KS1 reading (Aug: Sep)

Sensitivity analysis: additional adjustment by month of birth

	OR ^b (95% Cl); <i>p</i> -value					
KS1 outcome	Adjusted for site and minimisation variables ^c	Adjusted for site, minimisation variables ^c and month of birth				
Reading level						
Reaching at least the expected standard	1.23 (0.99 to 1.53); 0.051	1.26 (1.02 to 1.57); 0.035				
Expected standard	1.24 (0.99 to 1.56); 0.056	1.27 (1.01 to 1.59); 0.042				
Higher standard	1.20 (0.88 to 1.65); 0.250	1.26 (0.91 to 1.75); 0.161				
Mathematics level						
Reaching at least the expected standard	1.04 (0.84 to 1.28); 0.731	1.06 (0.85 to 1.31); 0.613				
Expected standard	1.06 (0.85 to 1.32); 0.611	1.07 (0.86 to 1.34); 0.527				
Higher standard	0.93 (0.64 to 1.35); 0.711	0.93 (0.74 to 1.17); 0.522				
Science level						
Reaching at least the expected standard	1.14 (0.91 to 1.43); 0.254	1.16 (0.92 to 1.47); 0.197				
Writing level, academic year 2017/18						
Reaching at least the expected standard	1.24 (0.97 to 1.60); 0.090	1.26 (0.98 to 1.62); 0.076				
Expected standard	1.29 (1.00 to 1.68); 0.054	1.30 (1.00 to 1.69); 0.050				
Higher standard	0.92 (0.51 to 1.64); 0.769	0.97 (0.54 to 1.75); 0.917				
Early-years assessment						
Achieving a GLD in all five areas of learning ^d	1.26 (1.03 to 1.55); 0.026	1.31 (1.05 to 1.62); 0.015				
Achieving a GLD in all 17 early-learning goals	1.24 (1.01 to 1.52); 0.043	1.27 (1.03 to 1.58); 0.027				
Total point score	0.65 (-0.11 to 1.41); 0.094	0.70 (-0.03 to 1.42); 0.060				

a Quarter of birth runs from September to November, December to February, March to May and June to August.

b Odds ratio represents the FNP arm compared with the usual-care arm.

c Gestational age, smoking status at recruitment, and first or preferred language.

d Children achieving a GLD were those achieving at least the expected level in the prime and specific areas of learning.

Note

Source: NPD, DfE.

Forest plot of estimates from sub-groups





National Pupil Database, The Department for Education

Vertical solid line represents no effect (OR 1), vertical dashed line indicates the overall treatment effect for the percentage reaching at least ES in reading (aOR 1.26).

Vertical solid line represents no effect (OR 1), vertical dashed line indicates the overall treatment effect for the percentage reaching at least the ES in mathematics (aOR 1.06).

Forest plot of estimates from sub-groups





National Pupil Database, The Department for Education

Vertical solid line represents no effect (OR 1), vertical dashed line indicates the overall treatment effect for percentage reaching at least ES in science (aOR 1.16).

aOR Vertical solid line represents no effect (OR 1), vertical dashed line indicates the overall treatment effect for percentage reaching at least ES in writing (aOR 1.26).



Centre for **Trials Research**

Costs consequences



Perspective

CCA over full follow-up period up (BB:0-2, BB:2-6) secondary healthcare perspective

Methods

- Data: HES (inpatient, outpatient, A&E) resource data matched to NHS Reference Costs
- Only direct healthcare costs available
 - No recorded data = no resource incurred •
 - Maternal reported primary care data restricted to 18 months postpartum
- Costs discounted back from year of event to baseline (2009/10) at 3.5% annual rate •

Results

- Negligible resource use and cost differences for both mothers (p=0.393) and children (p=0.865) between study arms.
- Adjusted incremental costs of programme delivery per women in BB:0-2 (£1,811) • remain the key observed cost difference between study arms.

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BUILDING BLOCKS: 2-6

outine data-linkage follow-up to the Family urse Partnership (FNP) trial in England

udy results



Strengths and weaknesses

- Retain benefits of trial allocation
- Administrative data: sample completeness, participant burden, bias, objectivity, nationally comparable
- Blending data from multiple sources within and across sectors
- A rich cohort with potential for growth
- Reliance solely on administrative data: maternal self-report, observational data / assessment, precision



Summary points

Main effects for maltreatment outcomes show no group differences by age 6

Main effects for developmental outcomes show differences favouring FNP by age 6-7

Sub-group analysis show some greater effects for children of younger mothers (EYFSP: TPS; KS1: mathematics, writing), for boys (KS1: writing), for children of mothers not in EET at baseline (KS1:writing)

Forest plot of estimates from all main outcomes.



Vertical solid line represents no effect (OR = 1). a, FNP compared with usual care. Analysis adjusted for stratification (site) and minimisation variables (gestational age, smoking status at recruitment, and first or preferred language). For Early Years and KS1 outcomes, additionally adjusted for month of birth. Source: NPD, DfE.



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Thank you for listening

Your questions?

https://evidencinghomevisiting.co.uk/

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