Right from the Start - *A pilot study for a randomised control trial of the New Baby Programme for improving outcomes for children born to socially vulnerable mothers*

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Background

- Children born to mothers who experience social complexities are at increased risk of adverse outcomes at birth and during development
- Evidence indicates that home based parenting programmes *work* to improve outcomes for disadvantaged mothers and children
- The New Baby Programme was developed in Northern Ireland. It augments the universal health visiting service in UK with content designed to promote maternal health and wellbeing in pregnancy, maximise secure attachments of children and parents, and enhance sensitive parenting and infant cognitive development

Key components of New Baby Programme

- Structured home visits start at 20 weeks gestation and frequency of visits are reduced as child gets older, then finish when child reaches 2 years of age
- Includes universal provision for children (healthy Child, Healthy Future) augmented with a range of interventions designed to help women with complex social factors e.g. stress (poor housing, debt, domestic violence), promotes responsive and sensitive caregiving, and secure attachment
- NBP HVs develop a collaborative approach to identify issues, set goals, review and select appropriate strategies, and facilitate their implementation.
- NBP HVs should have access to specialist clinical supervision and a training programme that is responsive to the situations they encounter
- NBP HVs have limited caseloads (n=25) that enable them to work to the specification of the programme manual
- Supervision is critical for NBP-HVs for the successful implementation of the programme. It should address all aspects of practice, including clinical and reflective practice, as these can significantly impact on progress and outcomes

Aims of the study

1. To test the feasibility of an RCT to investigate the effectiveness for pregnant women of any age (above 12 years old) presenting with socially complex circumstances

2. To determine the recruitment and retention rates required, the process of randomization, procedures for masking allocation from researchers, acceptability of both the intervention and participation in the study

Overall study design

A pilot study to investigate whether it is possible to recruit & retain socially vulnerable mothers to an RCT that compares the effects of NBP with standard care

A qualitative process evaluation to explore validity of logic model and pathways through which the programme might work

PICO

Participants

- *Inclusion criteria:*
- First time pregnant women over 19 years, or multiparous women of any age with one of more of the following: Social isolation/ low family support/ father in prison/ intimate partner violence/ substance misuse/ maternal stress/ history of mental health/ current involvement with social services or probation/ history of care or care leaver/ abnormal reaction to pregnancy
- *Exclusion criteria:*

Intervention

- New Baby Programme for socially vulnerable mothers with children between 0-2 years of age

Comparison

- Health visiting services as usual

Outcomes

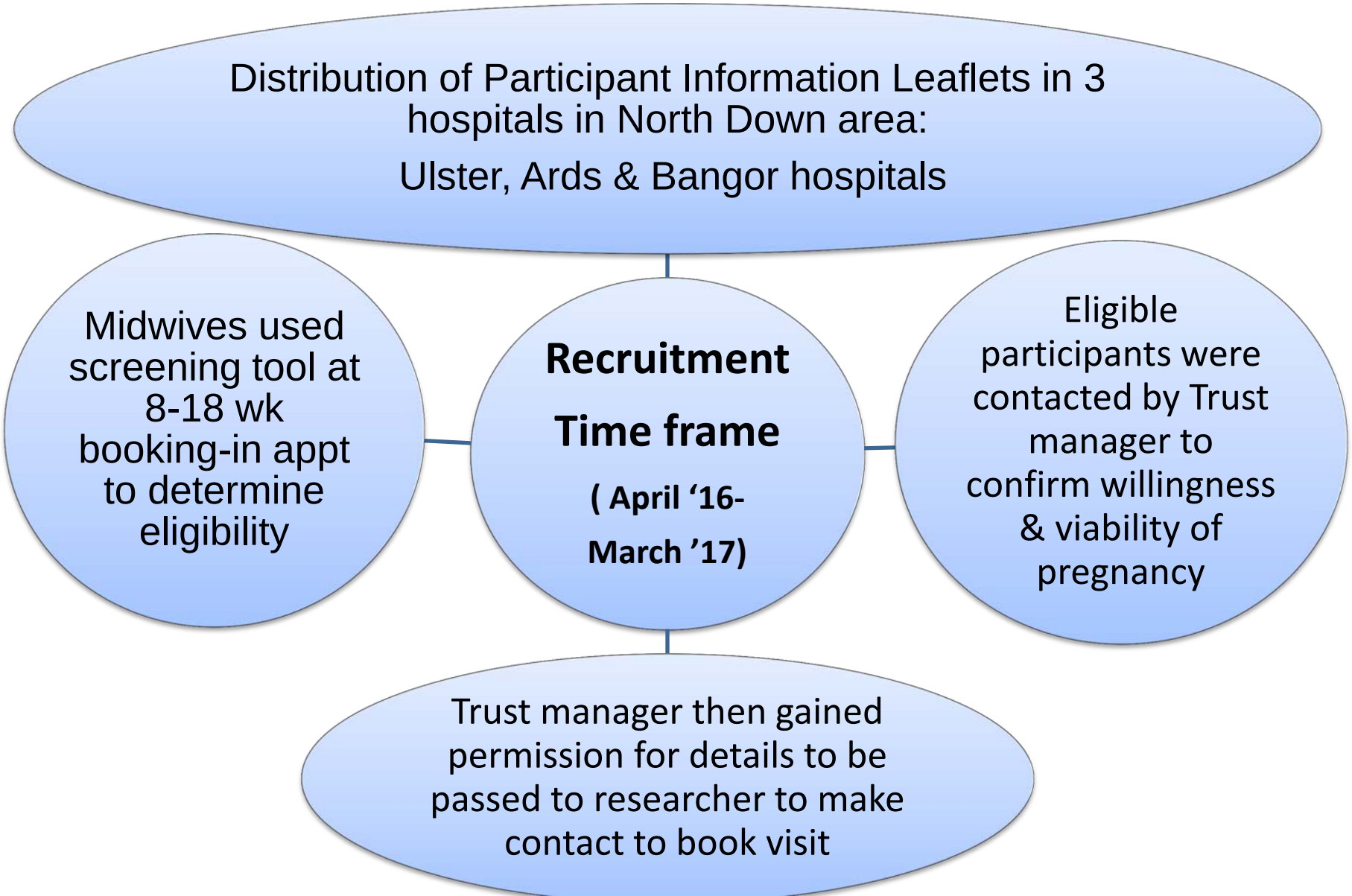
- Parent

Parenting confidence
Reduction in parent-related stress
Cessation/ reduction of substance misuse
Increase in positive coping strategies
Increased professional/ service support

- Child

Securely attached
Physical and cognitive development is age-appropriate
School readiness when starting school
Ability to regulate behaviour and emotion

Recruitment Strategy



Randomisation Procedure

Simple randomisation used to allocate 50 parents to IV or control using TENALEA computerized randomisation software.

- intervention (n=24)
- control (n=26)

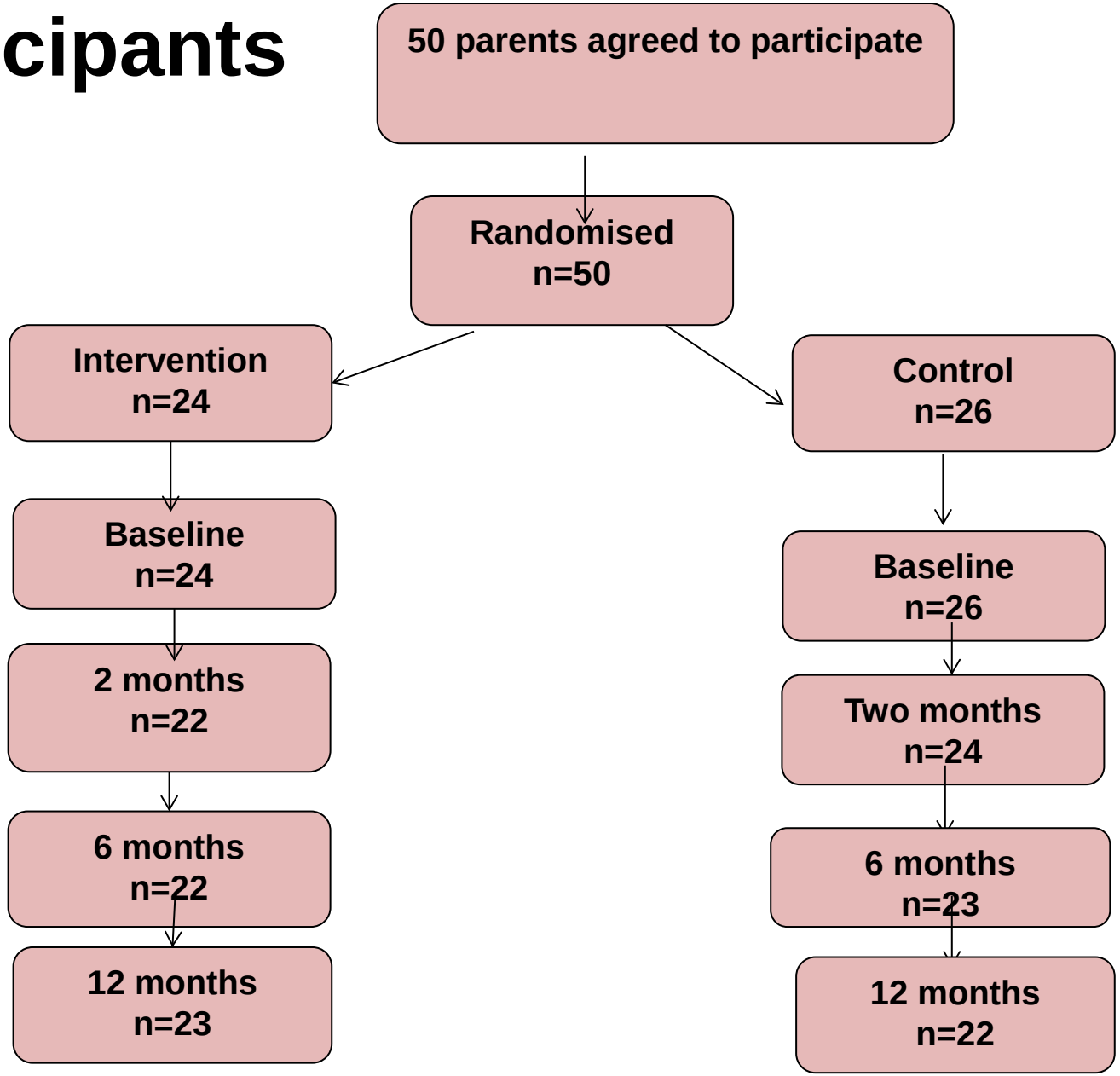
Intervention group received New Baby Programme for on average 82 weeks (2016-18)

Randomisation email was sent to designated officer in School of Nursing. Researchers were blinded

Allocation information was then sent to relevant staff in the SEHCT

The routine package of care was also offered to those who did not wish to take part in the study

Participants



Data collection

Parents were visited by the research team four times:

- **Baseline (mother 20 weeks gestation)**
- **2-months (child 2 months old)**
- **6-months (child 6 months old)**
- **12-months (child 12 months old)**

Each data collection visit approx. 45-60 minutes in duration

Subsample of 6 IV and 6 control participants participated in qualitive interviews.

NBP HV and control HVs participated in qualitative interviews

3 team members from SEHCT participated in focus group

Outcome	Measures	Average minutes to complete	Baseline, gestation 20 weeks	Infant 2 months	Infant 6 months	Infant 12 months
Attachment	Strange Situation	20				X
Maternal sensitivity	CARE Index	3				X
	Demographics	2	X	X(update)	X(update)	X(update)
Maternal Depression	Edinburgh postnatal depression scale (EPDS)	5		X	X	X
Infant questions	Brief questions on feeding & immunisations	4	X (feeding plans)	X	X (feeding)	X
Lifestyle issues	Brief questions inc drug use, smoking & alcohol use	1.2	X	X (update)		X (update)
Maternal quality of life	EuroQol (EQ-5D-5L)	5	X	X	X	X
Stress	STAI-S-6	2	X	X	X	X
Antenatal stress	NUPDQ	5	X			
Parenting Stress	Parenting stress index, short form (PSI)	10	X	X		X
Parents' sense of competence	Perceived parenting competence scale (PSOC)	5		X		X
Relationship violence	Brief Questions	1	X			X
Social Networks	Medical outcomes study (MOS) social support survey short form 36	5	X			X
Service use		3		X	X	X
Child development	Mullen Scales of Early Learning	15		X	X	X

Attrition Rate

- Total attrition rate is 4 out of 50 for home visit data collecton (8%)
- 1 visit was unable to be completed due to study time constraints at 12 months (control).
- **Reasons for attrition to date are as follows:**

Reason for drop out	Group allocation
One family moved to England	Control
one baby was born after baseline visit and did not survive	Control
one disengaged with health visitor and study	Intervention
one disengaged with study	Control

Overview of data collection at each time-points:

Status	Baseline	2 mth	6 mth	12mth	Infant CARE-Index	Strange Situation Procedure
Complete	**50**	**46**	**45**	**45**	**44**	**36**
Unable to complete	-	1	1	1	1	2
Withdrew be fore time point	-	3	1	0	2	9
Total	50	50	45	45	44	36

Participant qualitative findings (in brief)

Trusting relationship with NBP-HV emerged as key in successful long-term acceptability and enjoyment of programme

NBP-HV reassuring, informative and willing to accommodate family circumstances

knowledgeable about their child's development as a result of receiving NBP

Improved relationship with their child attributed to having better ideas for play activities and communication

Control participants complained about discontinuity of HV and lack of contact during early phase after birth

Control participants felt less supported when it came to information regarding signposting to other services

Summary

Preliminary statistical analyses is ongoing regarding parental questionnaires, child development assessments and differences over the four time points as well as economic evaluation as to the cost effectiveness of delivering NBP

The Infant CARE-Index scores (assessment of parental sensitivity) show a positive difference in favour of the intervention group

The Strange Situation scores (assessment of attachment strategies) show a positive difference in favour of the intervention group

Recruitment and retention rates as well as strategies used for researcher blinding were found to be accurate and successful and therefore next steps involve applying to NIHR for funding for phase 3 multi-site Randomised Control Trial for evaluation of the New Baby Programmer

Thank you

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