Cost-effectiveness of offering an area level financial incentive on breastfeeding: A within-cluster randomized controlled trial analysis

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Abstract

Objective: To provide the first estimate of the cost effectiveness of financial incentive for breastfeeding intervention compared with usual care.

Design: Within-cluster ('ward' level) RCT cost-effectiveness analysis.

Setting: Five local authority districts in the north of England

Participants: 5,398 mother-infant dyads (intervention arm), 4612 mother-infant dyads (control arm)

Interventions: Offering a financial incentive (over a 6 month period) on breastfeeding to women living in areas with low breastfeeding prevalence (<40% at 6–8 weeks)

Main outcome measures: Babies breastfed (receiving breastmilk) at 6–8week, and cost per additional baby breastfed

Methods: Costs were compared to differences in area level data on babies' breastfed in order to estimate a cost per additional baby breastfed and the quality adjusted life year (QALY) gains required over the lifetime of babies to justify intervention cost.

Results: In the trial, the total cost of providing the intervention in 46 wards was £462,600, with an average cost per ward of £9,989 and per baby of £91. At follow up, area-level breastfeeding prevalence at 6-8 weeks was 31.7% (95% CI, 29.4-34.0) in control areas and 37.9% (95% CI, 35.0-40.8) in intervention areas. The adjusted difference between intervention and control was 5.7 percentage points (95% CI, 2.7-8.6; $P < .001$), resulting in 10 (95% CI 6 to 14) more additional babies breastfed in the intervention wards (39 vs 29).

The cost per additional baby breastfed at 6-8 weeks was £974. At a cost per QALY threshold of £20,000 (recommended in England), an additional breastfed baby would need to show a QALY gain of 0.05 over their lifetime to justify the intervention cost. If decision-makers are willing to pay £974 (or more) per additional baby breastfed, then this intervention is cost-effective. Results were robust to sensitivity analyses.

Conclusion: This study provides information to help inform public health guidance on breastfeeding. To make the economic case unequivocal, evidence on the varied and long-term health benefits of breastfeeding to both the baby and mother and the effectiveness of financial incentives for breastfeeding beyond 6-8 weeks is required.

What is already known on this topic?

- There is evidence that incentive based breastfeeding programmes can increase breastfeeding in areas with low rates.

- Solid evidence of the value for money of these programmes is lacking despite calls for such evidence.

What this study adds

- This study reports, for the first time, cost effectiveness estimates of the offer of a financial incentive for breastfeeding in areas with low breastfeeding rates.

- This study provides new and high quality data from a large cluster RCT (with 92% follow up data), with resource use data collected prospectively.

- Our study shows that these programmes can increase breastfeeding and provide good value for money if decision makers are willing to pay £974(or more) per additional baby receiving breastmilk.

Introduction

Breastfeeding has benefits for both mothers and babies.[1] However, rates of any (i.e. exclusive and mixed) breastfeeding at age 12 months, are below 20%, on average, in high income countries. The UK has the lowest rate (0.5%), Oman the highest (95%) and the USA has a rate of 27%. [2] Even in low- and middle-income countries with relatively higher breastfeeding rates at age 12 months, only 4 out of 10 babies younger than 6 months are exclusively breastfed. [2] The low prevalence of breastfeeding is estimated to cost high income countries $231 billion (0.5% of gross national income) annually.[1] Policy makers in high income countries are seeking effective and cost-effective interventions to encourage breastfeeding.[3]

Offering incentives to women to breastfeed have been identified as an effective intervention to increase breastfeeding and have been implemented in the US,[4] France,[5] and Canada.[6] The first ever RCT of a financial incentive for breastfeeding was conducted among 36 low income Puerto Rican mothers who had initiated breastfeeding. This USA based RCT found higher rates of continued breastfeeding in the intervention group compared with control (89% vs 44% at 1 month; 89% vs 17%, at 3 months; 72% vs 0%, at 6 months).[4] The authors recommended large scale studies to assess clinical and cost-effectiveness of incentive based breastfeeding interventions.

The first UK based RCT of financial incentives for breastfeeding was conducted as part of the Nourishing Start for Health (NOSH) project [7]. This project developed and then trialled a structured population level financial incentive for breastfeeding intervention that offered shopping vouchers to women if their infant was receiving breastmilk. The intervention was offered to all women living in areas with low breastfeeding prevalence (<40% at 6–8 weeks) in five local authority districts in the north of England. Up to five vouchers (£40 each) were offered to women if their baby was receiving breastmilk at the following ages: 2 days, 10 days, 6 weeks, 3 months and 6 months.

To date no cost effectiveness studies of financial incentives for breastfeeding have been identified.[8] However, Moran et al's[3], review of breastfeeding incentive programmes, found eight studies with implementation costs data (but no cost effectiveness estimates). To ensure the efficient allocation of resources in health systems, global and national public health decision makers need information on the value for money of these interventions. The WHO Breastfeeding Policy Brief [9] identifies the need 'to increase attention to, investment in, and action for a set of cost-effective interventions and policies, that can help Member States and their partners' to increase breastfeeding and reach the WHO Global 2025 breastfeeding target of at least 50% of all infants being exclusively breastfed in the first 6 months.

This study, to the best of our knowledge examines, for the first time, the cost effectiveness of offering an area level financial incentive for breastfeeding intervention in a general population. Conducted alongside a large cluster (ward) RCT (Trial registration number ISRCTN44898617), the analyses examined the within-trial cost-effectiveness of financial incentive for breastfeeding in areas with low breastfeeding rates in the UK.

Methods

The within-trial cost-effectiveness analysis compared the cost and benefits (in terms of babies receiving breastmilk) of offering financial incentives to women over a 6-month period post birth versus control (no offer), from a healthcare provider perspective. The health outcome of interest was babies breastfed at 6–8week and cost-effectiveness was reported as cost per additional baby breastfed over the four quarters of the one year trial. Whilst data unavailability precluded estimating effectiveness at 6 months, total costs of vouchers were included in the analysis because the offer of vouchers up to 6 months was provided to participants at the outset of the trial and could therefore had impacted on the take up and duration of breastfeeding. The protocol planned cost-effectiveness analysis [10] was published prior to the analysis. The Trial Steering

Committee approved changes from protocol to analyses. Changes were necessary because logistical and data constraints precluded; (a) the collection of area-level data on hospital admissions (related to gastrointestinal infection , otitis media, respiratory tract infections and atopic eczema), and (b) beyond trial modelling of the long term cost effectiveness of the intervention. The trial protocol was approved by the National Health Service and local authority Research Governance and Research Ethics Committees (REC reference: 13/WM/0299).

The total costs of providing the intervention in the trial included set up (website development, design and planning, booklet production, procurement, initial local engagement, and staff induction) and delivery costs (including; vouchers, processing of claims). Resource use data were extracted from trial management records, computer-based diaries, and interviews with the trial manager. Resources were valued using national tariffs (e.g. [11]) to increase generalisability. The unit costs of the vouchers were obtained from administrative records. Costs are expressed in pounds sterling (2015-16), using the Hospital & Community Health Service (HCHS) inflation index where appropriate.[11] As the trial was within one year, a discount rate was not applied.

Multivariable regression models adjusting for baseline variables and potential imbalances in treatment group were used to generate the incremental cost-effectiveness estimates.[12] A generalised linear model using Poisson distributional family (and robust standard errors) was fitted to generate the cost per ward/trial arm and incremental cost per ward. As the control areas had zero cost, a constant value of £0.001 was added to observations for model convergence. Cost per baby/trial arm was derived by dividing the estimated mean cost per ward by the number of babies per ward. A negative binomial model was used to estimate the intervention effect following Relton et al.[7] albeit with different estimator. The outcome used in Relton et al.[7], percentage point increase in breastfeeding outcome, is a relative measure and not applicable to cost-effectiveness analysis.

To provide estimates of uncertainty, the ‘margins method’ generated sample means, by trial arm, for costs and breastfeeding.[12] The choice of distributional family for models was based on modified

Park test [12] and comparison of observed and predicted values. The covariates of the models included correlates of breastfeeding related outcomes [7,13-14]: deprivation (IMD) score for the wards, baseline breastfeeding rate, and ethnicity, and the inverse of the variance of breastfeeding rate (to account for the number of births in relation to breastfeeding). The choice of covariates was based on a literature review conducted as part of this study to identify the potential predictors of breastfeeding related outcomes.

Results are reported as cost per additional baby breastfed at 6-8 weeks. Deterministic sensitivity analyses assessed different components of total cost: (a) cost of routinely rolling out the scheme (covering induction and delivery costs); and (b) exclusion of the cost of voucher - this was to demonstrate the impact of assuming cost of vouchers is a 'transfer payment' (i.e. giving women vouchers without any service in exchange); and therefore not includable in an economic evaluation. Probabilistic sensitivity analysis estimated the precision of the estimates of cost and breastfeeding and investigated the robustness of potential differences in each. Bootstrap techniques (n=2000) based on regression models for costs and breastfeeding rates were employed to generate a sample of incremental costs and effects from an empirical distribution. This provided a measure of the probability that the intervention is cost-effective, at varying willingness to pay (WTP) values for changes in breastfeeding.

Results

Within trial cost-effectiveness

Table 1 shows the descriptive statistics (unadjusted estimates). The total cost of providing the intervention in 46 wards, over 12 months and 5398 births in the period, was £462,600 with an average cost per ward of £9,989 (Standard deviation (SD) £5538) and per baby of £91 (SD £22.40) (Table 1). Delivery costs constituted 86%, followed by recruitment (8%), set up (5%), and training (1%). The highest individual contributors were vouchers (74%; £342,840) and initial local engagement costs

(4%; £19,598). Total cost per ward ranged from £2,523 to £31,255 (Supplementary 1a-c). The control wards had no cost.

{Table 1 here}

Table 2 shows the regression-based estimates for costs, effects and incremental cost-effectiveness. Compared with control, the costs were higher for intervention wards (+£9738, 95%CI £8,520 to £10,957). Supplementary 2-3 show the regression based estimates.

At baseline, area-level breastfeeding prevalence at 6-8 weeks was 27.4 (95% CI, 25.2-29.6) in control and 28.7 (95% CI, 26.7-30.6) in the intervention areas. At follow up (for April 1, 2015, to March 31, 2016), area-level breastfeeding prevalence at 6-8 weeks was 31.7% (95% CI, 29.4-34.0) in control areas and 37.9% (95% CI, 35.0-40.8) in intervention areas [7]. The adjusted difference between intervention and control was 5.7 percentage points (95% CI, 2.7-8.6; $P < .001$), resulting in 10 (95% CI 6 to 14) more additional babies breastfed in the intervention wards (39 vs 29). The cost per additional baby breastfed at 6-8 weeks was £974. Thus, at a cost per QALY threshold of £20,000 (recommended in England), an additional breastfed baby would need to show a lifetime total QALY gain to the infant and/or mother of 0.05 to justify the intervention cost. The required QALY gain decreases further to 0.03 if the threshold is £30,000.

Deterministic sensitivity analyses (Table 2) show that voucher-only cost per additional baby breastfed at 6-8 weeks is £725 and £250 when only non-voucher costs are considered. Assuming the intervention is rolled out; the cost per additional baby breastfed will be £840. Probabilistic sensitivity analysis indicates that if decision makers' WTP for additional breastfed baby is £1000, the intervention has 54% chance of being cost-effective (Figure 1). At a WTP of £1500, the probability of intervention being cost-effective increases to 94% and to 99% if the WTP is £2000.

{Table 2 here}

{Figure 1 here}

Discussion

During the one year trial, the total cost of offering financial incentives for 5,398 mother-infant dyads living in 46 areas with low breastfeeding prevalence was £462,600. Intervention areas compared with control required an additional cost (adjusted estimates) of £9,738 (CI 95% £8,520 to £10,957) per ward, equivalent of £83 (95% CI £73 to £93) per baby. Compared with control areas, the intervention areas reported 10 more breastfed babies (95% CI 6 to 14) at 6-8 weeks per ward (39 vs 29). The mean cost per additional baby breastfed at 6-8 weeks was £974. There is a 54% chance of the scheme being considered cost-effective if decision-makers were willing to pay £1000 per additional baby breastfed. Sensitivity analyses did not change this conclusion.

These findings feed into a sparse and mixed evidence base on cost-effectiveness of interventions to increase breastfeeding.[15] One UK study reported that breastfeeding groups facilitated by a health professional led to higher costs (£5 per attendance) and a lower breastfeeding rate at 6-8 weeks (-4%).[16]. Other studies showed that more intensive support and contact with health professionals, offer good value for money with Rice et al [17] showing such interventions are cheaper and more effective. Hoddinott et al[18] compared the cost effectiveness of team (proactive) and women-initiated (reactive) telephone support for breastfeeding after discharge compared with reactive only and reported an incremental cost per additional woman breastfeeding of £87.

This is the first study to examine the cost effectiveness of a financial incentive for breastfeeding intervention. The data on cost and effectiveness were sourced from a cluster RCT with 92% follow-up. The resource use data for costing were collected prospectively using mostly logging system and computer-based records. This method led to minimal errors with respect to ascertainment of resource use and no missing data, a rarity in trial-based economic evaluations. [19]

There are a number of limitations to this analysis. First, breastfeeding has a wide range of benefits for both mothers and babies in both the short and longer term.[1] This analysis did not account for data on health service use or utility estimates and this limits the comparison with non-breastfeeding programmes in the health sector. Second, the lack of data on the longer term benefits of breastfeeding to both mother and child means that the value for money of the intervention is underestimated. Breastfeeding has health benefits to both mothers and babies over the whole life course.[1] Obtaining robust estimates of the life time costs and benefits of breastfeeding to both the mother and baby is difficult due to the need to model outcomes far into the future, and was outside the scope of this analysis.

A 2012 comprehensive review by Renfrew and colleagues found a clear association between increased breastfeeding and reduced cases of necrotising entercolitis in preterm babies, acute otitis media, lower respiratory tract infections and gastrointestinal infections, which was of sufficient quality to allow the estimation of the economic impacts of improved breastfeeding rates. [20] They showed that 45% of women exclusively breastfeeding for 4 months and 75% of babies in neonatal units being breastfed at discharge can lead to 3,285 fewer gastrointestinal infection related admissions and 10,637 fewer GP consultations (over £3.6 million treatment costs saving yearly); 5,916 fewer lower respiratory tract infection related hospital admissions and 22,248 fewer GP consultations (over £6.7 million treatment cost saving yearly); 21,045 fewer acute otitis media related general practice consultations (over £750,000 treatment cost saving yearly); and 361 fewer cases of necrotising entercolitis (over £6 million treatment cost saving yearly). The application of these cost savings to the

NOSH data is, however, challenged by the specific diseases included within the cost estimates. For example, the estimate on necrotising entercolitis was based on preterm babies within the neonatal intensive care unit (ICU). It would be inappropriate to attribute this cost savings to the increase in breastfeeding within the NOSH trial, as the intervention was not targeted at mothers of preterm infants, and breastfeeding rates within the ICU were not assessed within the trial.

However, although evidence supported an association between increased breastfeeding and improved cognitive outcomes, reduced early obesity and reduced Sudden Infant Death Syndrome (SIDS), the available literature was not of sufficient quality to allow estimation of the scale and scope of the risk reduction with precision. With respect to the association between breastfeeding and other diseases such as asthma, diabetes and cardiovascular disease, the strength of the evidence was also deemed not sufficient to allow estimation of the risk reduction and economic impact. Further well designed studies are needed which include adequate follow up of outcomes, accurate definition and measurement of breastfeeding and appropriate adjusting for confounding to inform the estimation of the long term health and economic impacts of improved breastfeeding.

With respect to quantifying how reasonable the 0.05 QALY gain over lifetime is (estimated to justify the intervention cost), with currently available data, this is difficult to do. The short term benefits on acute otitis media, lower respiratory tract infection and gastrointestinal infections are generally associated with mild sequelae within the UK and are of limited duration thereby resulting in only small utility deficits. [20-24] On the other hand, some of the longer term sequelae, which do not have adequate data available currently to quantify accurately the relative risk reduction associated with breastfeeding as listed above, would be associated with greater QALY deficits; however, many occur later in life and therefore the benefits and costs would be reduced due to discounting. Without an accurate estimate of the risk reduction associated with the increase in breastfeeding achieved within the NOSH trial, it is not possible to model the impact on the incidence of long-term outcomes and consequently the potential QALY gain. Future studies are recommended to measure the short and long-term health impact of interventions.

Our analysis was based on the evidence from one trial, which tested a single permutation of the idea of offering financial incentives to mothers to breastfeed. Future research is needed to help optimise this idea - testing a number of different variations. For example, would a universal single payment of £50 to mothers for exclusive breastfeeding at 6-8 weeks be more or less effective in increasing breastfeeding rates? Additionally, the data on breastfeeding was based on clinician reports collected as part of country-wide public health monitoring purposes. The validity of these reports are not usually assessed .[7] and therefore the use of objective measures of breastfeeding should be considered in future research.

This study provides information to help inform public health guidance on breastfeeding. Implementing financial incentives to increase breastfeeding in areas with low breastfeeding prevalence could offer value for money if policy makers are willing to pay £974 (or more) per additional baby breastfed. To make the economic case unequivocal, more research is required to provide effectiveness data on financial incentives for breastfeeding beyond 6-8 weeks and epidemiological evidence on the varied health benefits of breastfeeding to both the baby and mother. This will allow the incorporation of long term health benefits of breastfeeding in an economic analysis and facilitate the comparison of financial incentives for breastfeeding with a wide range of other public health programmes and healthcare technologies.

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List of Tables

Table 1: Average costs of intervention arm (£'sterling 2015/16)

Activities	**Activities**	**Average cost per ward (SD)** *n=46*	**Average cost per baby (SD)** *n=5,398*
Set up	Preparation of booklets describing the scheme	£336 (0)	£2.86 (0)
	Design of intervention	£96 (0)	£0.82 (0)
	Development of the website with information about the scheme – including the postcode calculator	£64 (0)	£0.55 (0)
	Procurement of the vouchers from vendors (supermarkets and Love2shop)	£39 (0)	£0.33 (0)
	Initial local engagement	£426 (371)	£7.34 (9.17)
	Advertisement	£394 (0)	£3.36 (0)
	Training/ Induction sessions for health visitors and midwives	£131 (70)	£1.65 (1.22)
Delivery	Vouchers	£7453 (5028)	£64.44 (18)
	Processing time for claim forms	£317 (214)	£2.74 (0.77)
	Information packs (including the booklets describing the scheme)	£283 (148)	£3 (1.46)
	Delivery of letters to mothers	£189 (122)	£2.10 (0.76)
	Costs of telephone, texts for processing claims	£166 (0)	£1.41 (0)
	Processing time for applications to join the NOSH scheme	£93 (60)	£0.84 (0.30)
Total cost		**£9989 (5538)**	**£91.45 (22.38)**

Table 2: Regression estimates for costs, effects, and cost effectiveness (£'sterling 2015/16)

	Control (46 wards; 4612 mother-infant dyads)		Intervention (46 wards; 5398 mother-infant dyads)	
	Mean	**(95% CI)**	**Mean**	**(95% CI)**
Base case analysis				
Total cost per ward (£)	£0	(0, 0)	£9738	(8520, 10957)
Incremental cost(£)	-		£9738	(8520, 10957)
Percentage of babies breastfed at at 6-8 weeks per ward	31.7%	(29.4, 34.0)	37.9%	(35.0, 40.8)
Total number of babies breastfed at 6-8 weeks per ward	29	(27,32)	39	(36,43)
Incremental number of breastfed babies	-		10	(6,14)
Cost per additional baby breastfed at 6-8 weeks (£)	-		£974	
Deterministic sensitivity analyses				
Assuming that the provision of vouchers is the only accruable to the intervention				
Total voucher cost per ward (£)	£0	(0, 0)	£7251	(6117, 8385)
Incremental non voucher cost(£)	-		£7251	(6117, 8385)
Total number of babies breastfed at 6-8 weeks per ward	29	(27,32)	39	(36,43)
Incremental breastfeeding	-		10	(6,14)
Voucher cost per additional baby breastfed at 6-8 weeks (£)	-		£725	
Assuming that the provision of vouchers will be free of charge to the providers				
Total non-voucher cost per ward (£)	£0	(0, 0)	£2498	(2355, 2638)
Incremental non-voucher cost(£)	-		£2498	(2355, 2638)
Total number of babies breastfed at 6-8 weeks per ward	29	(27,32)	39	(36,43)
Incremental breastfeeding	-		10	(6,14)
Non-voucher cost per additional baby breastfed at 6-8 weeks (£)	-		£250	
Cost of routinely rolling out intervention				
Total roll out cost per ward (£)	£0	(0, 0)	£8402	(7154, 9649)
Incremental roll out cost(£)	-		£8402	(7154, 9649)
Total number of babies breastfed at 6-8 weeks per ward	29	(27,32)	39	(36,43)
Incremental breastfeeding	-		10	(6,14)
Roll cost per additional baby breastfed at 6-8 weeks (£)			£840	