

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A cluster randomised controlled trial of a financial incentive for mothers to improve breastfeeding in areas with low breastfeeding rates: The NOSH study protocol.
AUTHORS	Relton, Clare; Strong, Mark; Renfrew, Mary; Thomas, Kate; Burrows, J.; Whelan, Barbara; Whitford, Heather; Scott, Elaine; Fox-Rushby, Julia; Anokye, Nana; Sanghera, Sabina; Johnson, Maxine; Easton, Sue; Walters, Stephen

VERSION 1 - REVIEW

REVIEWER	David Tappin University of Glasgow, Scotland I am a member of the trial steering committee for this study
REVIEW RETURNED	27-Oct-2015

GENERAL COMMENTS	<p>I think a flow diagram for patients/clusters through the trial should be included</p> <p>I think also a map of the area and clusters would be helpful</p> <p>My major criticism relates to structure of the paper</p> <p>The Abstract</p> <p>Structure is in keeping with the 'Instruction for authors' for protocol papers</p> <p>The sample size calculation should indicate the level of significance as well as power</p> <p>Cost effectiveness long term modelling should include ? cost per Quality Adjusted Lifeyear</p> <p>Main paper</p> <p>Structure is in not keeping with the 'Instruction for authors' for protocol papers</p> <p>Background should be changed to Introduction</p> <p>Introduction</p> <p>Should include sections: Breastfeeding, Financial Incentives for Behaviour Change, Breastfeeding and Public Health, Results of Developing and Testing Feasibility study, Aim of this study</p> <p>Methods and analysis</p> <p>Should include Study Objectives, Study design and Setting, The Intervention, Verification of Breastfeeding in order to receive incentives, Sampling frame and recruitment, Randomization, Outcomes when and how - to include data collection, primary outcomes and secondary outcomes and health economic outcomes, sample size calculation</p> <p>Data Analysis Plan</p> <p>To include statistical methods, economic analysis, and qualitative analysis.</p> <p>Ethics etc is fine</p> <p>Not sure discussion section is required</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1 David Tappin Our response/ actions

I think a flow diagram for patients/clusters through the trial should be included Added – see Figure 1 page 6

I think also a map of the area and clusters would be helpful Added – see Figure 3 page 10

My major criticism relates to structure of the paper – the structure should be in keeping with the 'Instruction for authors' for protocol papers We have revised the structure of the paper.

The sample size calculation should indicate the level of significance as well as power In our original manuscript, in the sample size section on page 12, the sample size calculation indicated the level of significance as well as power:

“statistically significant at the 5% (two-sided) level and 80% power.”

Cost effectiveness long term modelling should include ? cost per Quality Adjusted Lifeyear We are unable to calculate QALYs as no individual level data on quality of life of women or children is collected

Background should be changed to Introduction Done

Introduction: Should include sections: Breastfeeding, Financial Incentives for Behaviour Change, Breastfeeding and Public Health, Results of Developing and Testing Feasibility study, Aim of this study Done

Methods and analysis: Should include Study Objectives, Study design and Setting, The Intervention, Verification of Breastfeeding in order to receive incentives, Sampling frame and recruitment, Randomization, Outcomes when and how - to include data collection, primary outcomes and secondary outcomes and health economic outcomes, sample size calculation Done

Data Analysis Plan

To include statistical methods, economic analysis, and qualitative analysis Done

Not sure discussion section is required If possible, we would prefer to leave in the short discussion section.

Our additional revisions

We have recently rechecked the routinely collected data on births we used and found an error in the sample size calculations. The revised data and the revised sample size have been inserted into all relevant sections of the protocol and highlighted in yellow. (Sample size paragraph on page 12 and the abstract).

FYI - Errors we plan to report in the RCT results paper and not in the protocol

When conducting our checks we identified an additional four clusters with BF rates < 40% had been excluded due to errors in interpreting the routine data.

We also identified that one cluster had been included in error as there were no project approvals for midwives and health visitors to help deliver the scheme in that particular cluster. As it turned out this cluster had been randomly allocated to the control group.

We plan to report these errors in the results paper.

VERSION 2 – REVIEW

REVIEWER	David Tappin University of Glasgow UK I am on the steering committee for the NOSH study
REVIEW RETURNED	26-Nov-2015
GENERAL COMMENTS	'incentives' word missing after 'financial' line 1 page 17 Ethics section is repeated pages 16 and 19

Correction: *Cluster randomised controlled trial of a financial incentive for mothers to improve breast feeding in areas with low breastfeeding rates: the NOSH study protocol*

Relton C, Strong M, Renfrew MJ, *et al.* Cluster randomised controlled trial of a financial incentive for mothers to improve breast feeding in areas with low breastfeeding rates: the NOSH study protocol. *BMJ Open* 2016;6:e010158. The first and last names of the penultimate author of this paper are transposed. The author's name is 'Sue Easton'.

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