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RANDOMISED CONTROLLED TRIAL

Quality improvement interventions to increase the uptake of magnesium sulphate in preterm deliveries for the prevention of cerebral palsy (PReCePT study): a cluster randomised controlled trial

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Abstract

Objective: To compare two quality improvement (QI) interventions to improve antenatal magnesium sulphate ($MgSO_4$) uptake in preterm births for the prevention of cerebral palsy.

Design: Unblinded cluster randomised controlled trial.

Setting: Academic Health Sciences Network, England, 2018.

Sample: Maternity units with ≥10 preterm deliveries annually and $MgSO_4$ uptake of ≤70%; 40 (27 NPP, 13 enhanced support) were included (randomisation stratified by $MgSO_4$ uptake).

Methods: The National PReCePT Programme (NPP) gave maternity units QI materials (clinical guidance, training), regional support, and midwife backfill funding. Enhanced support units received this plus extra backfill funding and unit-level QI coaching.

Main outcome measures: $MgSO_4$ uptake was compared using routine data and multivariable linear regression. Net monetary benefit was estimated, based on implementation costs, lifetime quality-adjusted life-years and societal costs. The implementation process was assessed through qualitative interviews.

Results: $MgSO_4$ uptake increased in all units, with no evidence of any difference between groups (0.84 percentage points lower uptake in the enhanced group, 95% CI −5.03 to 3.35). The probability of enhanced support being cost-effective was <30%. NPP midwives gave more than their funded hours for implementation. Units varied in their support needs. Enhanced support units reported better understanding, engagement and perinatal teamwork.

Conclusions: PReCePT improved $MgSO_4$ uptake in all maternity units. Enhanced support did not further improve uptake but may improve teamwork, and more accurately represented the time needed for implementation. Targeted enhanced support, sustainability of improvements and the possible indirect benefits of stronger teamwork associated with enhanced support should be explored further.

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KEYWORDS
cerebral palsy, cluster analysis, extremely premature, infant, magnesium sulphate, midwifery, national health programmes, obstetrics, pregnancy, pregnant women, premature, quality improvement, quality of health care, randomised controlled trials

1 | INTRODUCTION

Neurodisability as a result of preterm birth, including cerebral palsy (CP), represents a significant burden for individuals, families,[1] and healthcare services.[2–4] Antenatal prophylaxis with magnesium sulphate ($MgSO_4$) reduces the risk of CP in preterm births by around 30%.[5] A dose costs approximately £1,[6] with estimated lifetime societal savings of approximately £1 M per case of CP avoided.[7]

Since 2015, the UK National Institute for Health and Care Excellence (NICE) has recommended the administration of $MgSO_4$ in preterm deliveries,[8] and non-compliance is considered suboptimal care. Yet, by 2017, only 64% of eligible women (<30 weeks of gestation) were receiving $MgSO_4$.[9]

The Preventing Cerebral Palsy in Pre-Term labour (PReCePT) quality improvement (QI) intervention was developed to improve maternity staff awareness and increase $MgSO_4$ uptake. The pilot study (five maternity units) improved $MgSO_4$ uptake from 21% in 2012–2013 to 88% in 2015.[10] The National PReCePT Programme (NPP) scaled-up the intervention and it was rolled-out across English maternity units, led by regional Academic Health Science Networks (AHSNs), to increase $MgSO_4$ uptake to 85% by 2020.[11]

A cluster randomised controlled trial (cRCT) was nested within the NPP. It evaluated the effectiveness and cost-effectiveness of the enhanced support model, compared with the standard NPP support model.[12] A qualitative process evaluation was conducted to understand the implementation process in both groups.[13]

2 | METHODS

2.1 | Trial design

This unblinded nested cRCT was set in NHS England maternity units. NPP (control) units received standard NPP support, including the PReCePT QI guide and toolkit resources (clinical guidance, preterm labour proforma, training presentations, parent leaflet, unit posters, learning log), regional AHSN-level support and up to 90 h of funded backfill for a midwife 'champion' to lead implementation. Enhanced support (intervention) units received this plus unit-level QI coaching, an additional 90 h of midwife backfill funding, approximately 104 h of backfill funding for the local obstetrician/neonatologist lead, team access to learning and celebration events, and a computer tablet for micro-coaching (Appendix S1). The trial was embedded within the NPP and aligned with its time frame of two waves (Figure 1). After randomisation, implementation ran for 9 months with a further 9 months of follow-up.

2.2 | Eligibility criteria

Maternity units in England participating in the NPP with ≥10 preterm (<30 weeks of gestation) deliveries annually and $MgSO_4$ uptake of ≤70% were eligible. Eligibility was assessed from 2017 UK National Neonatal Research Database (NNRD) data, in units that expressed an interest in participating. PReCePT pilot study units were excluded.

2.3 | Outcomes

The primary outcome was the unit-level proportion of eligible women receiving $MgSO_4$ post-implementation. Secondary outcomes included data completeness, reasons $MgSO_4$ was not given and cost-effectiveness (incremental net monetary benefit) from a societal perspective over the lifetime of a preterm baby. Qualitative interviews assessed the implementation process.

2.4 | Sample size and randomisation

At the time of study design, the background population was 153 English maternity units. There were limited data for power calculation parameter assumptions, but at the design stage, data from the 2016 National Neonatal Audit Programme (NNAP) data, the pilot study and clinical assumptions indicated an anticipated baseline $MgSO_4$ uptake in the control arm of 38%, uptake in the enhanced support arm of 80% and a high intraclass correlation coefficient (ICC) of up to 0.67 (with formulae for cluster trials taken from the literature).[14] To detect a difference of 40 percentage points in uptake between groups, which would be important and the available data suggested was feasible, with a 2-sided 5% significance level, 80% power, ICC = 0.67, coefficient of variation for cluster size = 0.48 and a 1:2 randomisation ratio, 11 intervention and 22 control units were needed.

Units were stratified by 2017 $MgSO_4$ uptake rates (0%–39.9%, 40%–49.9%, 50%–59.9%, and 60%–70.9% uptake). Taking into account these four strata and the two implementation waves, the target sample size was increased to 48.

Randomisation was performed in two tranches, in line with the two waves of implementation. It was performed with Stata command *stratarand* and carried out by a statistician independent of the trial and NPP (Appendix S2).

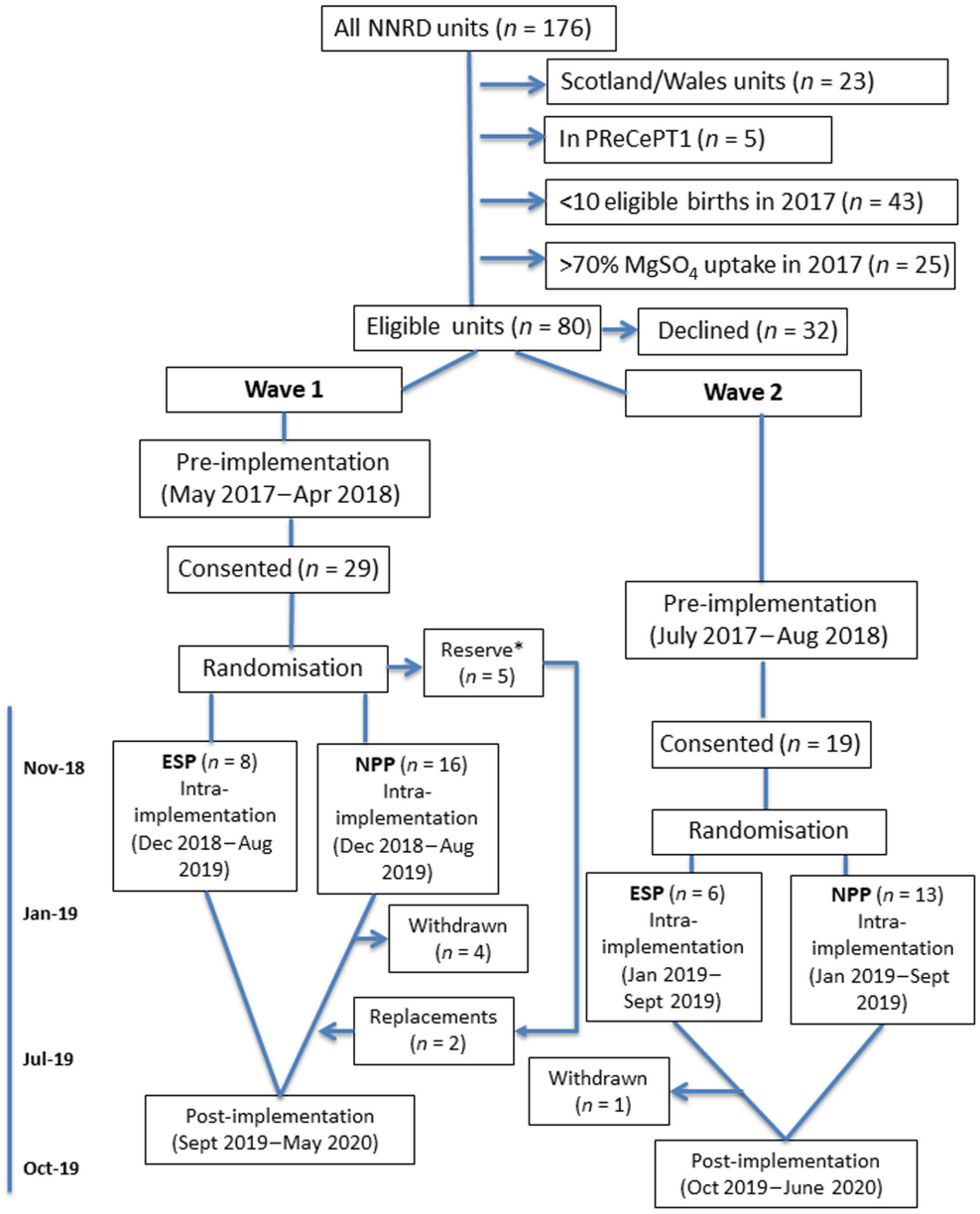

FIGURE 1 PReCePT study flow chart.

The nature of the interventions made it impossible to conceal allocation from maternity staff. The unequal randomisation ratio also made it difficult to conceal allocation from research staff performing the analysis.

2.5 | Data collection

We used pseudonymized patient-level data from the NNRD.[15,16] Baseline data were collected for the 12 months pre-implementation. Index of multiple deprivation (IMD) data were derived from published data for each lower super output area.[17] Data on number of beds and staff, amount of time spent on PReCePT-related activities and previous QI experience were collected via questionnaires completed by unit lead midwives. Cost data were supplied by the NPP team.

For the process evaluation, criterion-based sampling (trial arm, annual number of births, baseline $MgSO_4$ uptake, recent Care Quality Commission (CQC) ratings on leadership and patient safety) were used to select units for qualitative interviews. Implementers (unit lead midwife, obstetrician and neonatologist) were invited to participate in a semi-structured telephone interview near the end of the implementation period. Interviews explored: experiences of QI activities, staff engagement, perceived leadership support, and contextual factors, such as professional/cultural issues, organisational changes, staff shortages and the impact of coronavirus disease 2019 (COVID-19) (Appendix S3). Written informed unit and individual consent

were obtained and interviews were audio-recorded and transcribed.

2.6 | Data analyses

2.6.1 | Primary outcome

$MgSO_4$ uptake was defined as the number of mothers given $MgSO_4$ divided by the total number of eligible mothers, excluding missing values from the denominator, expressed as a percentage.[9] Baby-level demographic descriptions included all babies. In all other analyses, we only included data for singletons and the firstborn of multiples (for consistency with nationally reported audit data). Where only one baby had a record for $MgSO_4$, the missing $MgSO_4$ status of the other multiples was recoded to match that for their twin/triplet with a record. For babies with conflicting records, we recorded $MgSO_4$ as given.

Linear regression was used to assess differences in $MgSO_4$ uptake between trial arms post-implementation, adjusted for pre-implementation uptake. The model was weighted on the number of births in each unit and used robust standard errors. Sensitivity analyses adjusted for factors by which the trial arms differed appreciably pre-implementation.

2.6.2 | Secondary outcomes

Controlled interrupted time series (ITS) analysis using segmented linear regression was used to model differences in trends in uptake and missing $MgSO_4$ data, over three time periods: pre-, intra- and post-implementation. Newey–West standard errors (with one lag) were estimated by ordinary least-squares regression and used to handle autocorrelation in the model. Differences in slope (indicating trend) and intercept (value of $MgSO_4$ uptake) between trial arms, as well as differences across time periods, were described in the model.

2.6.3 | Cost-effectiveness

Implementation costs in both arms included management, AHSN support, and midwife backfill. Additional enhanced support costs were extra staff backfill, unit-level QI coaching and learning events. Staff time was costed using national salary data. Mean implementation cost per baby was calculated as the mean implementation cost per unit divided by the total number of babies eligible for $MgSO_4$ per unit delivered during implementation and follow-up. Mean staff time per week spent on PReCePT activities was estimated from questionnaires completed for the month before starting the QI and each intra-implementation month.

Decision-tree analysis estimated enhanced support net monetary benefit using a lifetime horizon and societal perspective. Model parameters were based on trial data for implementation costs and $MgSO_4$ uptake, literature estimates for lifetime gains in quality-adjusted life-years (QALYs),[7] and societal cost savings from $MgSO_4$ treatment for imminent and threatened preterm births (Appendix Table S2). Babies delivered by caesarean section were defined as imminent births (certain to occur within 24 h) and all others were defined as threatened. We used a £20,000 per QALY gained willingness-to-pay threshold.[18]

The probability of $MgSO_4$ treatment in the enhanced support group compared with NPP was estimated using a multilevel logistic regression model clustered at unit level to determine the odds ratio of imminent and threatened babies having received $MgSO_4$ during the 18-month implementation and follow-up period, adjusted for baseline uptake. For this analysis only, babies with missing $MgSO_4$ treatment records were assumed to have not received treatment.

We conducted a probabilistic analysis using Monte Carlo simulation with 10 000 samples drawn from the parameter distributions. Incremental costs and effects were plotted on the cost-effectiveness plane and a cost-effectiveness acceptability curve was plotted for willingness-to-pay thresholds from £0 to £100,000 per QALY gained. This analysis accounts for parameter uncertainties by drawing samples at random from parameter-specific probability distributions. (Appendix Table S3).

2.6.4 | Process evaluation

Semi-structured interviews were analysed using the framework method.[19] The matrix output, using rows, columns and 'cells' of summarised data, facilitated analysis by case (for example, site, professional group or individual) and by code (summarised data in relation to a particular theme, such as intervention fidelity). This allowed comparison of data across and within cases to inform understanding of the implementation processes by which this complex intervention is operationalised, embedded and sustained in practice. Analysis focused on aspects of individual and collective behaviour shown to be important in implementation processes.[20]

2.6.5 | Patient and public involvement

Two mothers who had experienced preterm births were involved in trial design and delivery, and were part of the Trial Steering Committee.

3 | RESULTS

Applying eligibility criteria to all 153 English maternity units left 80 units (52% of the total population) as potentially eligible participants. Of these, 48 (60%) were randomised. As a result of changes in the readiness of some units to start, and the need to balance randomisation between tranches and strata, 40 were included (13 enhanced support and

27 standard NPP; Appendix S2; Figure 1; Table S1). This covered 2962 babies born to 2597 mothers in the pre- and post-implementation periods, respectively. Trial arms were comparable at baseline. Enhanced support units saw more white British mothers and more mothers from socio-economically deprived areas. Standard support units had more experience with QI (Table 1).

3.1 | Primary outcome

The mean $MgSO_4$ uptake in the 12 months pre-implementation was 68.1% in NPP units and 64.3% in enhanced support units. This increased to 83.7% and 84.8%, respectively, in the 12 months post-implementation (Table 2). After adjusting for pre-implementation uptake, there was no evidence of a difference in uptake between trial arms (0.84 percentage points lower uptake in the enhanced support versus the NPP arms, 95% CI −5.03 to 3.35 percentage points, $p = 0.687$).

Sensitivity analyses adjusting for factors imbalanced pre-implementation (maternal ethnicity, socio-economic deprivation and previous QI experience) gave similar results (0.47 percentage points higher uptake in the enhanced support group, 95% CI −4.18 to 5.12 percentage points, $p = 0.840$).

3.2 | Secondary outcomes

Trends in $MgSO_4$ uptake were similar between groups. The proportion missing data for the enhanced support

TABLE 1 Sociodemographic and clinical characteristics of mothers and babies by trial arm.

	Enhanced support ($n = 13$ units)		NPP support ($n = 27$ units)	
Characteristic	**Pre-implementation**	**Post-implementation**	**Pre-implementation**	**Post-implementation**
Babies				
Number of babies	596	374	1148	844
Male sex, *n* (%)	333 (55.9)	207 (55.4)	624 (54.4)	465 (55.6)
Gestational age (weeks), median (IQR)	28.3 (26.6–29.9)	28.6 (26.4–30.0)	28.6 (26.6–30.0)	28.6 (26.6–30.0)
Birthweight (g), median (IQR)	1057.5 (800.5–1300)	1089.5 (806–1365)	1065 (825–1335)	1057.5 (840–1330)
Number born in multiples, *n* (%)	136 (22.8)	97 (25.9)	292 (25.4)	194 (23.0)
Mothers				
Number of mothers	530	328	997	742
Maternal age (years), median (IQR)	30 (25–34)	30 (26–35)	31 (26–35)	31 (26–36)
White ethnicity, *n* (%)	312 (72.2)	167 (68.4)	452 (56.8)	333 (58.3)
IMD quintile, *n* (%)				
1 – most deprived	199 (38.8)	135 (42.2)	306 (31.1)	242 (33.4)
2	114 (22.2)	71 (22.2)	252 (25.6)	152 (21.0)
3	73 (14.2)	50 (15.6)	189 (19.2)	156 (21.6)
4	66 (12.9)	35 (10.9)	140 (14.2)	105 (14.5)
5 – least deprived	61 (11.9)	29 (9.1)	97 (9.9)	69 (9.5)
Caesarean delivery, *n* (%)	287 (61.1)	176 (55.2)	581 (60.0)	429 (60.0)
Had pregnancy-induced hypertension, *n* (%)	26 (5.0)	19 (5.9)	52 (5.2)	36 (4.9)
Antenatal steroids given, *n* (%)	479 (91.4)	303 (93.2)	919 (92.2)	691 (93.6)
Maternity units				
Level of birth unit, *n* mothers (%)				
Special Care Unit (SCU)/High-Dependency Unit (HDU)	191 (36.4)	110 (33.8)	366 (36.7)	265 (35.9)
Neonatal Intensive Care Unit (NICU)	334 (63.6)	215 (66.2)	632 (63.3)	473 (64.1)
Number of staff per unit, median (IQR)				
Midwives (bands 5–8c)	83 (60–166)	Only collected pre-implementation	81 (57–161)	Only collected pre-implementation
Consultants	15 (11–22)		14 (9–24)	
Delivery suite beds per unit (median, IQR)	10 (8–12)		12 (9–15)	
Have previous QI experience, *n* (%)	6 (46.15)		19 (70.37)	

TABLE 2 $MgSO_4$ uptake in maternity units, by trial arm and study periods.

Variable	Enhanced support		Standard NPP support		Difference between groups post-implementation[a]
	Pre-implementation	Post-implementation	Pre-implementation	Post-implementation	
Total no. of eligible births[b]	525	325	998	738	
Mothers given $MgSO_4$, *n* (%)	357 (68.0%)	270 (83.1%)	675 (67.6%)	607 (82.2%)	
Mothers not given $MgSO_4$, *n* (%)	143 (27.2%)	51 (15.7%)	279 (28.0%)	109 (14.8%)	
With $MgSO_4$ data missing, *n* (%)	25 (4.8%)	4 (1.2%)	44 (4.4%)	22 (3.0%)	
Overall proportion uptake[c]	64.3%	84.8%	68.1%	83.7%	−0.84 percentage points in enhanced group (95% CI −5.03 to 3.35 percentage points, $p = 0.687$)

[a]Results from adjusted linear regression model.
[b]Records on singleton births and the firstborn of multiples included in the analysis.
[c]Total uptake over the follow-up and baseline periods. The 'uptake' proportion is calculated excluding missing values from the denominator, and only includes singletons and the firstborn of multiples.

group decreased in the pre-implementation period, compared with NPP units, and slightly increased post-implementation, but these trends represent negligible differences (Appendix Figure S2). Overall, the amount of missing $MgSO_4$ data reduced over the study period. The ICC was 0.019, indicating lower than expected clustering at the maternity-unit level.

3.3 | Costs and cost-effectiveness analyses

The incremental funded implementation cost was £16,869 per enhanced support unit, and £276 per preterm baby delivered (Appendix Tables S4 and S6). The incremental impact of enhanced support on $MgSO_4$ uptake over the 18 months implementation and follow-up was −0.79 percentage points (95% CI −6.00 to 4.41 percentage points). Deterministic results are included in appendix Table S5 and S6.

From a societal lifetime perspective, probabilistic analysis showed a decrease of −0.001 QALYs (95% CI −0.009 to 0.006 QALYs) and a cost increase of £315 per preterm baby delivered associated with the enhanced support model. This generated a net monetary loss of £340 for a willingness-to-pay threshold of £20,000, indicating that enhanced support was not cost-effective compared with the standard NPP model (Appendix Table S7). The probability of enhanced support being cost-effective was less than 30% across the range of plausible willingness-to-pay thresholds (Figure 2 and Appendix Figure S1).

Backfill funding for midwives and clinical champions allowed for, on average, 5.5 h (enhanced support) and 1.7 h (NPP) per week for PReCePT QI activities. The actual self-reported time spent per week over the first 9 months was on target for the enhanced group (5.6 h) but was double the funded time for the NPP group (3.4 h). This made the groups more similar than intended per protocol (Figure 3).

3.4 | Process evaluation

Fifty-one participants were recruited from 29 units, representing 10 out of the 12 AHSNs (Appendix S4). Twenty-two were lead midwives, 14 were lead obstetricians and 15 were lead neonatologists. Eighteen were from intervention units. Full results of the qualitative process evaluation are presented elsewhere.[21]

3.4.1 | Similarities

Commitment to improving $MgSO_4$ uptake was high among all units, encouraged by the NICE guidance, NNAP annual audit reporting and the recent formation of the Maternity and Neonatal Safety Improvement Programme (MatNeo). Several described other local QI initiatives targeting $MgSO_4$ administration, but overall there was variability between units in their readiness to change. Staff felt that the national character of the PReCePT programme

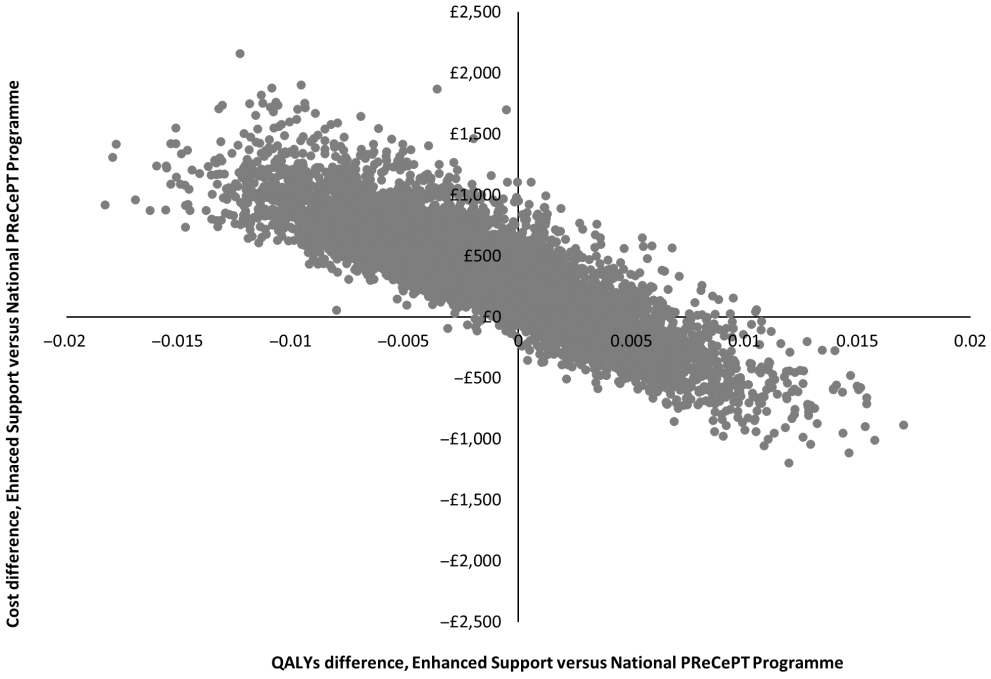

FIGURE 2 Cost-effectiveness plane.

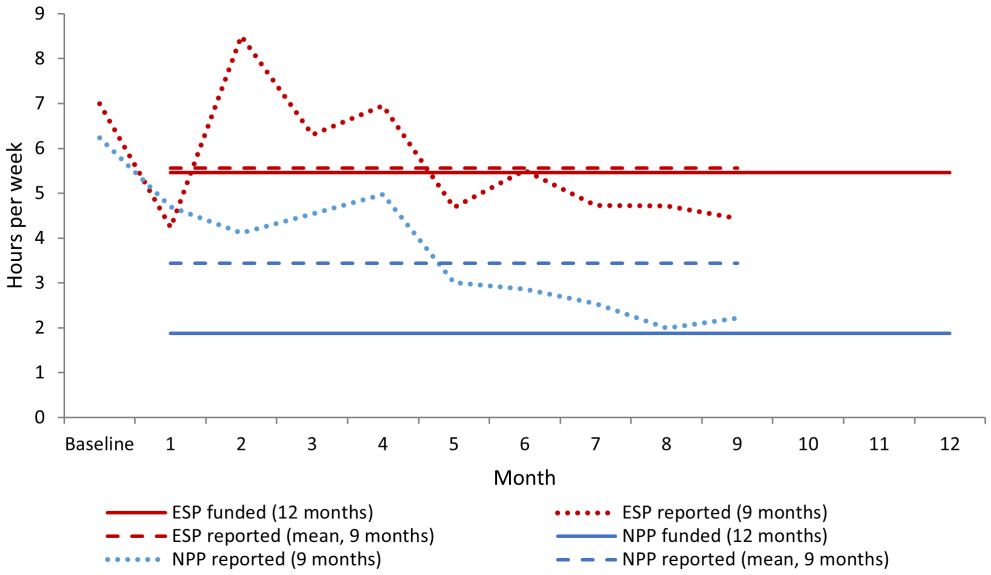

FIGURE 3 Funded time and reported time.

and how the $MgSO_4$ message was delivered was key to the intervention's success.

Support structures across both groups (e.g. WhatsApp groups of midwives, AHSN and regional clinical leads, Twitter, and regional safety and improvement networks) provided a 'community of practice' to share learning and ideas, and cultivate meaning and clarity of the implementation process. Staff from both trial arms interacted in these groups, leading to the diffusion of knowledge and practice, and similar approaches across the trial arms.

Existing QI and implementation skills and training and support needs varied across units. Some NPP midwives received no QI training from AHSNs and would have liked more support. Equally, some enhanced support midwives felt they did not need the intensive QI coaching on top of the support groups and activities that they were already part of.

Both groups implemented core components of PReCePT QI. The 'off the shelf' nature of the resources meant leads could choose from ready-made tools according to local needs and apply/adapt them with flexibility. Participants believed that improving collective knowledge and understanding through peer support and training, embedding $MgSO_4$ in documentation, workflows and clinical

processes, and better data monitoring helped to embed $MgSO_4$ use in clinical practice. The care of women in preterm labour and the timely administration of $MgSO_4$ required new routines that needed to be aligned with established responsibilities and a vision for joint working across perinatal teams. PReCePT tried to make $MgSO_4$ a shared goal and 'everyone's responsibility' by involving all members of the multi-professional care team in implementation activities.

3.4.2 | Differences

Enhanced support learning events brought together midwifery, obstetric and neonatology PReCePT leads, which helped develop relationships, and improved communication and collaboration. They collectively used their skills and networks to design and co-deliver PReCePT, with better support available to the lead midwife. Opportunities to come together helped counter the hectic silo working that is typical in many clinical settings.

In contrast, the NPP model delivered support to champion midwives only. This encouraged the idea of PReCePT as a midwifery-specific intervention, rather than a perinatal intervention. Team collaboration was more variable in NPP units and depended on existing perinatal teamworking and safety culture. Several NPP midwives reported poor involvement and support from lead clinicians. NPP midwives with less support or lower seniority/skillsets were less successful in delivering the full QI package and in overcoming challenges. NPP midwives were more likely to be left to manage implementation alone, which often resulted in them having to work over their funded hours.

3.4.3 | Impact of the COVID-19 pandemic

Implementers interviewed during the COVID-19 pandemic reported several factors that could negatively impact $MgSO_4$ use and reporting: the cessation of QI activities such as meetings and training, increased clinical pressures, staff shortages and the reliance on untrained/agency staff.

4 | DISCUSSION

4.1 | Main findings

$MgSO_4$ uptake increased across all maternity units. The NPP was effective and cost-effective,[11] and enhanced support did not appear to improve $MgSO_4$ uptake further. Success depended on staffing pressures, QI capacities, teamworking culture and access to senior support. Perinatal teamworking was an important enabler for improving $MgSO_4$ uptake, and for embedding practice. Enhanced support was associated with better integration and mobilisation of all members of the perinatal team. A slight decrease in $MgSO_4$ uptake between March and June 2020 was observed, which might correspond to the first peak of COVID-19 and the first UK lockdown.

4.2 | Strengths and limitations

This is the first national-scale RCT of a QI intervention in perinatal medicine. It benefitted from use of robust, high-quality, routinely collected data, a cluster design, to minimise contamination between trial arms, and the active engagement of two mothers with preterm birth experience in the trial steering group. Results represent 40/153 maternity units (26%) across England. Each perinatal team was able to tailor methods of implementing the toolkit to fit their local context, indicating that this sort of improvement programme can be successful while allowing flexibility, adaptability and personalisation.[22]

This study has highlighted some of the challenges of conducting RCTs of quality improvement interventions: there were variations in implementation between units, a key element of QI and a normal feature of real-world interventions, but a disadvantage for getting a clear comparison between groups. Variation in unit readiness suggests that more targeted support for units unused to QI might be a more effective use of resources. The unintended similarities between the groups in staff time, and contamination from the networking connections between groups, also made a clear comparison difficult. The changing landscape of policy and practice also presented a challenge: between trial design and trial start, the baseline rate of $MgSO_4$ uptake had considerably increased, meaning that large differences between the groups, as observed in the pilot study, would not be achievable. This, as well as budget and eligibility criteria constraints on sample size, limited the power of the study to detect small differences. However, confidence intervals around the null are reasonably narrow, and we do not think it is likely that they contain a difference that would be important for policy decisions. Longer-term analysis would be valuable to identify any differences in the sustainability of uptake. Analytically, we acknowledge that linear models for proportions have disadvantages, but the data (especially extreme values of the proportions) led to challenges with applying alternative regression methods; in any case, exploratory analyses utilising log transformations conferred no benefits here.

4.3 | Interpretation

There is no evidence that enhanced support would be justified on a universal national scale. However, part of the success of the NPP – and the reason for a lack of difference between the groups – was likely linked to midwives putting in many hours above their funded time, an amount of time that was only fully funded in the enhanced support

model. This real implementation cost should not be underestimated in future improvement programmes. The high level of commitment, QI capacity and teamworking culture already present in some NPP units, and the high levels of interaction of staff between trial arms (contamination), may also explain the overall similarity in outcome between the groups.

The confidence intervals were consistent with the possibility of a small advantage (up to three percentage points) associated with enhanced support. The potential for even a small advantage should be considered, given the substantial lifetime benefits of avoiding CP. However, it is debatable whether an intervention that delivered this small advantage would be considered clinically important. The NNAP annual report and a systematic review indicate that across many audit measures, a background annual improvement of a few percentage points is to be expected.[23,24] Moreover, analysis indicated a less than 30% probability that enhanced support was cost-effective.

The improved teamwork observed in the enhanced support group is particularly important in light of a recent independent review of maternity services (2022 Ockenden report),[25] which found that a root cause of poor perinatal care is tribalism and deficient teamwork. If an intervention can improve teamwork, this is likely to have far-reaching benefits across a broad range of perinatal outcomes.

Around the time of the first UK lockdown in the COVID-19 pandemic, women may have delayed presentation at hospital due to infection contact concerns, resulting in missed opportunities to give $MgSO_4$. Clinical pressures may also have contributed to the lower uptake or less consistent reporting of administration. Further analysis of data beyond June 2020 would be valuable to identify uptake trends throughout the pandemic and the longer-term sustainability of the PReCePT programme.

Uptake varies internationally, with reports of 0%–12.3% in Europe,[26] and 43.0% in Canada.[27] A single-centre Australian QI programme reported increased uptake from 63% to 86% (2018–2021).[28] A multicentre Canadian study (MAG-CP) reported increased uptake from 2.0% to 46.3% (2005–2015).[29] Studies have also evidenced the feasibility and success of implementing $MgSO_4$ clinical protocols in maternity units in the USA and France.[27,28,30]

5 | CONCLUSION

The use of antenatal $MgSO_4$ increased over the study period. The standard support of the National PReCePT Programme was effective and cost-effective. Enhanced support was not found to further improve uptake, but it was associated with better perinatal teamwork. Some of the success of the standard NPP group is likely linked to midwives putting in enhanced-support-level time. Assessing individual unit needs to tailor implementation may help to achieve greater uptake. The potential for indirect benefits, such as better teamworking, and the positive impact that this would have on services overall, should be explored further.

AUTHOR CONTRIBUTIONS

KL, BO and JD conceptualised the trial; KL and BO led the funding application to the Health Foundation supported by JD; KL is Chief Investigator and BO is Co-Chief Investigator. TP, MTR, SR, WH and HM led the design and analysis plan. ET advised on methodology. PC and EMH were trial managers. HE, MTR, RM, CSR and PC acquired NNRD and questionnaire data. HE, MTR and RM conducted the effectiveness analysis. CSR, HM and WH conducted the cost-effectiveness analysis. CPM, TS and SR conducted qualitative data collection and analysis. HE, MTR, CSR, CPM and RM wrote the original article and contributed equally to the work. All authors reviewed and edited the article and approved the submission. KL is the guarantor.

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Public and patient involvement for this trial built on the involvement work in the PReCePT pilot study.[10] This used a co-design and co-production approach, including a partnership with BLISS, a support organisation for mothers experiencing preterm births, and two mothers who had experienced preterm births, Elly Salisbury and Monica Bridge, who were involved in trial design and delivery (at the learning events) and were part of the Trial Steering Committee. Their input was invaluable in ensuring that the project, interpretation/communication of findings and considerations of next steps remained centred on the ultimate aim of improving care for mothers and babies. We also acknowledge: The Health Foundation and the West of England Academic Health Science Network, in particular Natasha Swinscoe and Ellie Wetz, for their support and guidance; the AHSN Network, in particular Gary Ford, for leadership and guidance; Anna Burhouse, for her continued input and inspiration; QI Coaches Noshin Menzies, Vardeep Deogan and Hannah Bailey; Jo Bangoura for producing the PReCePT QI toolkit; and all local champions who were instrumental in applying the QI training from learning events to their local perinatal teams.

CONFLICT OF INTEREST STATEMENT

All authors of this article have no conflicts of interest to declare aside from funding from NIHR ARC West and The Health Foundation. We declare that the study management group have no competing financial, professional, or personal interests that might have influenced the study design or conduct.

DATA AVAILABILITY STATEMENT

Pseudonymised individual-level data for this study come from the NNRD. Our data sharing agreement with the NNRD prohibits sharing data extracts outside of the University of Bristol research team. Copies of the NNRD data dictionary and the full study protocol are available

online,[12] and copies of the Statistical Analysis Plan are available on the University of Bristol Research Information System (https://research-information.bris.ac.uk/en/projects/precept-study-a-cluster-randomised-trial-evaluating-the-impact-of).

ETHICS STATEMENT

The UK National Health Service Health Research Authority (NHS HRA) approved the conduct of the trial (HRA ID 242419) and gave authorisation that it did not require Research Ethics Committee approval as a low-risk study involving NHS staff, who had given consent as participants, and used pseudonymised patient data.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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