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Title: Combining target trial emulation and qualitative research to understand the effect of health visiting on child hospital admissions in England

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¹ Study investigators, conference presentations, preprint publication information, thanks.

Abstract

Health visiting is a complex public health intervention in which specialist nurses work with families to support the healthy development of children up to five years of age. Using routinely collected administrative health data, we emulated a target trial to estimate the effect of enhanced health visiting services on potentially avoidable hospital admissions for children born in 10 local areas in England between 2016 and 2019. We found that receiving additional support from the health visiting team in the early weeks of life was associated with an increased odds of a child experiencing a potentially avoidable hospitalisation (OR = 1.28, 95% confidence interval 1.02 to 1.60). Health visiting may encourage families to seek secondary health care, for example by building confidence in public services or heightening parental anxiety about the risks of childhood health conditions. However, qualitative research and sensitivity analyses indicated that our effect estimate may have been subject to residual confounding, selection bias or both. An in-depth understanding of the intervention and the mechanisms through which treatments are assigned is essential for generating valid estimates of causal effects.

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Introduction

Health visiting in England is a complex public health intervention for families with children under five years old. Health visitors are specialist community public health nurses who aim to improve child health and development by providing tailored support to families in their own homes and in health and community settings. The health visiting service is designed to be 'universal in reach – personalised in response', which means that all families are offered a standard service comprising five mandated contacts between pregnancy and when their child is two-and-a-half years old.¹ An enhanced health visiting service, which includes additional contacts outside of the standard service, is offered to families in need of targeted support for issues such as breastfeeding, child development, or maternal mental health problems.¹

To maximise the effectiveness and efficiency of health visiting, policymakers need to understand the costs and benefits of different aspects of the service. One question of interest is whether enhanced health visiting has a greater impact on family outcomes than standard health visiting alone.² Health visitors promote the health of babies and young children by supporting breastfeeding and nutrition and advising parents on immunisation and safe care. Building on an existing logic model², we hypothesised that increased health visiting support in the early months may increase the capacity of families to avert or better manage minor health challenges, leading to a reduction in child hospital admissions for common childhood problems such as jaundice, gastroenteritis and feeding difficulties.^{3,4} Our mixed methods study therefore investigated whether enhanced health visiting helps to prevent 'potentially avoidable' child hospital admissions in the first year of life, compared to standard health visiting.

Health visiting is a well-established service in all areas of England and a randomised controlled trial was not considered appropriate on ethical and practical grounds. Instead, we used administrative health visiting data linked to hospital records to emulate a hypothetical randomised controlled trial of the effect of enhanced compared to standard health visiting on potentially avoidable child hospital admissions.

Successful target trial emulation requires a detailed understanding of the mechanisms by which treatments are assigned to participants.^{5,6} In a hypothetical trial of health visiting, families would be randomised to receive either the enhanced or standard service. In our real-world context, families were selected to receive enhanced rather than standard health visiting based on multiple factors, including family needs and the capacity of the local health visiting team. Our results could be confounded if we were unable to control for factors associated with both receiving enhanced health visiting and potentially avoidable child hospital admissions.

We assessed the robustness of our results by: integrating findings from qualitative research on why families receive additional health visiting support; identifying potential confounders that could not be measured using administrative data; and analysing the sensitivity of our effect estimates to unmeasured confounding. Our results reinforce the importance of acquiring in-depth knowledge of an intervention and the mechanisms through which it is assigned when using observational data to estimate causal effects.

Methods

Study design

Our study used an 'advanced multistage mixed methods framework' to integrate analysis of national administrative data with case studies in three local areas.⁷ Quantitative and qualitative research were carried out concurrently; we used emerging quantitative results to identify focus areas for interviews and qualitative analyses to draw meaning from the quantitative results.

Quantitative data sources

Data on health visiting in England are available in the Community Services Data Set (CSDS), a national, individual-level administrative dataset of publicly funded community services delivered to adults and children in England.⁸ We extracted all health visiting contacts of children born in England between April 2016 and March 2019. Some local authority submissions to CSDS are incomplete in terms of both population coverage and individual data fields.⁹ We restricted our analysis to 10 out of 149 local areas with sufficiently complete data in CSDS during our study period relative to external reference data. These 10 local areas have been shown to be less deprived and less ethnically diverse than the English population.¹⁰

We identified children born in the relevant time period in each of the 10 local areas with sufficiently complete CSDS data to measure health visiting contacts from birth to 12 months. We extracted the number and duration of contacts received by each child. We identified the three mandated contacts that take place in the first 12 months (a new birth visit, 6-8-week review and 1-year review) and categorised all other health visiting contacts as additional contacts.

We linked children in CSDS with Hospital Episode Statistics (HES), a dataset of National Health Service (NHS)-funded hospital admissions.¹¹ We also linked children to their mothers in HES¹², allowing us to capture information on confounders such as maternal medical history and birth characteristics.

All counts of children and contacts from CSDS are rounded to the nearest 5 to comply with NHS statistical disclosure rules for subnational data.

Target trial framework

We designed a hypothetical randomised controlled trial, which, if conducted, would estimate the effect of being randomised to initiate enhanced health visiting within 30 days of the new birth visit on the odds of experiencing a potentially avoidable hospital admission within 330 days of the new birth visit, compared to not initiating enhanced health visiting within 30 days (Table 1). In our emulated trial, children were recruited at the new birth visit, which takes place typically when the child is 10-14 days old. Treatment groups were assigned at the end of the 30-day 'grace period': children were defined as treated if they initiated enhanced health visiting (received at least one additional contact of at least 15 minutes) during this grace period and untreated if they received no additional contacts lasting 15 minutes or longer during the grace period. Follow-up began on the day of the new birth visit

and continued until the child or mother experienced the outcome of interest or 330 days after the new birth visit. There was no loss to follow-up.

In our emulated trial there was a 30-day gap between the new birth visit (when eligibility was assessed and follow-up began) and the end of the grace period (when treatment was assigned). This raised the issue of how to handle outcomes that occurred during the grace period. Suppose a child was scheduled to initiate enhanced health visiting but experienced a potentially avoidable hospital admission on day 20 after the new birth visit but before the additional health visiting contact could be conducted. Based on administrative data, such children would be classified as untreated at the point when they experienced the outcome, leading to an increased number of hospital admissions in the control group and potentially an overestimate of the 'protective' effect of health visiting. For simplicity, we excluded children who experienced the outcome during the 30-day grace period, effectively resetting time zero to day 31 (Figure 1). This removed the misclassification bias described above, but meant that the target and emulated trial estimands were no longer equivalent (Table 1).

Outcome

The target trial used a binary outcome for whether a child experienced a potentially avoidable hospital admission for reasons relating to jaundice, feeding difficulties or gastroenteritis during follow-up. This outcome was based on a definition developed by Jones et al. of hospitalisations of infants up to one year of age for conditions that could have been identified and treated by community care services (Appendix S1).³

Confounders

In the hypothetical trial, children would be randomised at the new birth visit to initiate enhanced health visiting within 30 days of the new birth visit or remain on standard health visiting. In the emulated trial, we controlled for three groups of potential confounders identified in our linked administrative datasets (Table 2, Appendix S1).

Matching

We used propensity score matching to create treatment groups that were similar with respect to the child, maternal and pregnancy and birth characteristics described in Table 2.¹³ We used logistic regression to estimate each child's propensity to initiate enhanced health visiting within 30 days of the new birth visit, given measured confounders (Appendix S2).

To ensure no positivity violations, we trimmed extreme propensity scores by removing children in the control group with an estimated propensity score lower than the lowest score in the treated group, and children in the treated group with propensity score higher than the highest score in the control group.

We matched treated children to controls using nearest neighbour matching on the logit propensity score, within caliper (0.25 x standard deviation of the logit propensity score), without replacement. We calculated standardised differences to check how well the treatment groups in the matched sample were balanced in terms of baseline characteristics.

Outcome analysis

We fitted a logistic regression model in the matched sample for the odds of experiencing a potentially avoidable hospital admission between day 31 and day 330 after the new birth visit with a single treatment variable indicating whether the child initiated enhanced health visiting within the first 30 days.

Qualitative data collection

We carried out qualitative case studies in three local areas in England. One case study site was selected from the 10 local areas represented in the quantitative dataset and the others provided variation in terms of geography, demographic profile and health visiting delivery models. Data collection in each site included documentary analysis of local policies and protocols, in-depth interviews with up to 10 health visiting practitioners and focus groups or interviews with up to 10 parents and carers. We asked health visitors how they identify families with different levels of need and how decisions are made about the number, type and timing of contacts. We asked parents and carers about their experiences and perceptions of health visiting.

Common themes were identified across interview and documentary data within and across sites. We extracted information on the mechanisms by which families are assigned to receive additional health visiting contacts in the weeks after birth. We compared qualitative descriptions of treatment assignment mechanisms with the list of confounders used to match treated and control children in the target trial emulation

Sensitivity analyses

We used the 'E-value' measure to assess the sensitivity of the quantitative results to potential unmeasured confounding. The E-value represents the minimum strength of association that an unmeasured confounder, or combination of unmeasured confounders, would need to have with both treatment and outcome to explain away the observed effect estimate. Following the method proposed by Vanderweele & Ding in 2017¹⁴, for an uncommon outcome and observed odds ratio OR:

$$\text{Null E value} = \text{OR} + \sqrt{\text{OR} \times (1 - \text{OR})}$$

We calculated null E-values for our effect estimate and the limit of the confidence interval closest to the null. We also calculated non-null E-values to represent the minimum strength of associations that would be required between unmeasured confounder and both treatment and outcome to shift the effect estimate and its confidence interval limit to an alternative value OR^T :

$$\text{Non null E value} = \frac{\text{OR}}{\text{OR}^T} + \sqrt{\frac{\text{OR}}{\text{OR}^T} \times \left(1 - \frac{\text{OR}}{\text{OR}^T}\right)}$$

We investigated the potential impact of selection bias resulting from the exclusion of children who experienced the outcome within 30 days of the new birth visit. First, we included these children in the treatment group and repeated the main analysis with outcomes measured from the new birth visit. This was repeated with children who

experienced the outcome during the grace period without first receiving an additional contact included in the control group.

Results

Quantitative results

Of the 59,255 children in our sample of 10 local authorities, 41,460 were eligible for the trial emulation (

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Figure 2). Of these, 365 experienced a potentially avoidable hospital admission within 30 days of the new birth visit and were excluded from the main analysis: 295 of these children experienced the outcome without first receiving an additional health visiting contact and 70 children experienced the outcome between receiving an additional contact and the end of the grace period. Of 41,095 children included in the trial emulation, 8,960 (22%) initiated enhanced health visiting within 30 days of the new birth visit and were defined as the treatment group. The remaining 32,135 children (78%) were defined as the control group. Children who initiated enhanced health visiting were more likely to live in deprived areas, be born to younger and first-time mothers or mothers with a history of adversity, and to have experienced birth complications (Table 3).

Prior to matching, the unadjusted analysis estimated the odds of a child having a potentially avoidable hospital admission between day 31 and day 330 after the new birth visit to be 52% higher among children who initiated enhanced health visiting within 30 days of the new birth visit, compared to children who received standard health visiting (OR=1.52, 95% confidence interval [CI] = 1.28-1.80; Table 4). This unadjusted estimate likely reflected confounding: children in families with a history of adversity and living in deprived neighbourhoods were more likely to receive additional health visiting contacts and, consistent with previous research¹⁵, were more likely to have a potentially avoidable hospital admission.

The matching process produced a sample that was well-balanced across treatment groups with respect to all measured confounders (Appendix S2). In the matched sample, children who initiated enhanced health visiting in the first 30 days were estimated to have a 28% higher odds of hospital admission than those who remained on standard health visiting (OR=1.28, 95% CI = 1.02-1.60; Table 4). Although accounting for measured confounders attenuated the association, the observed relationship between initiating enhanced health visiting and child hospital admissions remained the reverse of the hypothesised relationship.

Qualitative results

Analysis of qualitative data identified three mechanisms by which a family may be prioritised to receive additional health visiting support in the weeks after a child's birth.

First, participants described a standard practice in which midwifery teams provide health visiting teams with a list of families in their local area that are expecting a baby. A family on this list may be flagged to indicate to the health visiting team that the family should be prioritised for additional support, for example because there has been previous social work involvement, or concerns are raised around maternal mental health or other issues during pregnancy.

Second, at the new birth visit, or any subsequent mandated contact, health visiting teams aim to identify family problems that were previously unknown to local services or that arose since the baby was born. Common issues included postnatal anxiety and depression, social isolation, complex family structures, and babies with feeding problems or who were failing to thrive. Where health visitors were concerned about a family, they sought to schedule additional contacts or an appropriate programme of care, such as a short parenting course.

Finally, families themselves may initiate contact with the health visiting team to request advice on issues such as feeding or sleeping, or to seek general reassurance that their child was developing in a healthy way. Such parent-initiated contact could take the form of a visit to a clinic to weigh the baby or a phone call or text to the health visiting team. This communication may then give rise to further contacts or referrals.

The covariates used to match families in the propensity score analysis captured some, but not all, of the information used by health visiting teams to prioritise families for additional support (Table 5). For example, we were able to control for maternal history of comorbidities and difficulties relating to mental health, violence, substance misuse and self-harm that were severe enough to be indicated in hospital records in the three years prior to delivery. These factors may have led to families being flagged pre-birth to receive additional health visiting support. By contrast, we were unable to control for issues, such as social isolation, which may only have become apparent to health visitors after delivery.

Sensitivity analyses

The quantitative analysis reported an adjusted OR for initiating enhanced health visiting within 30 days of the new birth visit on potentially avoidable hospitalisations of 1.28 (95% CI 1.02-1.60). The E-value for the effect estimate was 1.88, implying that the observed 30% increase in the odds of a potentially avoidable hospital admission associated with initiating enhanced health visiting could be explained away if one of the unmeasured confounders (or combination of unmeasured confounders) in Table 5 increased the likelihood of both initiating enhanced health visiting and hospitalisation by around 90%, independently of the variables already controlled for in the propensity score model.

The E-value for the lower limit of the confidence interval was 1.16, suggesting that an unmeasured confounder associated with a one-fifth increase in the likelihood of both initiating enhanced health visiting and experiencing a hospital admission would be sufficient to shift the lower confidence interval to the null.

Our starting hypothesis was that receiving an additional health visiting contact in the 30 days after the new birth visit could be protective against potentially avoidable child hospital admissions. We therefore calculated a non-null E-value to assess how much unmeasured confounding would be required to shift the OR estimate from 1.28 to 0.9 i.e. to produce an estimate of effect in the opposite direction to the one observed. This non-null E-value was 2.20 for the effect estimate and 2.95 for the upper limit of the confidence interval. Thus an unmeasured confounder or combination of confounders would need to be associated with both initiating enhanced health visiting and child hospitalisations by a 3-fold risk ratio each, independently of the measured covariates, to shift the upper limit of the confidence interval to 10% below the null.

Assessment of the sensitivity of the results to selection bias produced a maximum adjusted odds ratio estimate of 3.55 (95% CI 2.98-4.25), when all children who experienced the outcome during the grace period were included in the treatment group. The minimum estimate was 0.94 (95% CI 0.79-1.13), obtained when children who experienced the outcome during the grace period without first receiving an additional health visiting contact were included in the control group (Appendix S3).

Discussion

This analysis of administrative health records found that children who initiated enhanced health visiting in the 30 days after the new birth visit were more likely to experience a potentially avoidable hospitalisation during the next 300 days than children with similar baseline characteristics who remained on the universal service for the first 30 days. This finding was counter to our original hypothesis that increased contact with the health visiting team in the early weeks of a child's life could build the capacity of families to prevent and manage common childhood health problems.

There are plausible mechanisms to explain why providing additional health visiting contacts over and above the mandated checks may lead to more children being admitted to hospital. For example, families that have a positive experience of additional health visiting contacts may become more confident about accessing other health services. Some health visiting staff, particularly those with less nursing expertise or experience, may be risk-averse and encourage families to seek hospital care for conditions that could, in theory, be managed in the community. Parents who request additional contacts are likely already concerned about their child's health; further discussions with the health visitor may raise their awareness of or anxiety about the problems affecting their child and reduce their willingness to manage these problems at home.

Another explanation for the observed association is that we were unable to control for all factors associated with the likelihood of both a family initiating enhanced health visiting and a child experiencing a potentially avoidable hospitalisation. Sensitivity analyses indicated that an unmeasured confounder associated with both treatment and outcome by a risk ratio of 1.16-fold each would be sufficient to reduce the lower limit of the confidence interval of our effect estimate to include the null, which would lead to a conclusion of no evidence of association between enhanced health visiting and potentially avoidable hospital admissions.

Our qualitative research highlighted unmeasured factors that influenced decisions to provide or seek additional health visiting contacts and that were likely to be associated with potentially avoidable hospitalisations in the first year of life. Maternal education, which was not available in our dataset, has been found to be associated with child hospital admissions. A cohort study in Norway reported an adjusted OR of 1.18 (95% CI 1.16 to 1.20) for the effect of low compared to high maternal education on hospital admissions among children aged 1 to 16 years.¹⁶ A case-control study in the US reported an adjusted OR of 1.5 (95% CI 1.0-2.3) for the effect of low maternal education (less than high school) compared to high on hospitalisations for rotavirus gastroenteritis among children under 5 years of age.¹⁷

For maternal education to confound the association between enhanced health visiting and child hospitalisations, it would also need to be associated with the likelihood of a family initiating enhanced health visiting within 30 days of the new birth visit. A study of England's Family Nurse Partnership (FNP), an intensive form of health visiting for younger mothers, found no association between academic attainment at 16 years and the odds of enrolling in FNP among mothers aged 20-24. However, mothers with a history of Special Educational Needs (SEN) were estimated to have twice the odds of enrolling in FNP after adjusting for academic attainment and other demographic and health characteristics (adjusted OR = 2.04, 95% CI 1.24-3.35).¹⁸ The same study reported a crude odds ratio of 1.18 for any unplanned

child hospital admissions at 2 years comparing mothers aged 13-19 with and without a history of SEN.¹⁹

While enhanced health visiting is not the same as FNP, and our cohort included mothers of all ages, we cannot rule out the possibility that a child of a mother with a low education level and history of SEN had a one-fifth increase in the likelihood of both receiving additional health visiting support and experiencing a potentially avoidable hospital admission. There may be other factors such as parental health-seeking behaviour and parenting style that have been found to be associated with children's health service use²⁰ and may be differentially distributed by health visiting status. Had we been able to control for these factors, the unexpected association we observed between enhanced health visiting and increased hospitalisations may have been explained away.

Further limitations

In addition to bias from residual confounding, our study was subject to selection bias because the children included in the emulated trial were not representative of all children in England who receive health visiting support. We excluded 365 children who experienced the outcome during the 30-day grace period, representing 1% of all eligible children and 36% of all eligible children who experienced a potentially avoidable hospital admission within 330 days of the new birth visit. Sensitivity analyses indicated that had most of these children been scheduled to receive additional health visiting support in the first 30 days, the estimated odds of child hospitalisation could have been as much as 3.5 times higher in the treatment group. It is unlikely that there would have been sufficient residual confounding to explain such a strong association between enhanced health visiting and potentially avoidable child hospital admissions. By contrast, when we considered children who experienced the outcome in the first 30 days without first receiving an additional health visiting contact as untreated, the estimated odds ratio fell below 1. In this albeit unlikely scenario there may have been sufficient residual confounding to mask a protective effect of enhanced health visiting against potentially avoidable child hospital admissions.

The generalisability of our findings was limited in other ways. We excluded children who did not receive a substantive face-to-face new birth visit and children with no linked maternal hospital record. These families may have been more likely to benefit from additional health visiting support than those included in the analysis. Further, due to data quality issues we were only able to include children living in 10 out of 149 English local authorities. The effects of health visiting on child health outcomes may be different in more deprived or more ethnically diverse places.

Future directions

Due to potential confounding and selection bias, this study was unable to rule out both a strong positive association between enhanced health visiting and increased child hospitalisations and the reverse association between enhanced health visiting and reduced hospitalisations. It would be beneficial to conduct further investigation of the likely impact of residual confounding, for example by collecting supplementary data on educational background and attitudes to healthcare and parenting among a sample of mothers who received different levels of health visiting support, and using this information to model probability distributions for unmeasured confounders in the main cohort.²¹ A clone-and-

sensor approach could be used to better handle uncertainty about the treatment status of children who experienced a hospital admission during the first 30 days.^{22,23}

More broadly, improving data quality and quantity is a priority for future health visiting research. Local authorities need support to submit regular, accurate data on health visiting contacts so that CSDS becomes more representative of England's child population and includes more detailed information on family characteristics and reasons for scheduling additional health visiting contacts. Future studies could focus on different research questions and investigate the effects of different levels of health visiting, over different periods, on a range of relevant outcomes – for example, does initiating and sustaining enhanced health visiting over the first 6 months of life lead to improved child-parent relationships at 12 or 24 months?

Conclusions

This mixed methods study found an increase in potentially avoidable hospitalisations among children receiving additional health visiting support in the early weeks of life, after adjusting for available child, maternal and pregnancy and birth characteristics. Health visiting may encourage families to seek secondary health care, for example by building confidence in public services or heightening parental anxiety about the risks of childhood health conditions. However, part or all of the positive association between health visiting and childhood hospitalisations may be due to unmeasured confounding and selection bias.

Using observational data to estimate causal effects of a complex public health intervention is challenging and requires in-depth understanding of the intervention and assignment mechanisms. We recommend that those commissioning and designing studies assess the feasibility of a quantitative evaluation using a staged approach:: first, specifying the randomised controlled trial that would ideally be conducted to evaluate the effectiveness of the intervention; second, carrying out qualitative research to understand how the intervention is assigned in practice; third, reviewing the available quantitative data to assess whether the target trial can be emulated with minimal bias from residual confounding or whether additional investment in data collection or access is required.

Data availability

The data do not belong to the authors and may not be shared by the authors, except in aggregate form for publication. The data is provided by patients and collected by the NHS as part of their care and support. Data can be obtained by submitting a data request through the NHS England Data Access Request Service.

Ethical approval

This work has been approved by University College London Research Ethics Committee (20561/002). This work uses Community Services Data Set and NHS Hospital Episode Statistics data and was provided within the terms of data sharing agreements (NIC-393510, NIC-381972 and DARS-NIC-393510-D6H1D-v8.10) to the researchers by NHS England. Qualitative work was approved by the NHS North East - York Research Ethics Committee HRA/REC (23/NE/0138 IRAS - 325066).

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Tables

Table 1: Protocol for target trial to estimate the effect of initiating enhanced health visiting on potentially avoidable hospital admissions for children born in England between 2016 and 2019, and emulation of trial components using administrative data

	Target trial	Emulated trial with administrative data
Eligibility criteria	<ul style="list-style-type: none"> Children resident in England Born between 1 April 2016 and 31 March 2019 No contact with health visiting service prior to the new birth visit, other than to schedule appointments Completed a “full” new birth visit (face-to-face, lasting at least 30 minutes) within 30 days of birth 	<ul style="list-style-type: none"> Children born between 1 April 2016 and 31 March 2019 and resident in one of 10 local authorities with sufficiently complete CSDS data to measure health visiting contacts from birth to 12 months Born in an NHS-funded hospital with a linked maternal hospital record No recorded contact with the health visiting service lasting 5 minutes or longer prior to the new birth visit Completed a “full” new birth visit (face-to-face, lasting at least 30 minutes) within 30 days of birth Complete data on duration of health visiting contacts Where multiple children were born to the same mother within the study period, one child was selected at random
Treatment groups	<ul style="list-style-type: none"> Initiate enhanced health visiting: at least one additional contact of at least 15 minutes within 30 days of the new birth visit Do not initiate enhanced health visiting: no additional contacts lasting 15 minutes or longer within 30 days of the new birth visit 	<ul style="list-style-type: none"> As per target trial
Assignment process	<ul style="list-style-type: none"> Random assignment at the new birth visit to initiate enhanced health visiting within the next 30 days or remain on standard health visiting for the next 30 days, unblinded to participants and health visiting staff 	<ul style="list-style-type: none"> Decision to initiate enhanced health visiting made by health visiting staff and parents based on family needs and available resources. Propensity score matching used to control for baseline child and maternal characteristics associated with the likelihood of initiating enhanced health visiting
Follow-up period	<ul style="list-style-type: none"> From day of new birth visit until child experienced the outcome of interest, family was lost to follow-up or day 330 after the new birth visit 	<ul style="list-style-type: none"> As per target trial; children who experienced the outcome within 30 days of the new birth visit were excluded from the analysis
Outcome	<ul style="list-style-type: none"> Child potentially avoidable hospital admission relating to jaundice, feeding difficulties, gastroenteritis 	<ul style="list-style-type: none"> As per target trial
Causal contrast	<ul style="list-style-type: none"> Intention-to-treat effect; per protocol effect 	<ul style="list-style-type: none"> Per protocol effect (data on treatment intention not available)
Estimands	<ul style="list-style-type: none"> Odds ratio (OR) comparing odds of experiencing outcome among those assigned to initiate enhanced health 	<ul style="list-style-type: none"> OR comparing odds of experiencing outcome among those who initiated enhanced health visiting and those with

	visiting and those assigned to remain on standard health visiting	similar baseline characteristics who remained on standard health visiting, conditional on remaining outcome-free for 30 days from the new birth visit
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Table 2: Potential confounders of interest, available in linked administrative data

Child	Maternal history	Pregnancy and birth
<ul style="list-style-type: none"> • Sex • Ethnic group (White, Black, Mixed, Asian, Other, Unknown) • Financial year of birth • Local authority of residence • Neighbourhood deprivation as defined by the Index of Multiple Deprivation quintile 	<ul style="list-style-type: none"> • Maternal age at current and first births • Number of previous births • Evidence in hospital records in the 3 years prior to delivery of problems relating to mental health, violence, substance misuse, or comorbidities 	<ul style="list-style-type: none"> • High-risk pregnancy • Preterm delivery • Low birthweight • Record of child or maternal hospital attendance prior to the new birth visit • Child record of jaundice, gastroenteritis or feeding difficulties prior to the new birth visit

Note: Detailed code lists are provided in Appendix S1.

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Table 3: Characteristics of all children born in 10 English local authorities between 2016 and 2019, eligible for the emulated trial, and characteristics of those who did and did not initiate enhanced health visiting within 30 days of the new birth visit

Characteristic		All trial participants (N=41,095)		Initiated enhanced health visiting (N=8,960)		Did not initiate enhanced health visiting (N=32,135)	
		N	%	N	%	N	%
Sex of child	Female	19,980	48.6	4280	47.8	15,700	48.9
	Male	21,115	51.4	4680	52.2	16,435	51.1
Ethnicity of child	White	32,515	79.1	7,055	78.7	25,460	79.2
	Mixed	3,120	7.6	680	7.6	2,440	7.6
	Asian	1,400	3.4	275	3.1	1,125	3.5
	Black	490	1.2	80	0.9	410	1.3
	Other	390	0.9	85	0.9	305	0.9
	Unknown	3,180	7.7	790	8.8	2,390	7.4
IMD quintile	1 (Most deprived)	4085	9.9	1055	11.8	3,030	9.4
	2	6155	15.0	1480	16.5	4,675	14.5
	3	8080	19.7	1945	21.7	6,135	19.1
	4	9245	22.5	1975	22.0	7,270	22.6
	5 (Least deprived)	13530	32.9	2500	27.9	11,030	34.3
Maternal age (years)	14-19	880	2.1	325	3.6	555	1.7
	20-24	5120	12.5	1170	13.1	3,950	12.3
	25-29	11670	28.4	2390	26.7	9,280	28.9
	30-34	14055	34.2	2910	32.5	11,145	34.7
	35-39	7710	18.8	1710	19.1	6,000	18.7
	40+	1660	4.0	455	5.1	1,205	3.7
Maternal age at first birth (years)	14-19	4050	9.9	1055	11.8	2,995	9.3
	20-24	9160	22.3	1865	20.8	7,295	22.7
	25-29	12480	30.4	2525	28.2	9,955	31.0
	30-34	11040	26.9	2370	26.5	8,670	27.0
	35-39	3730	9.1	935	10.4	2,795	8.7
	40+	635	1.5	210	2.3	425	1.3
Number of previous live births	0	19250	46.8	4690	52.3	14,560	45.3
	1	14900	36.3	2805	31.3	12,095	37.6
	2	4805	11.7	975	10.9	3,830	11.9
	3	1480	3.6	330	3.7	1,150	3.6
	4	425	1.0	105	1.2	320	1.0
	5+	235	0.6	55	0.6	180	0.6
Number of maternal mental health admissions in three years prior to delivery ^a	0	36605	89.1	7675	85.7	28,930	90.0
	1	3170	7.7	805	9.0	2,365	7.4
	2	760	1.8	245	2.7	515	1.6
	3+	565	1.4	235	2.6	330	1.0

Table 3: continued

Characteristic		All trial participants (N=41,485)		Initiated enhanced health visiting (N=9,135)		Did not initiate enhanced health visiting (N=32,350)	
		N	%	N	%	N	%
Number of maternal adversity admissions in three years prior to delivery ^a	0	40570	98.7	8770	97.9	31,800	99.0
	1	405	1.0	130	1.5	275	0.9
	2+	125	0.3	60	0.7	65	0.2
Number of maternal A&E attendances in three years prior to delivery	0	21435	52.2	4355	48.6	17,080	53.2
	1	9875	24.0	2140	23.9	7,735	24.1
	2	4530	11.0	1040	11.6	3,490	10.9
	3	2245	5.5	555	6.2	1,690	5.3
	4-6	2220	5.4	625	7.0	1,595	5.0
	7-9	485	1.2	145	1.6	340	1.1
	10+	305	0.7	100	1.1	205	0.6
Number of maternal comorbidities recorded in three years prior to delivery ^a	0	36300	88.3	7740	86.4	28,560	88.9
	1	4655	11.3	1170	13.1	3,485	10.8
	2+	140	0.3	50	0.6	90	0.3
Maternal history of mental disorders recorded in three years prior to delivery ^a		5950	14.5	1880	21.0	4,070	12.7
Evidence of maternal psychosocial problems recorded in three years prior to delivery ^a		790	1.9	370	4.1	420	1.3
Evidence of maternal tobacco use recorded in three years prior to delivery ^a		5300	12.9	1375	15.3	3,925	12.2
High-risk pregnancy ^a		3,610	8.8	940	10.5	2,670	8.3
Preterm and/or low birth weight ^a		2,715	6.6	1040	11.6	1,675	5.2
Admitted to special neonatal care		4015	9.8	1140	12.7	2,875	8.9
Maternal hospital admission between birth and new birth visit		1555	3.8	465	5.2	1,090	3.4
Child hospital admission between birth and new birth visit		2085	5.1	630	7.0	1,455	4.5
Child record of feeding difficulties, gastro or jaundice before new birth visit		3750	9.1	1175	13.1	2,575	8.0
Child A&E attendance between birth and new birth visit		915	2.2	245	2.7	670	2.1

^a Definitions provided in Appendix S1.

Table 4: Unadjusted and adjusted odds ratios for the effect of initiating enhanced health visiting within 30 days of the new birth visit compared to remaining on standard health visiting on the odds of a potentially avoidable child hospital admission between day 31 and day 330 after the new birth visit, for children born in 10 English local authorities between 2016 and 2019

Initiated enhanced health visiting	No. of children	Had a potentially avoidable admission		Odds ratio (95% confidence interval)	P-value
		N	%		
Unadjusted analysis					
No	32,135	455	1.42	1.52 (1.28-1.80)	< 0.001
Yes	8,960	195	2.18		
Propensity score-matched analysis					
No	8,420	135	1.60	1.28 (1.02-1.60)	0.035
Yes	8,420	175	2.08		

Table 5: Measured and unmeasured potential confounders of the association between initiating enhanced health visiting and potentially avoidable child hospital admissions, by mechanism for assigning enhanced health visiting, for children born in 10 English local authorities between 2016 and 2019

Assignment mechanism	Confounding factors		
	Measured in our administrative dataset	Unmeasured in our administrative dataset (described in qualitative dataset)	
		May be measurable in other administrative data sources	Unlikely to be measured in administrative data sources
Family flagged prior to birth	<ul style="list-style-type: none"> Maternal history of mental health problems, adversity, comorbidities, psychosocial problems in <u>secondary</u> care records Maternal history of A&E attendance Maternal age at current and first births High-risk pregnancy 	<ul style="list-style-type: none"> Maternal experience of mental health problems, adversity, comorbidities, psychosocial problems including presentations to <u>primary</u> care or mental health services Paternal experience of mental health problems, adversity, comorbidities, psychosocial problems Family history of contact with social care services 	
Family need identified by health visiting team	<ul style="list-style-type: none"> Neighbourhood deprivation Number of previous births Birth complications: preterm or low birthweight; admitted to neonatal intensive care Child jaundice, feeding difficulties or gastroenteritis recorded at birth Child and maternal hospital attendances between birth and the new birth visit 	<ul style="list-style-type: none"> Household income Maternal postnatal mental health problems Feeding difficulties and other infant health needs arising after birth Indication of developmental problems 	<ul style="list-style-type: none"> Family structure and networks Siblings with emotional or behavioural difficulties Quality of physical home environment
Family-initiated contact		<ul style="list-style-type: none"> Parental educational background 	<ul style="list-style-type: none"> Parental approach to health-seeking Accessibility and willingness to use services including drop-in, phone or text services Previous personal experience of professionals across health and social work

Figures

Figure 1: Timeline of an emulated target trial to estimate the effect of receiving initiating enhanced compared to standard health visiting within 30 days of the new birth visit compared to not initiating enhanced health visiting on potentially avoidable child hospital admissions between day 31 and day 330 after the new birth visit, for example children A to G

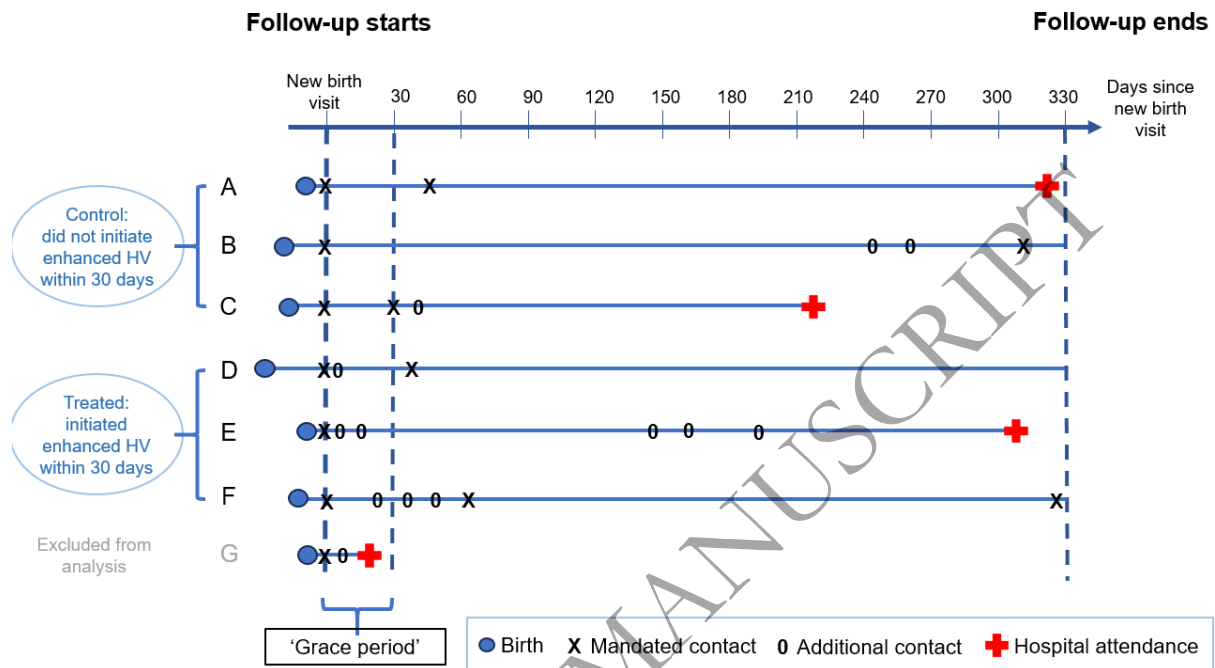


Figure 2: Identification of treatment groups for emulated trial

