UCL GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

Protocol Version 1.2 (incorporating revisions to v1.1 protocol, in yellow)

Full title: Which health visiting models in England are most promising for mitigating the harms of maternal Adverse Child Experiences?

Short Title: Health Visiting and ACEs (HV& ACEs)

IRAS ID: 340573

Sponsor number: To be completed

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Date: 19th April 2024

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Funding: This study/project is funded by the National Institute for Health and Care Research (NIHR) Public Health Research Programme (project reference 129909). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor: (to be completed)

Signature: .... Date: ....../....../......

Name (please print):

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Position:

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Signature: .... JWoodman .... Date: 19/04/2024

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Funder(s)	This study/project is funded by the National Institute for Health and Care Research (NIHR) Public Health Research Programme (project reference 129909). Elke Straight, NIHR: elke.streit@nihr.ac.uk

STUDY SUMMARY

Study Title	Full title: Which health visiting models in England are most promising for mitigating the harms of maternal Adverse Child Experiences?
Internal ref. no. (or short title)	Short title: Health Visiting and ACEs
Study Design	This is a mixed methods study using large-scale administrative data, primary collect of survey data and interviews. The quantitative analyses are in two parts: 1) descriptive analyses of a
Study Participants	Quantitative component using linked pseudoymised administrative data: children aged under 5 years and their mothers in 2018-2020 in areas o f England that have complete data in the national data set (CSDS) Survey: LA commissioners and NHS clinical service leads for the 0-19 service in each f the 152 local areas of England Case study (qualitative) component: Professionals (including health visitors, other members of the health visiting team, commissioners, service leads) in up to 6 local areas of England. Mothers who have experienced adversity and who have a child aged 5 or under in the same local areas of England (in up to 6 local areas)

Planned Size of Sample (if applicable)	Quantitative: children under 5 and their mothers in approximately 25% of all local areas in England which have complete data in CSDS. This will be which is equivalent to over 4 million mandated contacts given to children under 5 (our way of curating the data means our only possible unit of analysis is contacts, not children). Survey: Up to 304 participants (if a commissioner and clinical lead from each of the 152 local areas completes the survey) Case study (qualitative): Minimum of 4 sites, each with at least 4 professionals and at least 4 mothers (i.e. minimum 32 participants)
Follow up duration (if applicable)	N/A
Planned Study Period	2021-2025
Research Question/Aim(s)	1. What factors determine the coverage, frequency, type and resource-use of health visiting services, and the level of support for families with maternal ACEs? 2. Which health visiting models are most promising for mitigating the impact of maternal ACEs? 3. What do the results mean for DHSC, NIHP, LAs, and families?

Contents

1 Version Control Table

Version	Date	Comments
1.1. 1	17.06.21	This version is amended from the detailed research plan in the full grant application in 2 significant ways: • We will use a subset of the health visiting data (Community Services Dataset) and a survey to generalise to all areas of England. This is due to data quality issues. • We have now stated that all workshops may have to be virtual., dependent on restrictions to reduce the spread of COVID-19. This version has ethical approval from the ethics committee of UCL Institute of Education (for the analyses of pseudonymised administrative data component only). REC 1531:
1.2	19.04.24	This version is amended from V1.11 in X significant ways: • The investigator team has changed (with funder approval) due to retirement (JA), with additional investigators to cover those skills (SK and JK) and a promotion to leadership role in team (LmgL) • We have taken out references to Public Health England, as it no longer exists. We are now working with colleagues in the Start for Life team and other teams in the Department of Health and Social Care • We have now investigated using the Maternity Services Dataset and this will not be possible, which we make clear in V1.2 • We have added text to make it clear that we will request individual level data from case study sites but that it may not be possible to obtain this data within the timeline of the study. • We have amended our indicative sample size for the qualitative indicators as it is becoming clear that 4 local areas is more achievable than 6 local areas (we said 'up to 6' in grant application). We will recruit more participants in each site given a lower number of local areas, so have amended the protocol to state "4 or more" professionals and mothers in each site. Our indicative total interview participants is now amended to reflect a sample from 4 local areas.

2 Plain English Summary

As many as 1 in 10 children in England currently live with parents who are violent or abusive to each other, who misuse alcohol or drugs, or who have mental health problems. These problems have been described as adverse childhood experiences (ACEs). Children exposed to ACEs tend to have more physical and mental health problems as adults than other children, particularly those living with both poverty and ACEs. We focus on families with these types of ACEs.

Health visitors are a key profession for young children who are exposed to ACEs. Health visitors are qualified public health nurses who give advice, support and guidance to parents of young children about a broad range of child health issues. They work with a range of other professionals across sectors, and are key in referring families to support services. The government stipulate that all families in England should have five contacts with health visitors before the age of 3, and that those exposed to ACEs should have more. Frequent home visits are the way in which health visitors build a trusting relationship with parents, support parents to tackle their problems, change specific behaviours, and develop a strong bond with their child.

We do not know the best ways of balancing health visiting for all families with health visiting that targets support to those most likely to be affected by ACEs. Health visiting is organised differently across England and many families, including those with ACEs, do not see their health visitor as often as the government recommends. Two recent reports suggested that we need evidence about the number, duration, and type of health visitor contacts that families receive. We also need to understand which ways of organising health visiting are most promising for helping families with ACEs, and whether they are only likely to work in specific contexts such as where there are community services (e.g. Children's Centres). This research could provide answers to these questions and inform changes to government recommendations about health visiting.

We will use administrative data from health visiting services and hospitals as well as information on need in local areas to describe how often health visitors see families and whether they visit some families more than others. Although fathers are a vital part of the family picture, we cannot identify fathers in the data we use so our focus is on mothers. As the administrative data provide only core information, we will also carry out a survey and interviews with professionals and mothers to understand the full picture, including what services are used, how often, how the services might help families with ACEs, and how much they cost. We will combine all this information into 3-5 main 'models' that describe what is currently being done in England, for whom, at what cost, and why.

We will then use the administrative data to see if particular models of heath visiting services look promising for improving child development, or reducing the number of times children or their mothers are admitted to hospital because of key ACEs (maternal alcohol or drug misuse, domestic violence, or mental health problems). We will interpret our results in the context of COVID-19. We will check if the government is collecting the most useful information to monitor health visiting and will produce evidence briefings to support people making decisions about how to organise health visiting at national and local levels.

3 Background and rationale

3.1 Maternal adverse childhood experiences (ACEs)

Parental alcohol and substance misuse, parental mental health problems, and domestic violence and abuse (DVA) between parents, can compromise safe and nurturing home environments for children, and hinder secure parent-child relationships (see logic model upload). These problems are core to all definitions of 'adverse childhood experiences (ACEs)' and going forward we refer to them as parental or maternal related ACEs (maternal ACEs).(1-3)

More than 10% of children live with an adult who misuses substances, 4% live with parents dependent on alcohol or substances, and 20% live with parents who have high-risk alcohol use.(4, 5) Between 8-11% of children live with a parent who has mental health problems and 7% of adults with children have experienced DVA in the last year.(4, 6) Exposure to ACEs is associated with a range of health-harming behaviours, and physical and mental health conditions in adolescence and mid-adulthood.(3, 7-9) Because parental ACEs are socially patterned, they contribute to health inequalities that start in childhood and persist throughout adult life.(10, 11) Poverty might be a driver of ACEs or exacerbate the harmful effects of ACEs.(12) In addition to harms to individuals, parental ACEs place a large burden on public services and government spend, running into tens of billions of pounds annually.(13-15)

Although fathers play a key role in parenting and family wellbeing, for methodological reasons our study focuses on mothers and maternal ACEs. Developing linkages for father-child pairs remains work in progress. We have however included a workshop with fathers to ensure we have a mechanism for taking father perspectives into account.

3.2 Health visiting as an intervention for maternal ACEs

Health visiting (HV) is a long-standing, nationally implemented intervention aiming to prevent and mitigate the impact of adversity in early childhood and reduce the impact of inequalities in child development and safety, including for children affected by maternal ACEs.(16, 17) Health visitors lead the universal service for preschool children in England through the Healthy Child Programme, which is commissioned by Local Authorities (LAs). The Healthy Child Programme for children <5 includes health visiting, maternity services, immunisations and screening.(16-18)

Since March 2020, health visiting services have adapted to comply with the government's social distancing policies as a result of COVID-19 with variation across England in the extent to which all in -person visits by health visitors were stopped in the early stages (March-May 2020).(19) Pre-pandemic guidance from Public Health England (PHE) recommends that health visitors should have at least five contacts with every child and family in England (at 28 weeks pregnancy, 10-14 days and 6-8 weeks after birth, 9-12 months and 2-2.5 years) and that high risk families should receive more. *Types of contact* include home visits, individual or group clinic appointments, or phone calls.(20) Health visitors review parent and child health and child development, and offer support in a range of areas, signposting to community resources such as children's centres and state subsidised nurseries as appropriate.(21)

A key argument for frequent visits is repeat opportunities for health visitors to identify families who need extra support. Frequent contacts allows health visitors to develop relationships and trust with parents that are essential for the relational aspect of health visiting in which parents are supported, guided, and advised to negotiate the journey into and through parenthood, and which build self-efficacy, capacity and competence.(22, 23) Health visitors and parents agree that home visits rather than telephone or clinic contacts are best for this type of support.(22-24)

Some families are given extra help with feeding or sleeping whilst others (such as those with maternal ACEs) have complex needs requiring a multiagency coordinated response.(13, 16, 21, 25, 26) This model of 'dialling up' and 'dialling down' between universal and intensive services according to a continuous needs assessment is known as 'proportionate universalism', and is at the heart of health visiting policy in England.(21, 27, 28) In this model, health visiting provides four levels of service: Community, Universal, Universal Plus and Universal Partnership Plus.(16, 17)

The importance of the *intensity* of home visits (i.e. patterns of repeat contact) for helping the most vulnerable families underpins specialist programmes such as the Family Nurse Partnership (FNP), in which specially trained Family Nurses, some of whom are health visitors, visit young first time mothers up to 64 times before the child's second birthday.(29) FNP is an evidence-based intervention developed in the US, which theorises that frequent contact can mitigate the impact of adversity by improving parental access to support services, and by increasing warm, sensitive and competent parenting and parental self-efficacy, including through building relationships between care-giving adults. There is evidence that warm parenting moderates the relationship between adversity and poor child health,(30) and that co-parenting advice can increase family harmony, reduce family conflict, and improve child behaviour.(31) In summary, frequent contact with families is a theorised mechanism by which Family Nurses within the FNP programme can positively impact on the quality of care-giving, disrupt learned behaviours of coercive control and negative parenting, thereby improving the quality of a child's attachment to their primary caregivers, the child's development and behaviour, and child safety and risk of unmet medical need or injury.(29, 31)

This theory about how Family Nurses can positively impact on child and family outcomes can be applied to health visitors within standard and specialist health visiting services. In many areas of the country the FNP programme has been decommissioned and sometimes other specialist health visiting services for vulnerable families have been put in place instead, aligned with standard health visiting.(13) A trial of FNP in England highlighted that first-time teenage mothers receive a high level of support as standard (as usual care), which might explain why the trial of FNP in England only found small positive benefits in maternal sensitivity, parenting, and child development and no evidence of effect on unplanned hospital admissions or A&E visits, birth weight, rapid repeat pregnancies or maternal smoking. (29, 32)

A range of practices (from fewer than the recommended five health visiting contacts to the intensive FNP offer) existed across England before the pandemic but we lack evidence on who received what and how this varied across LAs. Despite the theorised importance of the intensity and type of health visitor contact, we know little about the intensity and type of health visiting services in practice, including families living with maternal ACEs. Our own analyses of the 2-2½ year health visiting review in 2018/9 suggests that the majority of vulnerable children in 33 local authorities received multiple face-to-face contacts with a member of the health visiting team in the year, often in the child's home. (33) However, 22% of children with safeguarding vulnerabilities recorded and 29% of Looked After children did not have a record of either a 2-2½ year review or any other face-to-face contact in the year, with no record of letters or calls from the health visiting team (33) There remain questions about how far this pattern is replicated across all of England and for different dimensions of vulnerability, why some children with known vulnerabilities are receiving frequent contacts from the health visiting teams and others none at all and what the impact of different service intensity might be for these children and families. Two evidence reviews highlight the need for more evidence on ‘business-as-usual’ health visiting, including different doses or types of contact.(18, 34)

3.3 Why do we need this evidence now?

There is live debate and decision-making about the delivery (intensity/type) and commissioning of health visiting, which will continue as we adapt to live with COVID-19. There will now be additional decisions about how health visitors can best support children with maternal ACEs as families recover from the anticipated secondary effects of COVID-19 (unemployment, debt, missed early years education, increased family conflict and/or relationship breakdown). In December 2019, the Institute of Health Visiting (iHV) recommended increasing the recommended universal contacts from five to eight, bringing England in line with other UK nations (Scotland: 11, Northern Ireland: 9, Wales: 8).(21, 35)

The organisation of the HCP and commissioning structure of health visiting is currently under review.(36) Since publication of the Leadsom review earlier in 2021, every local authority is expected to review, revise and make publicly available its Start for Life Offer (for children from conception to 2 years old).(37) Although it has now been confirmed that local authorities will continue to be responsible for commissioning health visiting (following a policy suggestion that there may be more NHS involvement) there remains a commitment for improvements such as more joined-up commissioning and pooled budgets.(36, 38) This is consistent with the government’s commitment to commissioning and providing integrated ‘place-based’ services across primary and secondary health services and social care services, using Integrated Care Systems and building on Sustainability and Transformation Plans for commissioning.(39) In addition, with the new National Institute for Health Protection replacing Public Health England (anticipated to happen in Oct 21), there comes both opportunity and risk for the commissioning and provision of health visiting services, the Healthy Child Programme and other early years services. Each time there is a spending review, the public health spend for children under five years will be reviewed and interrogated, in light of evidence about return on investment. These debates and policy and spending reviews are occurring in the absence of an evidence-base about business-as-usual health visiting.

On the ground, health visiting commissioners have been making difficult decisions about how to use scarce resources, with considerable variation in local need and service context (e.g. closure of Children’s Centres).(40) Pre-pandemic, some LAs responded to shrinking budgets, insufficient workforce and increased need in their population by using less qualified professionals, clinics instead of home visits, and groups instead of individual sessions, but without evidence to underpin such *resource-use* decisions.(38, 41) In contrast, Blackpool, where there has been substantial investment via the ‘A Better Start programme’ provides provides 8 universal contacts and up to 30 visits for vulnerable families.(13, 42) Before and during the pandemic, LAs have been making decisions about whether to focus limited resources on universal, targeted or specialist services, without evidence on the *coverage* of services for those most in need, and (pre-pandemic) partly driven by quality metrics set by PHE that focus on the universal delivery of the 5 recommended contacts.(43) We don’t know if these are the best indicators of a ‘good’ health visiting service, as is acknowledged by PHE.(44)

Our study will evaluate the coverage, intensity, type, recourse-use and costs of health visiting for families with and without maternal ACEs, how and why this varies across England, and how targeted services are balanced relative to universalism. We will seek to understand the impact of any temporary or permanent changes to health visiting during the Covid-19 emergency on our findings and have conducted preliminary work in this area (45). Our study exploits recent methodological developments enabling linkage of mother-baby pairs within hospital and health visiting data at a population level, providing detailed risk factor data (e.g. to identify exposure to ACEs) and outcomes.(46) We will combine this quantitative analysis with qualitative data to generate hypotheses about which models of health visiting for families with maternal ACEs are most feasible to implement in specific local contexts, and which are most promising for mitigating the impact of maternal ACEs for children and mothers. This evidence is needed by DHSC, the new Institute for Health Protection which replaces PHE and all professional bodies associated with health visiting to inform policy and structural changes (Institute of Health Visiting (iHV), Royal College of Nursing (RCN), the Community Practitioners' and Health Visitors' Association (CPHVA)). Local commissioners and health visiting managers need this evidence to inform their day-to-day decisions about how to maximise benefit from scarce health visiting resources and how to resume a post-pandemic service. This evidence is also crucial for providing baseline information to inform future evaluations of health visiting, e.g. following modernisation of the Healthy Child Programme.

4 Aims and Objectives

Our overall aim is to determine the context and mechanisms associated with differences in coverage (universal / targeted), intensity (duration and patterns of repeat contact), type (e.g. face-to-face or clinic), costs and outcomes of health visiting services for families with maternal ACEs in England. We use longitudinal, individual-level administrative data to capture exposure to maternal ACEs prior to birth (hospital data) and outcomes for mothers and their children born between 2015-2019 (hospital and health visiting data). We will achieve this aim by answering three main research questions (RQ, see Figure 1)

3.1 Research questions

1. What factors determine the *coverage, frequency, type* and *resource-use* of health visiting services, and the level of support for families with maternal ACEs?

The overall aim of RQ1 is to produce a rich theory about why, how and with what facilitating contexts and likely consequences health visiting is delivered in England. This will be presented in the form of a taxonomy. The taxonomy will demonstrate what is feasible and acceptable in health visiting and will facilitate our evaluation of child and maternal outcomes associated with health visiting in RQ2. The taxonomy will be generated from multiple sources of empirical data, which are summarised in Figure 3 and described fully in the 'data collection' section.

- ***Objective a:*** Develop a preliminary data-driven classification of 3-5 'models' of health visiting by grouping LAs providing similar coverage, intensity, and type of services for families with and without maternal ACEs, and describe the local context in which these models fit.
- ***Objective b:*** Refine the data-driven classification of models of health visiting from *objective a,* using case studies and a national online survey.
- ***Objective c:*** Determine indicative resource use and costs of providing each of the 3-5 different health visiting models in *objective b,* using a national online survey and cost data.
- ***Objective d:*** Produce an empirically-based theory of health visiting delivery in England in the form of a 'taxonomy' that provides rich descriptions and explanations of commonly used models of health visiting, and includes classification of each LA, using expert workshops.

2. Which health visiting models are most promising for mitigating the impact of maternal ACEs?

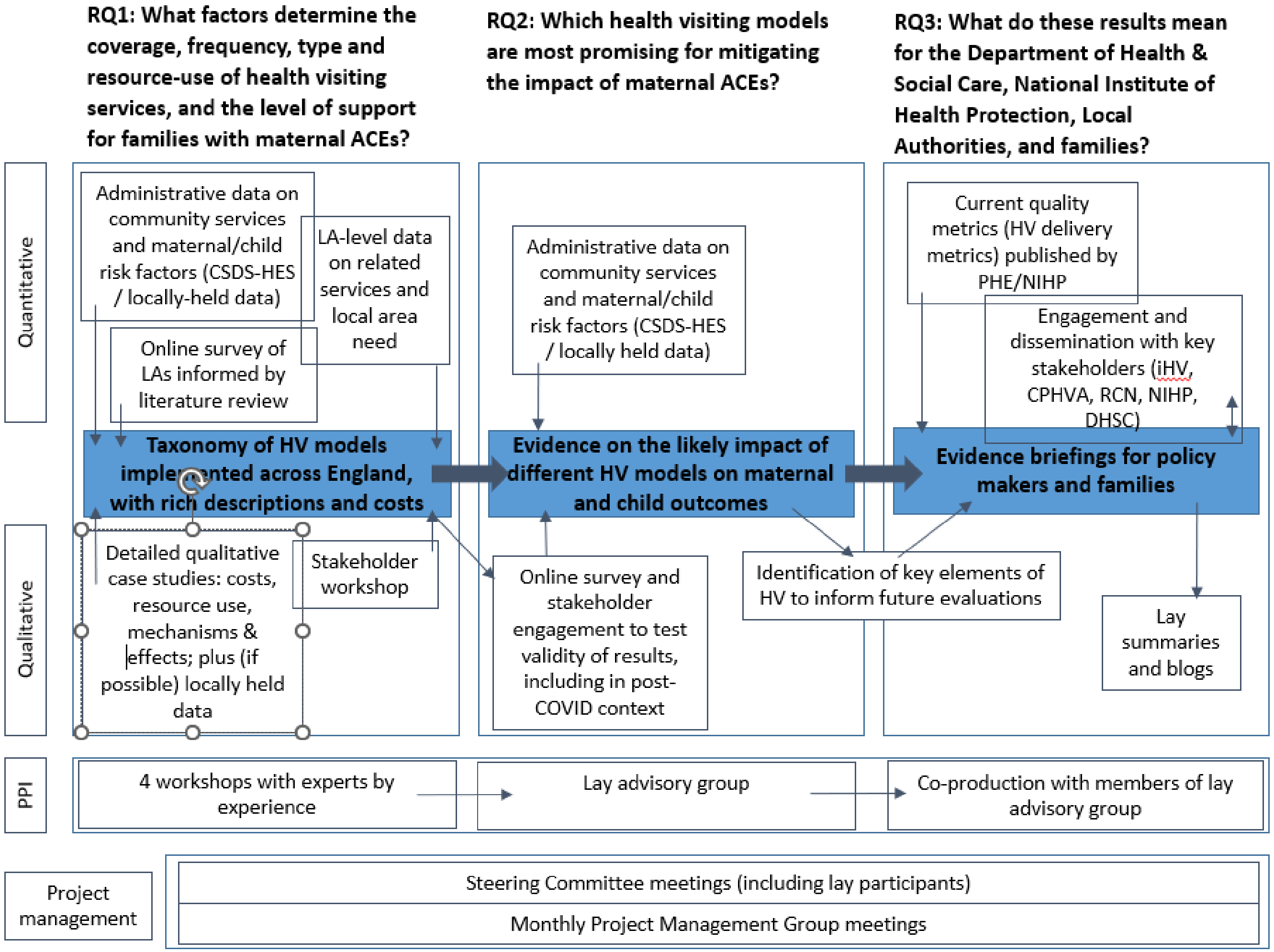
- ***Objective e:*** Explore the association between different health visiting models (from RQ1) and selected child and maternal outcomes captured in population-based administrative data.

- ***Objective f:*** Assess the meaning, validity and generalisability of these associations through qualitative work and engagement with key stakeholders, including assessing relevancy and meaning of results in a post-COVID_19 service context.
- ***Objective g:*** Establish next steps for further evaluating the effectiveness and cost-effectiveness of health visiting in preventing and mitigating the impact of maternal ACEs.

3. What do the results mean for DHSC, LAs, and families?

- ***Objective h:*** Review suitability of current health visiting quality metrics used for local monitoring, in the context of our findings on coverage, intensity and type of health visiting and outcomes.
- ***Objective i:*** Provide evidence briefings on the implementation, likely impact and indicative costs of different health visiting models in different settings for use by DHSC, the new National Institute for Health Protection and LAs, and provide lay summaries and blogs for the public, including for parents and older children.

Figure 1: Research flow diagram



ACES: Adverse childhood experiences; LA: Local Authority; DHSC: Department of Health and Social Care; PHE: Public Health England; NIHP: National Institute of Health Protection HV: Health visiting; iHV: Institute of Health Visiting; CPHVA: Community Practitioners' and Health Visitors' Association: RCN: Royal College of Nursing; PPI: Patient/Public Involvement

5 Research plan

5.1 Conceptual framework

We take an interdisciplinary mixed-methods approach, generating a taxonomy of health visiting to provide answers about the nature of health visiting for families exposed to maternal ACEs and how different models are likely to work, for whom and in which contexts. As taxonomies instil order on a complex, real-world situation by organising cases into groups with similar key characteristics, they are widely recognised as a useful way to describe and make sense of complex health services that are delivered with high variation across local areas, such as health visiting in England.(47-50)

In order to be a useful way of organising knowledge, a taxonomy needs to be concise and parsimonious whilst also acknowledging complexity.(49) In other words, if there are too many models in the taxonomy, it becomes unusable. A similar reasoning applies to latent class analysis: the optimal number of classes is chosen by balancing statistical measures of goodness of fit, with interpretability of classes. We judge that the taxonomy can have a maximum of 5 models to be useful and interpretable. This number is based on our literature review of studies that used quantitative or mixed methods to generate a taxonomy (or typology) of health care services. We found 5 studies, all of which presented taxonomies with 3 or 4 different models, including studies which used data driven classifications such as latent class analysis.(47, 51-54)

In our analysis of associations between different models of health visiting and child and maternal outcomes, we focus on relevant outcomes that are available in national and local administrative data on health visiting and hospital contact: 1) child development using Ages and Stages Questionnaire (ASQ), 2) child safety and harm from maternal ACEs (hospital admissions for injury and maltreatment), and 3) maternal ACEs post birth (from maternal hospital admissions). We know that children exposed to maternal ACEs have a lower chance of being 'school ready' by age 4 years and have a higher risk of emergency hospital admission than other children.(55, 56) These outcomes have been theorised as amenable to intervention by health visiting: Improving child development at age 2 and reducing hospital attendance and admissions for injury (through managing minor illnesses and accidents) are 2 of the 6 impact areas for health visiting in policy guidance.(29, 57-59) We will describe how maternal and child hospital admissions for any reason vary according to different models of health visiting. Whilst parent-child interaction, sensitive parenting, parental self-efficacy, and stimulation from the home environment are also relevant outcomes, these would need to be collected directly from parents, which is difficult and expensive. Data from GPs and on mental health cannot currently be linked to health visiting data on a national level.

The integration of quantitative and qualitative data is essential to ensuring the usefulness of our findings by providing both the big and the detailed picture. We take an explanatory sequential approach to integrating data, where qualitative data collection is used to challenge and explain findings from the quantitative data.(60) The administrative quantitative data will give us a complete picture of 'business-as-usual' health visiting for families with and without maternal ACEs. The rich descriptions of services, contexts and resource-use obtained from the case studies are necessary to sense check the administrative data and will provide rich descriptions of each model of health visiting, including theorised mechanisms for improving outcomes. The detail from the case studies is necessary for findings to be applied to local and changing contexts by national and local decision-makers. The use of case studies, stakeholder engagement and a series of workshops with experts by experience will mitigate the risks of drawing incorrect causal inferences from the data by identifying whether there are other likely explanations for associations.

PHE states that a key role of the health visiting service is to reduce inequalities in children, specifically inequalities in child development and safety.(16) Research on child protection intervention from children's social care in England suggests that children living in deprived neighbourhoods within deprived LAs receive fewer and shorter interventions from children's social care than children living in similarly deprived neighbourhoods within relatively affluent LAs.(61, 62) This 'inverse intervention law' is likely due to higher thresholds and greater rationing of resources in deprived LAs, and therefore signals more unmet need.(63) The inverse intervention law may also exist within health visiting services, which operate within similar constraints to children's social care (high demand, insufficient budgets and limited workforce). This study will indicate which models of health visiting have the most potential for reducing inequalities between children with/without maternal ACEs, by exploring whether gaps in outcomes differ for individuals living in LAs with different models of health visiting. We will incorporate LA-level indicators of local area need that measure the wider determinants of health including area-level measures of deprivation (IMD, % children in low income families, levels of homelessness) and indicators of high need in mothers (e.g. <18s conception rate, young maternal age, smoking status at delivery and rates of infant mortality, which is driven in part by health and socioeconomic disadvantage at conception and during pregnancy).(64) Our case studies and lay and expert input will help understand which differences in outcomes might plausibly be affected by health visiting.

5.2 Study Population and Setting

The study will include all children born in England between 2018 and 2021, for whom sufficiently high-quality data is available in national or local administrative data.(33) Information on these children and their mothers will be ascertained from longitudinal administrative data from health visiting linked to hospitals admissions data. Our timeframe includes service provision pre- and post-COVID-19 in order to test the relevancy of our findings for services operating in the context of COVID-19, i.e. post March 2020. Our qualitative case studies will be conducted in up to 6 LAs.

5.3 Data collection

Table 1 gives an overview of data sources; Figure 3 gives an overview of data sources for RQ1, *objectives a-d.*)

5.3.1 Administrative individual-level data: CSDS-HES and locally-held data (objectives a and e)

We will use the Community Services Data Set (CSDS), an individual-level longitudinal administrative dataset that captures basic child characteristics and health visiting contacts (type, frequency, length, date) by LA of residence. CSDS is used to generate aggregate health visiting and early child development statistics, but our study will be the first time the individual-level data is used to evaluate health visiting services.(65-67)

We will enhance the information recorded in CSDS through linkage with a cohort of mothers and babies in Hospital Episode Statistics (referred to as CSDS-HES).(46) Maternal risk factors derived from HES (e.g. hospital admissions for substance misuse, mental health conditions and violence prior to birth) will supplement those recorded in CSDS (e.g. safeguarding and vulnerability factors). We will not be able to use linked data from the Maternity Services Dataset (MSDS) due to availability (this includes information captured during the booking appointment e.g. on complex social factors for around 50% of mothers.(68)) The CSDS-HES cohort will allow us to assess any differences in the level of health visiting contact families receive, according to exposure to maternal ACEs recorded in hospital data. It will also provide outcome data for children and their mothers for up to five years after birth.

Data collection in CSDS began in 2015, but data quality is only sufficient for analysis from 2018.(33) Even from 2018, there are high levels of incompleteness in CSDS. We will therefore base analyses on data from a subset of local authorities with sufficiently complete data (a research-ready subset of CSDS). We anticipate that the research-ready subset will contain data from approximately 25% of all 152 local authorities in England. We will supplement this data with a national survey.

5.3.2 Aggregate data on LAs (objective b)

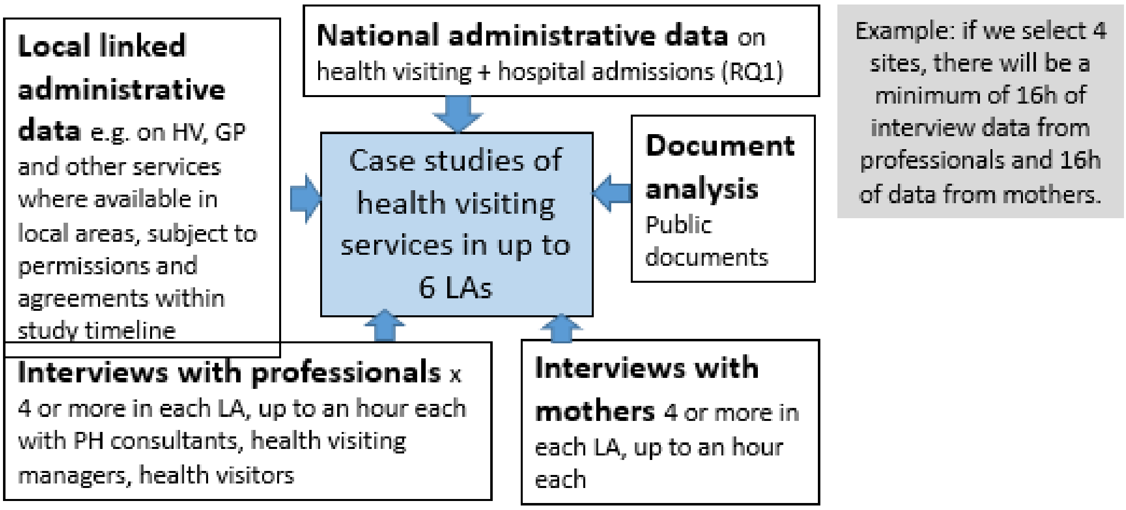
Publicly available aggregate data on LAs will be used to describe the local context in which different models of health visiting sit, including local need (e.g. deprivation, homelessness, infant mortality rates), expenditure on local services (public health services, children's social care, and early years education), and information on how health visiting integrates with other local services (e.g. rates of referrals to social care, or targeted support for teenage mothers, e.g. through FNP).

5.3.3 *Detailed case studies of different health visiting models (objectives b and f)*

We will conduct case studies of health visiting in up to 6 LAs (Figure 2) comprising interviews with professionals and mothers, documentary analysis, and analysis of locally held administrative data where available which contains additional information not available nationally. The LAs will be sampled according to our health visiting models in *objective 1a* and will cover a range of local deprivation and need, rural/urban settings and geographical spread across England. Data from the case studies will be combined with the LA specific results from the CSDS-HES data (*objective a*). The exact number of case studies will depend on the results from RQ1 and logistical considerations which depend on the specific sites chosen and our assessment of data saturation.

The case studies will provide rich detail about the different types of health visiting services and theorised mechanisms of effect. We will explore the principles, functions and wider context of the service for all families, including those with identified domestic violence, parental mental health problems and/or substance misuse. Characterising principles and functions of health visiting will allow us to describe and evaluate this complex and flexibly implemented intervention across settings.(69) The case studies will also allow us to obtain information about the resource use and costs to LAs of providing health visiting services. We will work with health visiting service managers, commissioners, and finance staff to obtain detailed information on the resources used to provide health visiting (including the process used for targeting more vulnerable families). Interviews with mothers will enable us to explore other services that families are signposted to as a result of health visiting (e.g. mental health and other community health services that might support these families), and any out of pocket costs to families associated with accessing and using the health visiting service.

Figure 2: Data collected for case studies



Interviews: We will ask health visitors how they identify and work with families at differing levels of need, We will ask health visitors how they identify and work with families at differing levels of need na and how they decide whether to offer universal, targeted or specialist services by asking about specific families on their case-load.(16, 17) We will ask all professionals to reflect on the characterisation of their LA in our data-driven preliminary classification of health visiting. We will ask mothers about their experiences and perceptions of health visiting, including the role of health visiting and any out-of-pocket costs associated with increased levels of health visiting. To develop the interview topic guides we will conduct a literature review of the key principles, functions and mechanisms of effect within health visiting for families experiencing maternal ACEs, and consult with our collaborators to capture expert knowledge on how different elements of health visiting models work together. The interview topic guide will also be informed by results from *objective a*) and will include prompts related to priorities, constraints and local factors that have shaped health visiting. Interviews will be piloted within our collaborator networks.

Local linked administrative data: We will request locally held child level data, which might include information on: community services and/or GP consultations, hospital services, early help and children's social care services, adult social care and/or mental health services for carers, parental demographics and known ACEs. We will prioritise case study sites where we know from our networks that we are likely to be able to access good quality linked data.

5.3.4 Online survey (objectives b and c)

Survey questions will be based on a literature review, consultation with stakeholders, the case studies, and our ongoing PPI work. We will identify relevant information associated with differences in services between LAs that is not available in the administrative data, e.g. use of Band 5 nurses in place of health visitors, local innovation, or targeting guidelines. The survey will also be used to collect information on costs, including identifying contacts for possible follow-up telephone interviews, and as a way of recruiting stakeholders for our expert workshop (*objective d*). The survey will be piloted with collaborators and circulated to commissioners and other relevant staff within all LAs in England through contacts at the National Institute for Health Protection (NIHP).

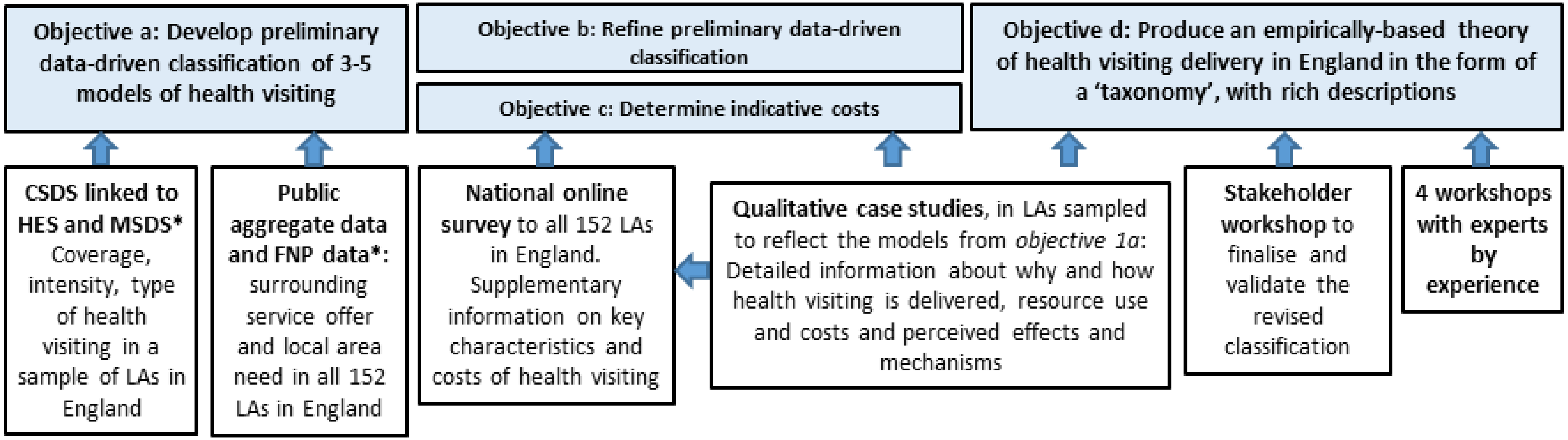
5.3.5 Resource-use and cost data on health visiting (objective c)

For indicative costs we will use the individual-level administrative data on numbers of families and average contacts per family in each LA, supplemented by information from the online survey, expert workshops, commissioners in the case studies and relevant literature. The key perspective will be the LA (we will concentrate on resource items that cost from the LA viewpoint).(70) From the case studies, we will obtain information on out-of-pocket costs incurred by families, e.g. travel and time off work to use the service. We will generate hypotheses about other key services used alongside health visiting (e.g. mental health or community services) to indicate wider societal costs. We will conduct a scoping review (including consultation with professionals) to determine how existing information and our study findings can inform a future full economic evaluation.

5.3.6 Expert and lay workshops, including webinar (objectives d, h and i)

We will invite up to 40 stakeholders (e.g. Public Health consultants, health visiting professionals and representatives from the iHV, CPHVA, RCN, FNP, DHSC and NIHP) to a half-day workshop to refine our classification of models of health visiting and ensure relevance to practice. We will also run 4 workshops with experts by experience to gain views about the acceptability and meaning of the different types of health visiting for mothers (see Participant Involvement). Professional and lay participants from these workshops will be invited to join workshop in the final year of the study to shape our interpretation of results at the final integration of all data sources from the study. We hope that the workshops in the second half of the study can be held face-to-face but this will depend on the COVID-19 restrictions. The workshop in the final year of the study is planned as a virtual webinar.

Figure 3: **Overview of data sources for RQ1 (What factors determine the *coverage, frequency, type* and *resource-use* of health visiting?)**



Approach: We will use an empirical-to-conceptual approach to developing this taxonomy, starting with analyses of empirical administrative data (*objective a*) and refining this with empirical qualitative and costs data (*objectives b&c*) before generating a theory of health visiting in the final stage (*objective d*) with support from stakeholders, including experts by experience.

*CSDS: Community Services Dataset; FNP: Family Nurse Partnership; HES: Hospital Episode Statistics; LA: Local Authority; MSDS: Maternity Services Dataset

Table 1: **Description of data sources**

Objective	Description	Source	Variables	Notes
1a: Generate preliminary classification of HV service models and 2f: Assess meaning, validity and generalisability	Characterise the frequency and nature of HV contacts by LA using data before COVID-19 (2018-2019, *objective 1a*) and after COVID-19 (2020-2023, *objective 2f*)	Community Services Dataset (CSDS); individual level data on health visiting contacts in a sample of LAs from 2018-2023. Supplemented with locally held data from the case studies of local areas	Health Visitor contacts per child: - Frequency - Type (e.g. face to face, group, letter, telephone, telemedicine, email, SMS, other) - Location (e.g. home or children's centre) - Duration (in minutes)	CSDS contains only minimal information on the demographics and social status of families receiving HV services. Research-ready data (of sufficient quality for analysis) is only available from a subset of LAs in CSDS so these data will be supplemented by locally-held data from a sample of LAs.
1a: Generate preliminary classification of HV service models	Characterise the balance between universal and targeted HV within each LA	CSDS linked with mothers and children in Hospital Episode Statistics (HES); individual level data for births in a sample of LAs 2018-2020	% of children receiving each of the 5 mandated visits; % receiving <5 visits, % receiving >5 visits; average (and range) number of visits according to markers of vulnerability, e.g.: - Exposure to maternal ACEs (identified through maternal admissions for mental health conditions, substance abuse or violence in the 2 years prior to birth).(56, 71) - Child disability (identified through childhood admissions for chronic conditions).(72) - Preterm birth (identified via gestational age) to identify children likely still in hospital at the 2 and 6-8 week health visitor contact.	Linkage with risk factor data in HES will allow us to quantify whether there are differences in the numbers of visits received according to maternal ACEs exposure (and other risk factors). This will provide a measure of targeting within each LA. Depending on data quality, we will also use the 'Safeguarding and vulnerability factors' variable within CSDS, and complex risk factors captured in linked MSDS data, to quantify targeting.
1a: Generate preliminary classification of HV service models	Characterise the coverage and timeliness of HV contacts by LA	Child and Maternal Health Statistics (Public Health England); quarterly, aggregate data from 2018-2020	Health Visitor Service Delivery Metrics for each LA, published by PHE:(43) - % receiving new birth visits, 6-8 week reviews, 12 month reviews and 2-2½ year reviews	Data provide detail on the timing of visits (e.g. the % receiving a new birth visit within vs after 14 days from birth). As only the number (and not % of antenatal visits are reported, information on antenatal visits cannot be used to inform coverage/timeliness of contacts. These data are collected in parallel with the CSDS and will provide an opportunity for validation.
1a: Generate preliminary classification of HV service models	Characterising the surrounding service offer within the LA	Family Nurse Partnership programme data; Quarterly, aggregate data from 2018-2020	- number of FNP places taken up by first time teenage mothers in each LA - characteristics of participating mothers - number and intensity of visits delivered	Data available via the FNP National Unit.

1a: Generate preliminary classification of HV service models	Characterising the surrounding service offer within the LA	Child Health Profiles via the PHE Fingertips portal; aggregate data	- Children in care per 10,000 population - New child protection cases per 10,000	Data used to describe how HV services work alongside other local services.
1a: Generate preliminary classification of HV service models	Characterising the surrounding service offer within the LA	Revenue account budgets; aggregate data	% total spend on public health services, children's social care, and early years education (which we can contextualise with information about local need).(73)	Data used to describe how HV services work alongside other local services.
1a: Generate preliminary classification of HV service models	Describe local area need	Child Health Profiles via the PHE Fingertips portal; aggregate data 2018-2020	Infant mortality rate, children <16 in low income families, family homelessness, under 18 s conception rate / 1000, smoking status at delivery.	Data used to describe how HV services are related to need in the local area.
1a: Generate preliminary classification of HV service models	Describe local area need	CSDS linked with mother-baby HES; individual level data 2018-2020	Area-level deprivation (IMD), ethnicity, maternal age, prevalence of maternal ACEs (hospital admissions for mental health conditions, substance misuse, or violence in the 2 years prior to birth).	Data used to describe how HV services are related to need in the local area.
1b and 1c. Refine initial classification of HV service models, generalise to all of England and determine costs	Characterise local innovation and detailed information about HV services not available in national data; obtain resource use and cost data	Qualitative case studies; LA level data	Detailed description of local HV services including priorities, constraints and local factors that have shaped HV and the principles, functions and wider context of services for families	
1b and 1c. Refine initial classification of HV service models and determine costs 2f: Assess meaning, validity and generalisability	Characterise local innovation and detailed information about HV services pre and post Feb 2020 (COVID-19) to gain information not available in national data; obtain resource use and cost data	Online survey; LA level data	Supplementary information on characteristics of local HV e.g. banding and salaries of HV / nurses; information on innovation and local guidelines on how to identify those in need of additional contacts.	
1c. Produce taxonomy of HV service models	Interpretation of groupings generated using all above data.	Expert / lay workshops		

5.4 Data Analysis

5.4.1 RQ1: What factors determine the coverage, frequency, type and resource-use of health visiting services, and whether families affected by maternal ACEs receive extra support?

Objective a: *Develop a preliminary data-driven classification of 3-5 'models' of health visiting by grouping LAs providing similar coverage, intensity, and type of services for families with and without maternal ACE and describe the local context in which these models fit.*

Preliminary classification, using individual-level and aggregate data

The preliminary data-driven classification will group LAs that deliver similar coverage, intensity, and type of services for families with and without maternal ACEs, based on individual-level administrative data (CSDS-HES and locally-held data for 2018-2020). To avoid issues of reverse causality (where more frequent contacts might lead to greater identification of ACEs), we will identify groups exposed to maternal ACEs independently of health visiting data, using individual-level HES data to identify mothers admitted to hospital in the 2 years prior to delivery for substance misuse, violence or mental health issues.

We will use CSDS-HES to determine coverage for families with and without ACEs, to understand the extent to which services are delivered universally (i.e., consistent delivery of 5 recommended visits). It is important to stratify and assess health visiting services for families both with and without maternal ACEs, in order to identify any knock-on effects of directing resources towards more targeted versus universal services. The preliminary classification will also include aggregate LA information on health visiting quality metrics on the % of the mandated universal health visitor contacts completed and % completed 'on time' (published quarterly), % of LA expenditure on public health services for 0-5s, and information on how health visiting is integrated with other services (e.g. children's social care and FNP).

We will generate our preliminary classification using latent class models that will identify similarities and differences in health visiting services between LAs in terms of health visiting service provision, availability of other local services, and public health expenditure. Latent class analysis assumes that there are a number of distinct subgroups within a population that cannot be directly observed (i.e., the latent classes) but for which probabilistic membership can be inferred from a set of other observable variables, known as indicators. The advantage of latent class models over other clustering methods is therefore that they are more flexible, as clustering methods rely on similarities of observed data only. Latent class models describe and statistically model the structure of the data, meaning that model selection and goodness of fit tests can be used to inform groupings. We will explore changes over time for each LA in two ways. First we will develop latent class models by year of data. Second, we will use latent class growth analysis to identify whether there are typical patterns of movement between health visiting models within LAs. For example, we will aim to identify if there are groups of LAs which move between health visiting model A and health visiting model B. This second approach is dependent on sufficiently good quality data being available in all years of data. The latent class approach has previously been used to classify longitudinal care histories of looked after children, to identify discrete approaches to specialist healthcare support for older care home residents, to classify compliance to standards for patient centred care, and to classify substance use disorder treatment facilities.(47, 52, 54, 74)

Description of local context, using aggregate information on LAs

Once we have identified a number of latent class models (we expect 3-5), we will describe how each of the health visiting models is associated with the varying levels of local need in different LAs. This will enable us to describe whether, for example, LAs with high levels of deprivation or high concentrations of vulnerable families are also those with highly targeted health visiting services (i.e. those consistently providing more contacts to vulnerable families). It will also enable us to explore outlier LAs that do not fit with the usual patterns.

It may be difficult to conceptualise whether particular contextual factors should contribute to the latent class categorisations of LAs or to the descriptions of the local area need in which a health visiting model operates. For example, we will initially consider including LA data on related services (e.g. child protection and child in need plans in the latent class model as these could be directly related to how health visitors integrate with other services. However, child protection plans will also be related to local levels of need, which will be described alongside but not included within the latent classes. We will revise these decisions according to learning from the case studies (*objective b).*

Objective b: *Refine the data-driven classification of models of health visiting from objective a, using case studies and a national online survey*

Case studies

We will adopt the flexible and iterative approach to case studies proposed by Stake (1995), based around core critical questions.(75) We will use thematic analysis to identify common and recurring themes across interview and documentary data within and across case study sites. We will use quality assurance techniques of simultaneous data collection and analysis, open coding of data to generate new ideas and develop the initial coding framework, constant comparison between cases, looking for negative ('deviant') cases to expand and test emerging theory, and building theory (moving from specific ideas to unifying concepts).(76, 77) We will explore the themes and hypotheses generated from the literature review and collaborators, and also allow the case-study data to generate its own themes and concepts. In other words, we will combine a deductive and inductive approach. For example, the young mothers we spoke to when designing our study said they value their health visitor's advocacy role. Therefore, in our case studies we will explore advocacy and service coordination as important characteristics for distinguishing between models of health visiting as well as allowing the data to generate its own themes. All data will be stored and coded in NVivo, including interview transcripts, publically available documents, field notes about the LA sites and the emerging findings from the analyses of locally held linked data. Including emerging findings as a source to be coded within the qualitative analysis will facilitate integration of data sources in our case studies.

In all of the case study LAs, we will request detailed, locally held linked data (see Data Collection) to supplement our findings on how LA-level factors and local level of need drive differences in health visiting models. If this cannot be achieved within the timeframe of the study we will request aggregate data from each LA, If it is not possible to gain aggregate data, we will request a key informant interview with a service lead or data manager (guided by advice from the service lead in each LA) to gather key statistics about their service. Within each model of health visiting, we will explore levels of engagement and estimate whether particular types of families are more likely to decline services by looking at patterns of visit types (e.g. repeated letters and no face to face contacts), which we will then interrogate through the qualitative data. This will help us to interpret findings related to the intensity of health visiting and understand the extent to which coverage is determined by health visitors or families. We will also use these data to explore associations between maternal and child risk factors, delivery of health visiting services and use of other services (e.g. GP consultations and children's social care). In combination with our qualitative interviews in these LAs, this analysis will provide further descriptive information about the factors influencing the intensity and targeting of health visiting services within each model of health visiting.

<u>Online survey</u>

We will analyse survey responses in order to a) further refine our health visiting models developed in *objective a*, by including additional information on characteristics of local health visiting provision (e.g. use of Band 5 nurses in place of health visitors, local innovation, or targeting guidelines) and b) generalise our taxonomy to all local authorities in England including in a COVID/COVOD-recovery context.

Objective c: *Determine indicative resource use and costs of providing each of the 3-5 different health visiting models in objective b, using case studies, a national online survey and cost data*

We will identify and measure the resources used to provide health visiting services, including staff type (e.g. health visitors or nurses), salary band and FTE and also capital and non-capital overheads. Where possible, costs will reflect local prices.

Using the <u>national survey</u> of LAs, supplemented by cost data obtained via contact with LA Commissioners, and the administrative data on numbers of families and average contacts per family in each LA, we will report on:

- Resources (including staff type (e.g. health visitors or staff nurses), salary band, FTE and capital and non-capital overheads) used to provide health visiting services.
- Average cost of health visiting services per episode of care per family (e.g. per number of contacts offered) for each LA.
- Total, average and variation in costs to LAs of health visiting services.

Based on the <u>taxonomy</u> of health visiting models, and using the national survey data and Finance Officers in LAs we will:

- Calculate a unit cost of each model of health visiting.

Analysis of <u>administrative data</u> will enable us to explore:

- The link between the Ages and Stages Questionnaire on child development, as measured at age 2-2.5 years, to long term outcomes via Quality Adjusted Life Years (an outcome which NICE advocates).(78)

The <u>case studies</u> including interviews, and published literature on unit costs will enable us to explore the resource use and costs:(79)

- of other health and social care resources used alongside health visiting, such as primary GP consultations and mental health care support, and secondary care sector use.
- to families in order to access and utilise health visiting, e.g. out of pocket costs such as travel, unpaid care or child care.

We will calculate:

- Total expenditure on health visiting services by LA: average and variation in cost of service.

- Cost of health visiting per episode of care per family (e.g. per number of contacts offered).
- Average cost per contact/appointment, for each of the 3-5 models of health visiting.

In the scoping review, we will determine what data is available for use in a cost-effectiveness model, considering parameters of relevance for inclusion in a full cost-effectiveness study. For example, we will explore linking ASQ data on child development (obtained from CSDS) to future health economic outcomes such as QALYs, through simulation.(80) We will explore the availability of data to generate cost impacts over the short term (the time horizon of the intervention), and the longer term. We will explore costs external to the health visiting service (e.g. complementary LA

Objective d. *Produce an empirically-based theory of health visiting delivery in England in the form of a 'taxonomy' that provides rich descriptions and explanations of commonly used models of health visiting and includes classification of each LA, using expert workshops*

We will use an empirical-to-conceptual approach to developing a taxonomy (Figure 3).(49) We will start with the classification generated from our latent class analysis of health visiting coverage, intensity and type derived from CSDS-HES (for families both with and without maternal ACEs), independently of outcomes *objective a*). Then we will deductively conceptualise the nature of each cluster and refine our classification, based on all other available data (LA case studies, literature review, consultation with collaborators and online survey; *objective b*). We will present the revised classification to stakeholders at an expert workshop (see Data Collection) for final refinements and validation. We will group attendees into small groups based on how their local health visiting services are classified in our taxonomy. In these groups, attendees will discuss how far they feel our classification of 'their' model of health visiting reflects the service they deliver, and similarities and differences between the LAs in the cluster. Comments will be captured and written up, and higher-level comments will be fed back from each group at the end of the workshop. Based on this feedback, we will finalise the taxonomy by revisiting the latent class definitions and/or changing the way we report the models. We will derive evidence on the acceptability and meaning of the different types of health visiting for mothers from our lay workshops (see PPI section).

By combining results from these different sources, we will create a final taxonomy of health visiting service provision and associated costs, with rich descriptions of each model, including local context and perceived drivers, consequences, barriers and facilitators. Our approach assumes an implicit hierarchy of information sources: where data conflicts, we will prioritise case-studies, surveys, expert opinion and finally latent class analysis.

5.4.2 RQ2: Which health visiting models are most promising for mitigating the impact of maternal ACEs?

To answer this question, we will analyse the association between different health visiting models defined at the LA level, and selected child and maternal outcomes captured at the individual level, for families with and without maternal ACEs. We will test the validity of these findings through qualitative work and stakeholder engagement. We will then establish next steps to inform future evaluations of health visiting effectiveness.

Objective e. *Explore the association between different health visiting models (from RQ1) and selected child and maternal outcomes captured in population-based administrative data.*

Population: Children born in England between 2018-2021, exposed or not to maternal ACEs

Maternal ACEs will be identified in HES, by looking back in the maternal hospital record to identify admissions related to mental health conditions, substance misuse, and violence in the two years prior to birth (based on published lists of ICD10 codes).(56, 71) Although CSDS records some information on safeguarding and vulnerability factors related to maternal ACEs, these data are highly correlated with intensity of health visitor involvement (frequent visits are likely to increase the likelihood of identification of problems as well as identification of need triggering increased visits). Defining exposure in HES mitigates this problem by allowing us to determine exposure to ACEs independently from problems identified by health visitors.

Our definition will only capture ACEs severe enough to meet the threshold for admission and therefore we may underestimate any associations (since the non-ACEs group will also include those with ACEs that we have been unable to identify). To explore the effect of this definition, we will conduct sensitivity analyses using information on complex social factors captured at booking (estimated at around 20% of mothers based on data submitted for approximately 50% of mothers in linked MSDS data).(68)

Intervention & **C**omparison: Different health visiting models (from RQ1, defined at the LA level)

By defining the intervention at the LA level, we avoid the issue of confounding by indication whereby individuals exposed to maternal ACEs trigger increased intensity of health visiting contact.

Outcomes: Child development, child safety/harm from adverse caring environments, maternal ACEs (post-birth)

Child outcomes:

i) Child development measured through the Ages & Stages questionnaire (ASQ) at 2-2½ years (captured in CSDS). ASQ is completed by parents and scores five domains of child development. Scores are compared with cut-offs and categorised as ‘on schedule’, ‘requires monitoring’ or ‘requires further assessment’. ASQ has been identified as a suitable tool for generating a population measure of child development.(81)
ii) Safety: Unplanned hospital admissions for injuries, and mortality, up to age 3 (HES) based on published lists of ICD10 codes.(82)
iii) Harm from adverse caring environments: Unplanned, maltreatment related admissions up to age 3 (HES) based on published lists of ICD10 codes.(83, 84)

Maternal outcomes:

Evidence of maternal ACEs: Hospital admissions for mental health conditions, substance misuse, or violence, up to 3 years after birth (HES).

Outcomes captured in hospital data will represent only the severe end of the spectrum, i.e. those indications of harm that are severe enough to result in a hospital admission. However, it is not currently possible to link national health visiting data to other relevant health outcome data (e.g. GP or social care) and so we cannot evaluate outcomes that do not meet the threshold for hospital admission. Length of follow up for each outcome will vary according to the number of children eligible for health visiting services for each birth year (Figure 4). We will have decreasing numbers of children for each additional year of follow-up to the age of 3. This follow-up period is commensurate with the period for which health visitors have regular contact with families (the 2-2½ year review is the last of the five mandated visits).

Figure 4: Approximate numbers of children included in our study, based on live births

		Follow up year				
		2018	2019	2020	2021	N births
Birth year	2018	0	1	2	3	625651
	2019		0	1	2	640370
	2020			0	1	
	2021				0	

This figure shows the number of live births per year in England from the Office for National Statistics (not yet available for 2020/21). Age at follow up is given in shaded boxes; exact numbers of eligible children for our study will depend on levels of immigration/emigration. The numbers of children in our analysis for objective 1 a and 2f (data-driven preliminary classification of health visiting models and application of these models to a post-covid context) will depend on data completeness in CSDS (see below) but we estimate it to be children from approximately 25% of all local authorities in England.(33) For objective 2a (associations between different models of health visiting and

Statistical analysis

We will compare child and maternal outcomes captured at the individual-level data in CSDS-HES according to the model of health visiting defined at the LA level from RQ1. Using the LA-level indicator of health visiting model minimises the issue of reverse causality (i.e. where greater need triggers greater contact). We will adjust for predictors of both maternal ACEs and outcomes (e.g. deprivation). The model will provide evidence on whether particular models of health visiting are effective at reducing harms associated with ACEs, for LAs with similar levels of need.

In order to evaluate the impact of different models of health visiting for families exposed to maternal ACEs, but also those who are not, we will stratify analysis according to exposure (any, multiple or no ACEs). This will allow us to explore for example, whether high-risk families benefit under health visiting service models that prioritise targeting over universal health visiting, but also whether low-risk families suffer in LAs that do not consistently deliver universal services. It will also enable us to determine which health visiting models are most associated with reduced inequalities between these two groups.

We will model the risk of outcomes using generalised linear models, accounting for clustering within LAs. All outcomes will be treated as count variables: child development (measured by ASQ-3) will be defined as per standard cut-offs for 'on schedule' development; hospital admission outcomes will be analysed as the number of children/mothers with at least one admission. Model fit (i.e. how well the health visiting models predict outcomes) will be assessed using resampling methods (e.g. bootstrapping). We will include data from all LAs captured in CSDS which have sufficiently complete data to anlayse. The final sample size will depend on the number of LAs contributing to the research-ready subset of CSDS data for each year. For 2018, this comprised 180,000 births when evaluating data for the 2-2½ year health visiting review.(33) Based on previous research using HES, we expect around 7% of births each year to be exposed to maternal ACEs, and approximately 5% of children to be admitted with injuries within 2 years of birth.(85)

We will evaluate the way in which socioeconomic position affects the impact of different models of health visiting on inequalities in order to determine whether specific models of health visiting work differently according to local context.(86) We will explore LA-level indicators of local area need that measure the wider determinants of health, including measures of deprivation (Index of Multiple Deprivation), % ethnic minority population, accommodation status, child poverty, prevalence of looked after children, disabilities, and teenage pregnancies. We will use interaction terms for these different indicators of socioeconomic position, which will allow us to determine whether particular models of health visiting are better than others at narrowing inequalities.(86, 87)

Objective f: *Assess the meaning, validity and generalisability of these associations through qualitative work and engagement with key stakeholders, including relevancy and meaning of results in a post COVID-19 service context*

We will assess the validity of our findings by evaluating their congruity with our case-study results and how far they make sense to and resonate with stakeholders at national and local levels. As our initial latent class analysis (*objective 1a*) will be based on data from 2018-2020, we will use a refreshed extract of data in the final year of the study to re-run the latent class analyses on this newer 'post-COVID-19' data. We will use the survey data about pre-post COVID services in each locality (collected as part of objective b) and conduct telephone or video interviews with stakeholders. We will use these methods to ascertain whether the distinct elements of health visiting which distinguish better outcomes (RQs 1&2) remain relevant and whether there are now additional characteristics to consider in a taxonomy of health visiting services. We will analyse data to March 2023 to evaluate health visiting as delivered after the easing of lock-down and revised guidance in July 2020 from NHS England for community health service delivery during COVID-19, including for vulnerable children.(88)

To obtain feedback from stakeholders at a local level, we will present geographically relevant results at the six LAS who participated in the case studies, either as a face-to-face presentations or briefings that can be circulated, as they prefer. At a national level, we will gain feedback from expert workshop attendees (*objective d*) and any additional stakeholders recruited since the workshop. Feedback will be obtained via a webinar with opportunity for comment both live and after the event. We will use this feedback to frame and interpret findings from RQ2.

Objective g*. Establish next steps for further evaluating the effectiveness and cost-effectiveness of health visiting in preventing and mitigating the impact of maternal ACEs.*

Based on our findings from *objectives a-f,* we will identify key elements of health visiting models that vary between LAs or over time, are associated with maternal or child risk factors (including maternal ACEs), and are potentially related to outcomes. This will allow us to identify what data are available and what data would be worth collecting in a systematic way in order to be used in a comparative analysis, including a cost-effectiveness analysis. We will assess the availability of relevant data sources at national and local level and consider parameters of relevance for inclusion in a full cost-effectiveness study e.g. data to generate cost impacts over the time horizon of the intervention, and long term and/or data to take a broader societal perspective such as contributions from the third sector, and costs incurred by families and their network.

5.4.3 RQ3: What do our results mean for DHSC, NIHP, local commissioners, local performance managers and families?

We will combine and interpret our findings from RQ1 and RQ2 to understand implications and develop evidence summaries for professional stakeholders and families.

Objective h. *Review the suitability of current quality metrics used for local monitoring, in the context of our findings on coverage, intensity and type of health visiting services and outcomes.*

There is a lack of evidence on the most appropriate quality measures for health visiting. In light of our findings from RQ1 and RQ2, we will review whether the current metrics collected by PHE are appropriate (i.e., to what extent they are associated with local and individual indicators of need, variation, and outcomes) and consider whether there are alternative metrics that might be more informative. The existing PHE measures are:(43)

- C1: number of mothers who received a first face-to-face antenatal contact with a health visitor at 28 weeks or above
- C2&C3: percentage of new birth visits completed within/after 14 days
- C8i: percentage of 6-8 week reviews completed
- C4&C5: percentage of 12 month development reviews completed by the time the child turned 12 months / 15 months
- C6i: percentage of 2-2½ year reviews completed
- C6ii: percentage of 2-2½ year reviews completed using Ages and Stages Questionnaire

Objective i. *Provide evidence briefings on the implementation, likely impact and indicative costs of different health visiting models in different settings for use by DHSC, NIHP and LAs, and provide lay summaries and blogs for the public, including for parents and older children.*

In collaboration with our collaborators in DHSC, NIHP and LAs, we will produce evidence briefings to guide decision-makers in these organisations. The format will be developed collaboratively and iteratively and will be aimed at specific stakeholder groups. These will be supported by a longer policy-orientated document, separate from academic outputs, which policy and practice stakeholders can access for further details. See dissemination section for further details.

In collaboration with our lay collaborators (from our study steering group and lay workshops, see Participant Involvement), we will co-produce summaries of our findings to disseminate to the public, including for parents, older children, and those living with ACEs. This will be a two-way process in which lay contributors will help determine what aspects of the study are most relevant, important and interesting, the most appropriate forms of dissemination, and the best forums for sharing results.

6 Participant involvement

We will involve, collect and integrate the views of the public and experts by experience through three main routes: steering committee membership, workshops with experts by experience, and an informal, lay advisory panel.

6.1 Steering committee membership

Throughout the study, two mothers will contribute to our Study Steering Committee. Through our collaboration with Care City, we will recruit a mother who has personal experience of substance or alcohol misuse and/or mental health problems and/or domestic violence and abuse. This experience might be of living with a partner who has these problems and/or personal experience. We will also recruit a young mother (<19 at first birth). These lay members will make sure we remain sensitive and accountable to the views and experiences of women with children throughout the study.

6.2 Workshops with experts by experience

We will conduct three workshops with experts by experience (parents) to gain their views about the acceptability of the different service models that we have identified in *objectives 1a-c* (and health visiting more generally). We will ask workshop mothers and fathers if they are willing to provide addition input by email at the interpretation and dissemination stage. The charities we are working with will provide support and training for the participants. The third sector organisations who are recruiting for and facilitating the lay workshops are experts at engaging and capturing the views of marginalised groups. We will record details about participants, so we know which minority voices are represented and whether these participants expressed different views.

Workshop 1: Mothers who self-identify as survivors of domestic violence and abuse, accessed via Voices in Bath, a survivor-led Domestic Violence and Abuse organisation who aim to ensure that research and policy reflects the experiences of this group.

Workshop 2: Mothers who have experienced mental health problems themselves or via their partner during parenthood, accessed via CareCity in Barking and Dagenham.

Workshop 3: Mothers who have experienced their own or partner's drug and/or alcohol misuse, accessed via the National Children Bureau's lay advisory research group of parents and children with 'additional support needs'.

Workshop 4: Fathers who have experienced adversity and/or social exclusion, accessed via Future Men in South London.

6.3 Informal lay advisory panel

Our advisory panel will comprise mothers with whom we consulted prior to the study start plus mothers from each of the workshops. We will consult this lay advisory group by email about priority topics and characteristics of health visiting to inform our case-studies of health visiting and survey of health visiting practice (Figure 2), asking them 'what is the most important part of health visiting, in your opinion and why?' Additionally, we will ask these lay advisory group members to engage with us on an as-and-when basis throughout the study and at key study milestones, also by email, particularly to help shape interpretation and dissemination.

7 Governance

7.1 Project management

The PIs will be responsible for the day-to-day management of the study and lead a Project Management Group consisting of all Co-Is. Monthly meetings will enable Co-Is in different institutions to communicate. Collaborators will join specific meetings at certain study phases. Co-Is will provide advisory support and contribute to research design, interpretation, and write-up of results, based on their extensive experience.

The study will also be overseen by a Study Steering Committee (SSC), who will provide overall supervision and ensure the study is conducted to rigorous standards. The SSC will meet at the project start and then at least once per year. The SSC will include an independent chair, two parent representatives, and other independent experts (including a statistician and a health visiting professional). The NIHR Research Design Service has independently reviewed the study protocol. The study is sponsored by UCL, who provide indemnity insurance.

7.2 Approvals

The main ethical issue arising from this study is the use of several administrative datasets that are collected and disseminated without explicit consent, particularly when focussing on the sensitive area of ACEs and vulnerable families. We will mitigate against this issue by only using anonymised data, so that no individuals can be re-identified. Approvals for the use of the CSDS linked with HES are already in place via NHS Digital's Independent Group Advising on the Release of Data (IGARD). As we will be conducting secondary analysis of existing, anonymised datasets, ethical approval for the national datasets is not required. Approvals for the use of any local data as part of the case studies will be obtained through local governance systems. All data will be stored on the UCL Data Safe Haven.

We will seek NHS Research Ethics Committee ethical approval for interviews with mothers, as participants will be recruited through their contact with health visiting services and for health visiting managers and health visitors if they are employed by the NHS. For these NHS employed professionals we will also seek approvals from NHS Trust Research and Development Teams. For the rest of the case-study data, including health visitors employed by LAs or other organisations, we will apply for UCL ethics committee approval and approvals from local LA Research and Development teams or other relevant organisations.

7.3 Data Protection

Our study will adhere to the eight data protection principles (Table 2).

Table 2: Data Protection Principles

1. *Fair processing*	Privacy notices posted on our institutional website will be used to give information to individuals whose personal data may be processed, stating the purpose for which data will be processed, and including a mechanism for opting out. we will publicise the study on our institutional websites (e.g. www.ucl.ac.uk/child-health/research/population-policy-and-practice/research/research-approaches/electronic-health-records-and). Information posted on these websites will include details of how patients within England can opt out of their personal confidential information being shared by NHS Digital for purposes other than their own direct care ('Type 2 opt-out').

2. Used for specified purposes	The data requested will only be used for the purposes set out in this protocol.
3. Minimum necessary for the purpose	We request only those variables necessary for analysis, and have limited the sensitivity of our request e.g. by asking for month and year rather than full date of birth or death, and for IMD rather than postcode. No additional data will be gathered or linked to the dataset.
4. Accuracy	We will validate data quality prior to analysis.
5. Kept for minimum time necessary	In accordance with University research data policy, research data will be kept for ten years after the end of the study.
6. In accordance with rights of data subject	Individuals will not be identified in the anonymised linked dataset used for analysis.
7. Security and confidentiality protection	Data transfers from NHS Digital will be encrypted and managed according to standard operating procedures. Data will be stored in a secure safe haven, which is a state of the art facility that is both NHS IG Toolkit Level 2 compliant and ISO/IEC 27001:2013 independently audited and certified (IS 612909). All data backups for the safe haven are encrypted. Access to the safe haven is restricted to authorised users who are required to have certified training in its use and data governance. Authorised users require a PIN, password, and dual authentication, and will sign a data confidentiality declaration before using the data. All exports of data from the safe haven are logged and audited, and authorised by the principal investigator. Only aggregate data, subject to statistical disclosure control (e.g. avoidance of small cell sizes), will be exported from the safe haven. No potentially disclosive outputs will be shared or published.
8. Not disclosed outside the EU	Data will not be disclosed outside the EU.

8 Dissemination and output

8.1 Plans for disseminating the findings of the research

DHSC, NIHP, iHV, CPHVA, RCN, local Directors of Public Health and commissioners of health visiting services need evidence to support decisions and directives about how to implement intensive home visiting service for families with maternal ACEs (and other vulnerabilities) within a service that remains universal. We have established communication channels with relevant teams in DHSC through the NIHR Children and Families Policy Research Unit (CPRU). Colleagues at DHSC have emphasised that this study would fill an important gap in their evidence needs (see letters of support). There will be a two-way conversation with DHSC colleagues throughout the study so that DHSC will inform the study as well as hear about findings. Our study will be particularly relevant for decisions about modernising the Healthy Child Programme, a policy initiative which is already underway and will take several years (personal communication with DHSC).

We will engage stakeholders at iHV, CPHVA and RCN, including through the expert workshop (RQ1). We will share our results with Directors of Public Health, commissioners of heath visiting, health visiting managers and health visitors. Tailored briefings will be disseminated via the same routes as the online survey (RQ1), through iHV, CPHVA and RCN, NIHP , ChiMat (or new equivalent), via NIHR CPRU, and through collaboration with the National Children's Services Performance and Data Management Group.

Through the stakeholder workshop (RQ1), we will share initial findings with key stakeholders and establish new relationships through which we will inform and engage appropriate audiences. Again, these networks will comprise a knowledge exchange where stakeholders will help inform the research as well as hear about and further disseminate results.

For academic beneficiaries and other researchers, we will publish peer-reviewed journal articles, present at conferences (e.g. Annual iHV Health Visiting Conference, CPHVA Annual Professional Conference), and disseminate our findings via social media networks and institutional blogs (e.g. iHV Voices Blog).

We will work with our parent representatives (see Participant Involvement) to identify relevant streams of communication (e.g. social media, charity websites) and co-produce lay summaries and blogs. For the broader public, we will write for the Conversation (a free, online, independent source of news and views from the academic community aimed at the broader public).

8.2 Expected outputs

Our results will comprise a taxonomy of 3-5 models of health visiting implemented in LAs across England for families with and without maternal ACEs, including detailed descriptions of local context and estimates of likely impact on child development, child safety/harm, and maternal ACEs. The rich descriptions will draw on our qualitative work and include a narrative about the plausibility of attributing effects to health visiting and the perceived mechanisms of effect.

We will tailor and co-produce briefings for policy-makers at DHSC and NIHP, and evidence summaries and blogs for the iHV, CPHVA and RCN, Directors of Public Health and commissioners of health visiting. With our parent representatives we will co-produce outputs for families, e.g. fact sheets about the Healthy Child Programme and the role of health visitors from parent perspectives.

We expect 4 peer-reviewed, open access publications aiming to reach Public Health and health visiting academics, Public Health consultants and health visitors and published in high impact journals (e.g. Lancet Public Health, Journal of Epidemiology and Public Health, BMC Public Health) and journals read by relevant commissioners, managers and professionals (Journal of Public Health, Journal of Health Visiting). Secondary outputs will include methodological research on the quality of the CSDS as a data source for evaluating community services. These subsidiary analyses will be published to inform data providers and other researchers on the use of these data for future or ongoing studies. For this work, we will target journals such as PLoS One.

8.3 Anticipated impact

Our study will provide the first indication of which health visiting structure is most promising for mitigating the impact of maternal ACEs, for which groups of individuals, in which contexts across England and at what costs. This evidence is needed by those making difficult decisions about how to run, commission or direct health visiting in the current context of austerity and workforce shortages. At a local level, our findings will inform policy and commissioning decisions that are being made in reaction to budget cuts, workforce challenges and quality metrics reported by PHE. In some areas it has become hard to protect health visiting services in the absence of evidence of likely impact. We anticipate that our findings will inform decisions about how far LAs should invest in intensive health visiting for families with maternal ACEs and what wider factors will need to change to maximise implementation and effectiveness. As we ground our study in the real and current world of health visiting practice and provide resource use and costs of different health visiting models, Directors of Public Health, and commissioners and providers of health visiting will be able to translate findings into local practice and apply findings to their current decisions.

At a national level, the results will inform discussions at DHSC about changes to the structure of health visiting commissioning (NHS possibly taking back responsibility for commissioning). Our findings will also inform changes to policy on the delivery of health visiting, to maximise outcomes for families in receipt of these large and costly services, including those with high needs such as maternal ACEs. Our research has the potential to influence policy recommendations about what is feasible in terms of a minimum number and type of health visitor contacts for universal and high need families in differing local contexts. Our results will have implications for influential policy advocates, such as the iHV who are petitioning for a higher number of universal visits. Our research will provide insight into the implications of increasing the number of recommended visits for the delivery of intensive health visiting to high need families such as those with maternal ACEs. Our study has the potential to inform discussions between Central Government and PHE (NIHP) about the public health spend for preschool children in the 2024/5 spending review.

Our study is foundational for further evaluation of health visiting, a costly and universally implemented intervention with a limited evidence base but with potential for reducing harms associated with maternal ACEs. We will generate robust hypotheses about effectiveness that could be tested in quasi-experimental studies. RQ1 will identify key factors associated with differences in coverage, intensity and type of health visiting for families with and without maternal ACEs that are likely to influence effectiveness. Once we know the important characteristics, changes can be mapped at an LA level across England and used to facilitate a difference-in-differences approach to estimating effectiveness and cost-effectiveness. We will undertake a scoping exercise to review the existing literature in the field and establish what data are available in the public domain and/or feasible to collect at a local level for a future economic analysis. Our study will act as a baseline to evaluate effectiveness and cost-effectiveness of changes to health visiting for vulnerable families within the modernisation of the Healthy Child Programme.

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