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Health Visiting in England: For families facing adversity
RESEARCH STUDY

Full/long title of study	Which health visiting models in England are most promising for mitigating the harms of maternal related Adverse Child Experiences?
Short title	Health visiting for families facing adversity
Version and date of protocoL	Version 3.1 16.10.24
Sponsor:	UNIVERSITY COLLEGE LONDON
Sponsor reference number:	**167646.**
Funder (s): **IRAS Number:** **ISRCTN / Clinicaltrials.gov no:**	National Institute for Health and Care Research (NIHR129901) 340573 Not applicable
UCL Data Protection Number: **Chief investigator** Dr Jenny Woodman Associate Professor in Child and Family Policy Room 2.16 55 Gordon Square London WC1H 0NR	Z6364106/2024/05/128 **Sponsor Representative**: Pushpsen Joshi, Joint Research Office, UCLH/UCL Joint Research Office, part of the Research Directorate, 4th Floor, West, 250 Euston Road, London, NW1 2PG -uclh.randd@nhs.net UCLH/UCL Joint Research Office,

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Previous	V1.11	17.06.21	Dr Jenny Woodman	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). 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. We received ethical approval for the first phase of this study (secondary analyses of administrative data) from UCL Institute of Education ethics committee on 21.07.21 (REC 1531)
Previous	V 1.2	19.04.24	Dr Jenny Woodman	This version is amended from V1.11 in 5 significant ways: • The investigator team has changed (funder approval received) 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 • 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.

Previous	DRAFT v2.1	17.08.24	Dr Jenny Woodman	• Reformatted to comply with our university template for sponsorship ahead of the NHS REC application for the qualitative component. The university format requires additional information about data protection, which has also been added. We have also added more detail on the process of recruiting and interviewing professionals and parents, in order to gain university sponsorship and NHS REC approvals. These are not study changes - just more detail in the protocol in order to gain university sponsorship and NHS ethics. Please note the retention of anonymised data will now be for 10 years from study end date (as requested by university ethics committee in our amendment to add the qualitative data collection sites) • Added the names and contacts for the additional data collection sites which we have now onboarded ahead of NHS REC

Current	V3.1	16.10.24	Prof Jenny Woodman	• Amendments to economics component, namely: Use publicly available national unit costs and individual level data from the community services dataset to cost models of health visiting instead of a national survey, change senior co-investigator team to facilitate the amended analyses, remove scoping review to underpin future cost effectiveness model (as relevant review published in 2021) • Change consultation with professionals (stakeholder work) to individual interviews rather than a large virtual workshop • Remove analyses of locally held data from case study analyses and replace with analyses of relevant Community Services Dataset for 4 case study sites • Reduce scope of objective f to focus updated analyses of the administrative data on the 4 local authority sites • Changed title for Jenny Woodman to reflect promotion to Prof

DECLARATIONS

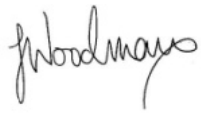
The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor (UCL).

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor (UCL) green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly 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. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigators:

Signature: .....  **..... Date 03/07/24**

Print Name (in full): Jenny Woodman.....

Position: ..Associate Professor in Child and Family Policy.....

On behalf of the Study Sponsor:

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

Print Name (in full): .....

Position: .....

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	340573
REC Reference No.	
Sponsor Reference No.	167646
Other research reference number(s) (if applicable)	UCL Data Protection number Z6364106/2024/05/128
Full (Scientific) title	Which health visiting models in England are most promising for mitigating the harms of maternal related Adverse Child Experiences?
Health condition(s) or problem(s) studied	Families with young children who have experienced domestic violence and abuse, addiction or substance misuse or mental health problems and/or other adversity which has resulted in (or could have resulted in) additional support from the health visiting team.
Study Type i.e. Cohort etc.	Quantitative analyses of linked pseudoymised administrative data: children aged under 5 years and their mothers in 2018-2020 in areas of England that have complete data in the national data set (CSDS) 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) We are only applying for HRA approval for the case study (qualitative interview) component
Target sample size	Minimum 32 interviews across four case study sites (i.e. 8 interviews per site)
STUDY TIMELINES	
Study Duration/length	Study started in Feb 2022 – 48 months duration to 31st Jan 2026. The case study qualitative interview data collection will take place from September 2024 to July 2025
Expected Start Date	Interview data collection start date September 2024
End of Study definition and anticipated date	Interview data collection expected to finish July 2025
Key Study milestones	For case study qualitative component August – March 2024 recruit participants Sept 2024-July 2025 conduct interviews Sept 2024 – Dec 2025 analyse interviews Jan 2026 write funder report and publications
FUNDING & OTHER	
Funding	National Institute for Health and Care Research
Other support	Not applicable
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	Not applicable

Data collected / Storage	Not applicable
KEY STUDY CONTACTS	
Chief Investigator	Prof Jenny Woodman Associate Professor in Child and Family Policy UCL Social Research Institute 55 Gordon Square London WC1H 0NR j.woodman@ucl.ac.uk
Study Coordinator	Jenny Woodman (Chief Investigator) as above
Sponsor	**University College London Hospital**, Joint Research Office, UCLH/UCL Joint Research Office, part of the Research Directorate, 4th Floor, West, 250 Euston Road, London, NW1 2PG
Funder(s)	NIHR Coordinating Centre National Institute for Health and Care Research University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS
Committees	Study Steering Committee (SSC) which provides feedback on study progress and challenges arising as well as ensuring that 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, at least one parent representatives, and other independent experts (including a statistician and a health visiting professional)
Sub-contractors	Not applicable
Other relevant study personnel	Not applicable

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

KEY WORDS

Health visiting, families, early years, adversity

LIST OF ABBREVIATIONS

Not applicable

CONTENTS

1 INTRODUCTION

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). Based on work with our lay contributors, we refer to families living with these experiences as "families facing adversity". Families facing adversity tend to have more physical and mental health problems as adults than other children, particularly those living with both poverty and other adversity.

Health visitors are a key profession for young children who live in families facing adversity. 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 with additional needs, including because they are facing adversity 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 families facing adversity. Health visiting is organised differently across England and many families, including those facing adversity, 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 facing adversity, and whether they are only likely to work in specific contexts such as where there are community services (e.g. Children's Centres or Family Hubs). This research could provide answers to these questions and inform changes to government recommendations about health visiting.

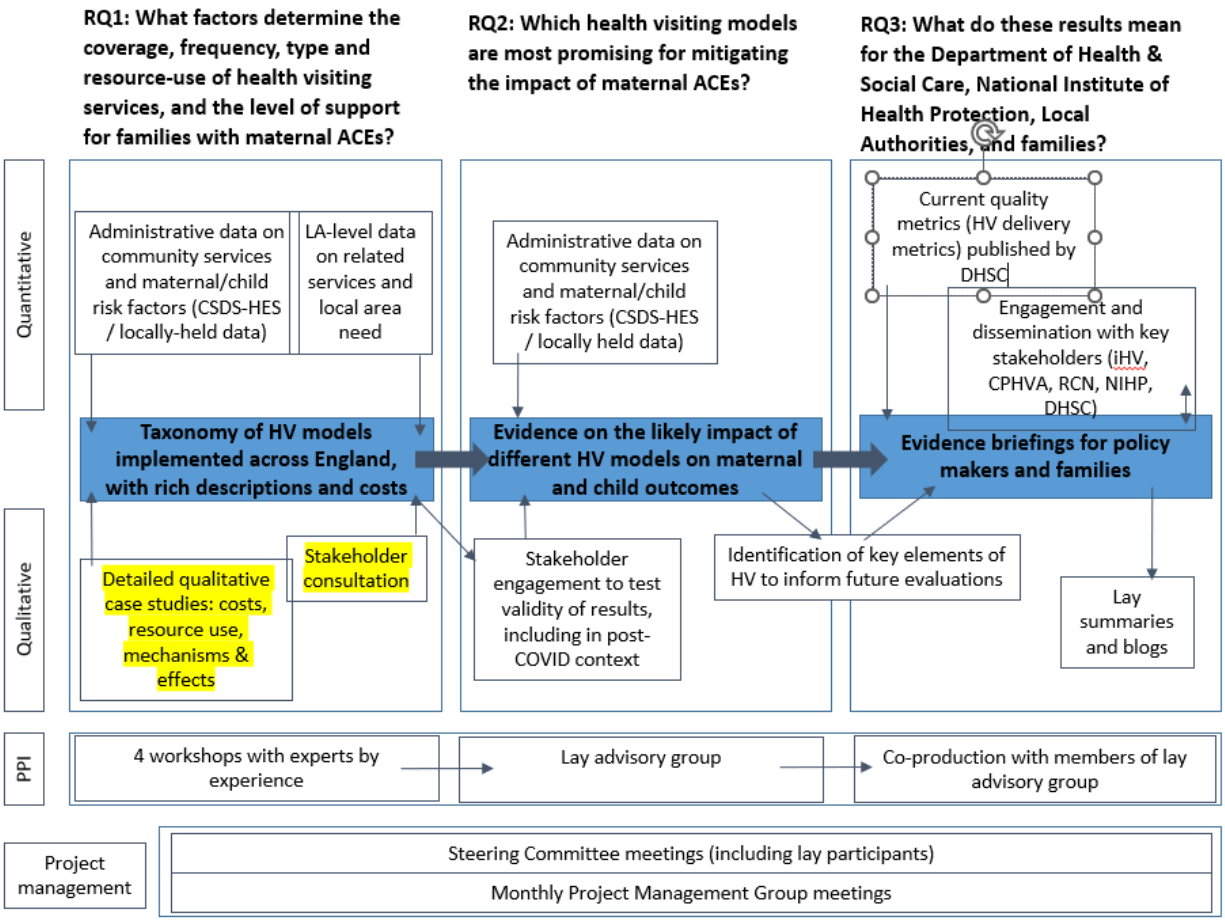
We will use multiple different types of information and research methods to describe health visiting and think about what might be the best ways of delivering this service (see Figure 1 research flow diagram). We will use data routinely collected as part of health visiting services and hospitals in England (known as administrative data) 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 conduct approximately 32 interviews with professionals and mothers in four different local areas in England to understand the full picture. We will investigate how services are organised, what services are offered and used, how often, how the services might help families facing adversity, 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 in terms of health visiting, 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 the adversity they are facing (maternal alcohol or drug misuse, domestic violence, or

mental health problems). 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.

This project is not being conducted in relation to any academic qualification (i.e. not a student or a student project) and is not related to any previous research sponsored by UCL/UCLH.

Figure 1: Research Flow



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

2 BACKGROUND AND RATIONALE

Background and rationale

How many families are facing adversity in England?

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 we have previously called them parental or maternal related ACEs (maternal ACEs).(1-3) However, based on feedback from our lay contributors (mothers who have experienced domestic violence and abuse, mental health problems and living with a partner who is addicted to illicit drugs), we now use the phrase "families facing adversity".

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) Living as part of a family that is facing adversity is associated with a range of health-harming behaviours, and physical and mental health conditions in adolescence and mid-adulthood.(3, 7-9) Because adversity is socially patterned, these problems contribute to health inequalities that start in childhood and persist throughout adult life.(10, 11) Poverty might be a driver of adversity or exacerbate the harmful effects of adversity.(12) In addition to harms to individuals, family adversity places 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 their experiences and outcomes. 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.

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 in families facing adversity.(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) Guidance from the Department of Health and Social Care 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 allow 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 facing adversity) may 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)

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 facing adversity. 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)

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 living in families facing adversity 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 Office for Health Improvement and Disparities (OHID) within the Department of Health and Social Care (DHSC) replacing Public Health England and the creation of a specific Start for Life Unit in DHSC (focusing on conception to age 2) 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 (next one anticipated in 2024) 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 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 the government.(44)

Our study will evaluate the coverage, intensity, type, recourse-use and costs of health visiting for families facing adversity, 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 adversity) and outcomes.(46) We will combine this quantitative analysis with qualitative data to generate hypotheses about which models of health visiting for families facing adversity are most feasible to implement in specific local contexts, at what cost, and which models are most promising for mitigating the impact of adversity for children and mothers. This evidence is needed by DHSC (OHID and the new Start for Life Unit) 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.

3 AIM(S) AND OBJECTIVES

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.

- ***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

- ***Objective c:*** Determine the cost of providing each of the 3-5 different health visiting models in *objective b,* using national unit 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 stakeholder work.

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 relevance 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, Local Authorities 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 costs of delivering different health visiting models in different settings for use by DHSC, and LAs, and provide lay summaries and blogs for the public, including for parents and older children.

4 STUDY DESIGN & METHODS OF DATA COLLECTION

Conceptual framework

This is a multi-component observational study comprising analyses of linked administrative data from health, a costings component and interviews with professionals and mothers with young children who have experienced adversity. We are asking for UCL sponsorship of the qualitative interview component of the study because this is the study component requiring HRA approval.

We take an interdisciplinary mixed-methods approach, generating a taxonomy of health visiting to provide answers about the nature of health visiting for families facing adversity and how different models are likely to work, for whom, at what cost 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 family adversity (hospital admissions for injury and maltreatment), and 3) adversity post birth (from maternal hospital admissions). We know that children living in families facing adversity 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 who are and are not facing adversity. 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.

(Ex) Public Health England 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.

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.

Data collection

Table 1 gives an overview of data sources; Figure 2 gives an overview of data sources for RQ1, *objectives a-d.*)

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.

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).

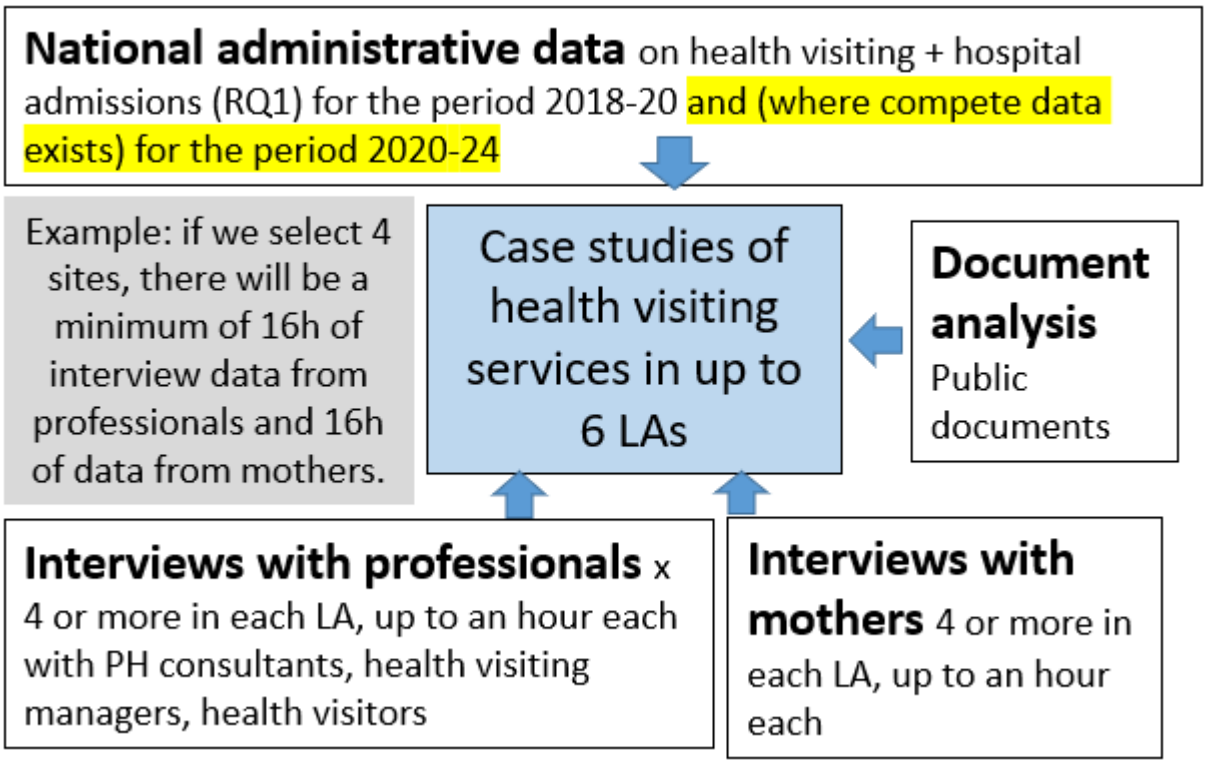
Detailed case studies of different health visiting models (objectives b and f)

Local area case study sites, minimum 4 sites across England

We will conduct case studies of health visiting in up to 6 LAs (minimum 4 LAs) (Figure 2) comprising interviews with professionals and mothers and analysis of locally held administrative data where available. We have sampled 4 sites to-date (see attached IRAS form) and are about to apply for HRA ethical approval for these 4 sites. These four sites were chosen (as planned) based on our analyses of administrative data, sampled to reflect differences in the frequency and reach of health visiting and representing local areas with most complete data in our administrative data source (so we can compare interview and administrative data on the same area).

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 more 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 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 to ask about any out of pocket costs to families associated with accessing and using the health visiting service.

Figure 2: Data that will be collected or used for case studies



Study population and number of qualitative interviews

We will interview a minimum of 8 participants for up to an hour in each of our case study sites, to a minimum of 4 sites (i.e. a minimum of 32 interviews, anticipated to be 50% professionals and 50% mothers). This number has been derived from considering the need for data saturation (i.e. no new emerging themes at last point of data collection) and feasibility within study timeline.

Professionals will comprise: clinical leads of the 0-19 service, health visitors, staff nurses, nursery nurses and any other members of the health visiting team that out local area contacts tell us are important for supporting families facing adversity as well as health visiting commissioners. We will interview mothers with at least one child under 5 years old (i.e. eligible for health visiting service) who the health visiting team or local charity (e.g. Home Start) identify as facing adversity. We will ask health visiting teams to focus on families who have experienced mental health problems, domestic violence or abuse or substance or alcohol misuse in the household for our study but we will also interview families with other issues that have led to intensive health visiting where signposted by the health visiting team or charity.

We will interview professionals in their place of work (or virtually if they prefer) at a time and date convenient to them. We will interview mothers in health visiting or community buildings or in charity buildings, both of which will ensure a quiet safe space for mother and researcher. If mothers prefer, we can offer them a virtual interview. Mothers will be able to bring babies, if they would like and we will cover any extra costs incurred for childcare for older children in order to attend the interview. Mothers will receive a

£30 voucher for participating. Interviews will be conducted by a UCL employed member of the research team or Prof Woodman (Chief Investigator).

We anticipate a maximum of 90 minutes time for each participant to be involved in the study, although professionals may have an opportunity to attend presentations where we feedback results to their local teams (this is not study 'participation' but knowledge exchange with the case study sites). The 90 minutes will be concentrated across 2 or 3 weeks and largely accounted for by an interview of up to an hour

We anticipate that data collection will begin in September 2024 and go onto June 2025, rolling across sites (i.e. site 1 may have all data collection in September and October 2024, site 2 in October to December)

Topic guides for interviews

We have developed interview topic guides for parents and mothers, through a literature review of the programme theory of health visiting, through stakeholder engagement and through working with 2 mothers (2 lay collaborators who have experienced domestic violence and abuse, mental health problems and living with a partner who misuses substances).

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 and how they decide whether to offer universal, targeted or specialist services by asking about specific families on their case-load.(16, 17) Where possible, we will ask professionals to reflect on the characterisation of their LA in our data-driven preliminary classification of health visiting. We will ask mothers who have faced adversity 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. We have piloted interviews within our existing networks and used these pilots to refine the questions and wording.

National Administrative data analyses for 2020+: We will investigate data completeness of our case study sites with CSDS for the more up-to-date time period of 2020 onwards. Where data is complete enough in CSDS to update the analyses on the case study sites, we will use this data to repeat some of our analyses in obj a and explore how far health visiting delivery has changed in these case study sites compared to 2018-20.

Cost of health visiting service delivery models (objective c)

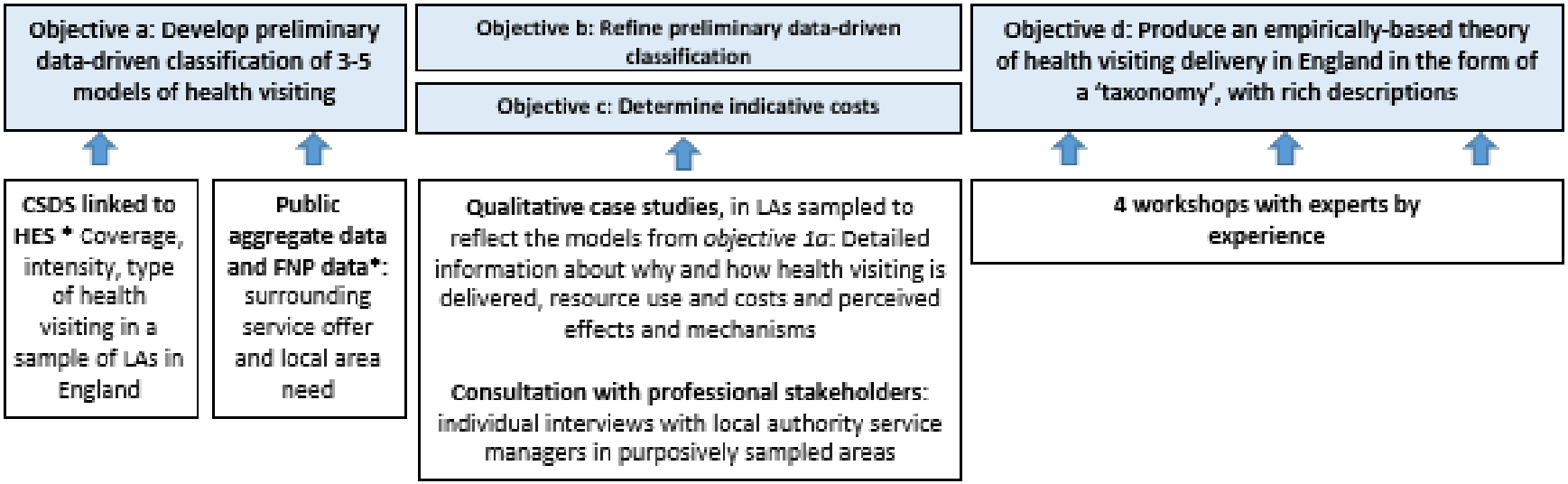
We will use the individual-level administrative data on numbers of families, average number and duration of contacts (separate by mandated and additional contacts) per family in each LA, supplemented by information on unit costs from national databases (namely, the NHS Reference costs) . The key perspective will be the LAOverall, this analysis will describe the cost of the different health visiting service delivery models (identified in objective b) and help decision makers understand which health visiting models are most costly.

Stakeholder consultation and lay workshops (objectives d, h and i)

We will consult with professional stakeholders in at least 15 local areas, targeting stakeholder interviews to gain feedback on our classification of services across the service models we have identified. We will present

results for each area from 2018-20 to the service manager in that local area, alongside an overview of study results for the whole of England. Each interview will last approximately 45 minutes. This will provide insights into why we may be seeing differences from the average in their local area (e.g. recording practices or targeted focus or the needs of the population) and sense-check our classification of 'models' of health visiting. We will also run 4 in-person workshops with experts by experience to gain views about the acceptability and meaning of the different types of health visiting for mothers. If our lay collaborators prefer, we can offer these as virtual workshops.

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;

Table 1: Description of anticipated 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 family adversity (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 family adversity 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
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)	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

			- % receiving new birth visits, 6-8 week reviews, 12 month reviews and 2-2½ year reviews	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	Characterise local innovation and detailed information about HV services not	Qualitative case studies; LA level data	Detailed description of local HV services including priorities, constraints and local factors that have	

models, generalise to all of England and determine costs	available in national data; obtain resource use and cost data		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; estimate cost of different HV service models	National unit costs (NHS Reference costs) and individual level CSDS data	Contact duration, contact type (mandated or additional)	
1c. Produce taxonomy of HV service models	Interpretation of groupings generated using all above data.	Lay workshops		

5 STUDY SCHEDULE

Enrolment for interviews
We will work with gatekeepers (0-19 clinical service leads) to recruit professionals for interviews and with the health visiting teams and local charities to identify mothers for recruitment (details above). Potential participants will be given information by their clinical service lead or research team (professionals) and be the health visiting team or charity (mothers).

Eligibility
We will check eligibility of the potential participants at the first contact with the research team and consent stage. If a participant wishes to withdraw, they are free to do so at any stage (including after data collection) and can do so by emailing the research team (contact details on all study material). This process is stated on the Participant Information Sheets and consent forms and will be mentioned again by the researcher at the beginning of each interview.

Withdrawing
If a participant withdraws we will securely delete any of their data as soon as possible including interview recording and/or transcript if they participated in an interview.

Follow-up
We will provide participants with a written summary of results and links to any publications up until Jan 2027 when we will securely delete their personal data (including email address).

Timeline
Participants will end their participation in the study after the interview. End of study will be a year after funding end date (i.e. Jan 2027 a year after study end in Jan 2026)

6 ELIGIBILITY CRITERIA

7 Inclusion Criteria

MOTHERS

- Live in one of our case study sites
- Are a mother aged 18 or over
- Have at least one child currently under 5 years old
- Must consent to participation and be well enough for participation (as identified by themselves, the health visiting service or local charities)
- Are not currently in the middle of a crisis or particularly bad time (as identified by themselves, the health visiting service or local charities)
- Have been identified by the health visiting service or local charity as a family facing adversity
- Must have opportunities for continued support from either the health visiting team or local charity after the interview

STAFF

- Must be part of the health visiting team in one of our case study sites and/or work closely with the health visiting team and/or commission health visiting.
- Must consent to participation

8 Exclusion Criteria

MOTHERS

- Outside of stated age range (mother or child)
- Outside stated location
- Unable or lacking capacity to give consent or not well enough to take part in interview (including in acute crisis situation e.g. with their own mental health or partner's substance misuse)
- No contact with health visiting service or charity for on-going support
- Not willing to consent

STAFF

- Not part of health visiting team (or manager or commissioner)
- Outside location
- No consent

9 RECRUITMENT

Method for identifying

We will identify professionals for interview with the assistance of our gatekeepers at each site (the 0-19 clinical service lead). We will offer to come to a meeting and talk about the study (or give a virtual presentation if that suits the health visiting team better) and will provide the study flyer (which links to an online information sheet) and information sheets. We will also ask the gatekeeper to disseminate the study flyer to staff by email. Professionals will be free to send the details of the study to others in their local team and/or follow up directly with the research team for more information and participation. To recruit mothers, health visiting teams and/or the local charity partner will talk to and hand out our flyer (which links to an online information sheet) and information sheet to mothers who the professional think may be eligible to participate. The mother will then decide whether to contact the research team for further information and participation by email on the flyer and information sheet or via the QR code on the flyer. We have been advised by the Clinical Research Network (CRN) that the NHS sites will not be eligible for any costs from CRN due to study design (i.e. research team consenting the mothers)

The research team will never have any access to any information from the health records of the participants.

Either the main researcher on the study (currently in recruitment) or Dr Woodman (PI) will check eligibility and consent all participants by sending them the consent form and being available to answer any questions and/or talk the participant through consent. A log of ineligible participants will be kept (without personal data – as we will not delete personal data of non-participants) with reasons for ineligibility

We will use purposive sampling: making sure we interview professionals across a range of staff roles within each local area and mothers with a range of adversity (e.g. including history/experience of substance misuse where we anticipate more difficulty in recruitment as well as mental health and violence and abuse). This sampling approach will ensure that we can compare views and experiences across the full breadth of the health visiting team and as many experiences of adversity as we can within the confines of the study timelines.

Reimbursement to mothers
Mothers will be provided with a 'thankyou' for participation in the form of £30 digital High Street vouchers which will be emailed after the interview.

We will also offer a £30 voucher to offset childcare costs (per child) and to offset any travel costs (up to £5).

10 CONSENT

For analyses of large scale administrative data
There is no consent process for using the pseudonymised health care records. It would not be feasible to obtain consent, because i) we do not have access to names and addresses with which to contact individuals, and obtaining these contact details would require a further disclosure of personal information, and ii) we are requesting to use national data for almost 1 million families; it would not be possible to contact this large number. However, CSDS-HES does not contain any direct patient identifiers such as names, addresses, NHS numbers or full dates of birth. This means the threat to patient anonymity is very low. 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) All data will be stored and analysed within the UCL Data Safe Haven.

For interviews

We will seek informed written consent and participants cannot be part of the study without this consent. We will not start any interview without written consent, but we may arrange an interview time and place with the agreement that the consent form will be filled in at the start of the interview (to accommodate mothers who may find adding electronic signatures to documents difficult).

We will provide the participant information sheet and consent form to participants by email and the main researcher on the study or the Chief Investigator will offer to talk to the potential participant to

answer questions and talk through the consent form. We would then ask that the consent form is filled in electronically and sent back or if participants prefer, we can bring a hard copy and gain written consent before the interview starts. We will seek ethical approval from NHS REC for the information and consent forms.

During conversations between the researcher/Chief Investigator and the participants, the researcher team will make judgements about capacity to consent, including how far the potential participants

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision.
- be able to make a free choice
- be capable of making this decision at the time it needs to be made

Where potential participants need an interpreter for consent, we will provide one on a Zoom call and we will also provide a translator for an interviews if required.

11 DATA ANALYSIS

RQ1: What factors determine the coverage, frequency, type and resource-use of health visiting services, and whether families facing adversity 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 who are and are not facing adversity 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 who are and are not facing adversity, 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 adversity), 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 who are and are not facing adversity, 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 who are and are not facing adversity, 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*

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.

Our interview data will be transcribed by TP Transcriptions, a UCL supplier https://www.tptranscription.co.uk/ who will de-identify at the point of transcription to create anonymised transcripts. We will email the audio-recordings of the interviews to the transcriber using encrypted 7Zip files, one way of transferring data to external parties recommended by UCL https://www.ucl.ac.uk/information-security/what-should-i-do-transferring-sensitive-or-personal-data. Once we acknowledge receipt of the transcripts, the transcription company will securely delete the audio-recording.

A copy of the audio files and personal data (e.g. names, emails etc) of participants will be stored on password protected files on the UCL S drive accessed only by the main researcher and one of the Chief Investigators (Woodman). The anoymised transcriptswill be stored and coded in NVivo on the UCL S drive, including interview transcripts, publicly 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. Only the UCL study team will have access to these NVivo files (the two Chief Investigators, the main researcher on the project and the UCL co-investigators). The main researcher (currently being recruited) and one of the Chief Investigators (JW) will code the transcripts in Nvivo, with interpretative input from the wider team in meetings.

Prof Woodman (Chief Investigator) will archive and then destroy the personal data at 12 months following study end (Jan 2027) and the interview transcripts at 10 years after study end (Jan 2036).

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In order to aid the added value from combining quantitative and qualitative data about our case study sites, we will investigate data completeness for the post 2020 period in CSDS for our case study sites. If these sites have sufficiently complete data in our CSDS refresh, we will update some of our analyses for these specific sites to more current data using CSDS.

Objective c: *Determine the cost of providing each of the 3-5 different health visiting models in objective b, using national unit cost data*

We will identify and measure the frequency and duration of the different types of contacts (i.e. mandated and additional) at the LA level and for each of the different health service delivery models. Frequency and duration will be combined with national unit costs (i.e. NHS Reference costs) to calculate the total cost of delivering each model at the LA level, which will formulate the main analysis for this objective. An additional analysis will consider the percentage of skill-mix reported nationally in the annual Institute of Health Visiting survey report to explore whether it will impact the cost of the different models of health visiting.

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 who are and are not facing adversity), 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 andconsultation with collaborators; *objective b*). 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-studiesexpert opinion and finally latent class analysis.

RQ2: Which health visiting models are most promising for mitigating the impact of adversity in families?

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 who are and are not facing adversity. 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 family adversity

Adversity 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 adversity, 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 adversity independently from problems identified by health visitors.

Our definition will only capture adversity severe enough to meet the threshold for recording at the point of admission and therefore we may underestimate any associations (since the non-adversity group will also include those with adversity that we have been unable to identify).

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 children in families facing adversity trigger increased intensity of health visiting contact.

Outcomes: Child development, child safety/harm from adverse caring environments, family adversity (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 adversity: 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 record during 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)

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 family adversity and outcomes (e.g. deprivation). The model will provide evidence on whether particular models of health visiting are effective at reducing harms associated with family adversity for LAs with similar levels of need.

In order to evaluate the impact of different models of health visiting for families exposed to family adversity, but also those who are not, we will stratify analysis according to exposure (any, multiple or no adversity). 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 analyse. 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 family adversity, 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 for the four case study sites.(88)

To obtain feedback from stakeholders at a local level, we will present geographically relevant results to professionals in theLAS who participated in the case studies, either as a face-to-face presentations or briefings that can be circulated, as they prefer. We will also present findings to purposively sampled local areas to gain their insights on their own local results in comparison to the national picture (based on areas with complete data).

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 feasibility and next steps for further evaluations of health visiting.

RQ3: What do our results mean for DHSC, 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 the Office for Health Improvement and Disparities (in DHSC) 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 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 and LAs, and provide lay summaries and blogs for the public, including for parents and older children.*

In collaboration with our collaborators in DHSC 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), we will co-produce summaries of our findings to disseminate to the public, including for parents, older children, and families facing adversity. 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.

12 PATIENT AND PUBLIC INVOLVEMENT (PPI)

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.

Steering committee membership

Throughout the study, up to two mothers will contribute to our Study Steering Committee. We will recruit mother(s) who have 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. These lay members will make sure we remain sensitive and accountable to the views and experiences of women with children throughout the study.

Workshops with experts by experience

We will conduct four 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. We will work with charities to set up and conduct these workshops and to support and training for the participants. We will choose these charities because they are experts at engaging and capturing the views of marginalised groups. We will record some 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, hopefully 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, hopefully accessed via CareCity in Barking and Dagenham.

Workshop 3: Mothers who have experienced their own or partner's drug and/or alcohol misuse, hopefully 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, hopefully accessed via Future Men in South London.

Informal lay advisory panel

Our advisory panel will comprise up to two 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 (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. To date (May 2024) these mothers have been involved in feedback on the acceptability of the research (e.g. terminology around adversity and families and acceptability of interview questions), design (e.g. piloting and commenting on interview questions) and they will also be involved in interpretation of results and input into our lay summaries for dissemination.

13 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via the Local Clinical Research Network.

The study wis funded by the National Institute of Health and Care Research (NIHR) with a grant of £808,393.59. The date of funding decision was 16th March 2021 and the study runs from 1st Feb 2022-31st Jan 26. add funder, including funding amount and date of award). Grant number NIHR129901

We have been advised by the Local Clinical Research Network that there are no eligible costs that they can support, due to study design (i.e consent being taken by the research team).

Neither the Chief Investigators or any other investigators have any direct personal involvement (e.g. financial, shareholding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest

14 DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is Spenser Crouch (data-protection@ucl.ac.uk). The data processors are UCL.

The study will be collecting the following personal data:

Pseudonymised administrative data (CSDS-HES admin):

- month/year birth of child and mother
- ethnicity
- gender of child
- Date and diagnoses of hospital admissions for mother and child
- Date and type of health visiting contact for child

This CSDS-HES data is stored and processed on the UCL data Safe Haven and subject to independent checks outside the research team before exporting of any results.

Interviews:

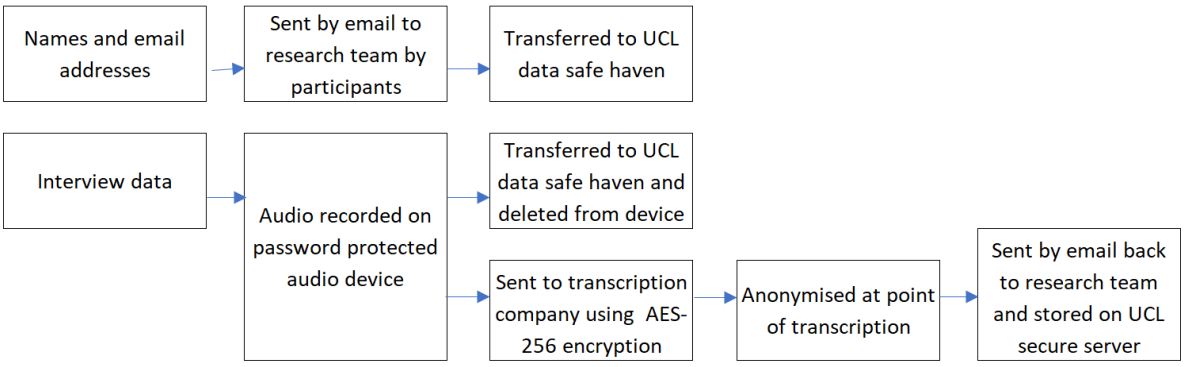
- Name and email given when contact is made by the participant with the research team
- Name and signature on consent form given by participant
- Number of children, number of adults in household, age (to nearest decade), self-reported ethnicity all given directly by participant in interview.
- Any other personal data the participant chooses to disclose will be collected as part of the interview conversation (e.g. details of medical history)

The personal data collected as part of the interview component (name, email and personal data contained in the audio-recording) will recorded on a password protected audio device and will be transferred to the UCL S drive within 24h of interview using a direct USB connection with a computer on the UCL network (i.e. no internet transfer). The audio-recording will then be deleted from the recording device. The audio recording will be stored on a password protected file on the S drive and only Jenny Woodman (Chief Investigator) and the main UCL research on the study (currently in recruitment 10.05.24) will have access to these files. After each interview, the interviewee will be given a number, stored along side their personal data. We will extract the personal data and add it to to aggregate counts across interview participants (i.e. anonymise it). Once the interviewee key has been generated, personal data extracted and anonymised in the aggregate data sheet and the audio recording has been transcribed, we anticipate accessing the personal data only rarely (if at all) until it is deleted a year after study end date (study end date Jan 26, destruction of personal data Jan 27). We will use TP transcription (UCL approved supplier) https://www.tptranscription.co.uk/contact/ to transcribe. TP Transcription will anonymise at the point of transcription. We will use AES-256 encryption to transfer the audio file from UCL to TP Transcription using the free archiver 7-Zip as per UCL recommendations, https://www.ucl.ac.uk/information-security/technical-advice/encryption/guidance-email-encryption. We will have a confidentiality agreement in place with TP Transcription prior to first transfer of data. The transcribers will permanently delete audio-recordings once we have confirmed safe receipt of transcript.

The anonymised transcripts will be stored on the S drive, with access by Jenny Woodman (Chief Investigator), the main UCL research on the study (currently in recruitment 10.05.24 and any other members of the UCL employed research team who may support data analysis (N=1/2).The transcripts will remain on the S drive for 10 years after study end date at which point they will be deleted (Jan 2036). Jenny Woodman (Chief Investigator) has responsibility for data deletion.

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality. The Chief Investigator will inform the sponsor (UCL) should he/she have concerns, which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures

15 DATA TRANSFER DIAGRAM



16 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL

The Sponsor (UCL) considers the procedure for obtaining funding from National Institute of Health and Care Research to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies (UCL Ethics approval and HRA Approval). Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, Capacity and Capability is confirmed and Sponsor (UCL) green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor (UCL), will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor (UCL), REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor (UCL) and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor (UCL) and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor (UCL) and to the REC and HRA.

17 ASSESSMENT AND MANAGEMENT OF RISK

The proposed case study research is a qualitative study, it is not experimental in nature, nor will any tissue samples be collected from participants. The main risk through participation is the potential for psychological or emotional harms through participation (especially for mothers) and/or unnecessary burden of time for participating.

All necessary and reasonable steps will be taken by the research team to guard against any such distress or embarrassment and to minimize time for participation, whilst maximizing reciprocity and reward to participants. All participant information about the study will clearly state the participants role in the research and that participation is voluntary and contain no unsubstantiated claims or benefits. There will be no follow up of health visiting recipient/clients during the study.

The research is intended to cause minimal inconvenience to participants, interviews will be arranged at a time and location for their comfort. Physical risks are not anticipated. We will keep data collection to a one off interview.

Mothers have been recruited for their lived experience of parenting in adversity so they will likely narrate sensitive and upsetting accounts. We have experienced qualitative researchers who will undertake this work, with training and senior support. These researchers will use judgement as to when to withdraw or cancel interviews, if the participant is distressed and will make sure that mothers understand voluntary participation and that they can withdraw at any time. Our researchers will keep the interview questions open, to give participants control over 'their' story. We are selecting mothers through the health visiting team and through local charities (e.g. HomeStart) with the specific purpose of minimizing the risk that mothers will be in an acute period of crisis at the time of recruitment/interview and to ensure that there is follow-up support available to the mother and child/ren.

If during the interviews with mothers, our researcher becomes concerned about the current welfare or safety of the participant of a participant or a third party such as a child, we will initiate UCL safeguarding protocols. In the first instance, this will involve speaking to the participant at the end of the interview to gain consent to share the concern with the health visiting team or local charity. We will make it clear at the beginning of the interview (and in the consent form) that we may have to break confidentiality if we become concerned about the welfare of a child in their household. If a safeguarding concern is identified, we will contact UCL's Designated Research Safeguarding Lead (Claire Glen, Executive Director of Research and Innovation Services c.glen@ucl.ac.uk Deputy Designated Research Safeguarding Lead or the deputy Designated Research Safeguarding Lead (Gail Adams). We may then discuss this concern with the health visiting team in the relevant case study site, which may result eventually in this health visiting team making a referral to Children's Social Care.

The research will be carried out in accordance with good ethical practice for social science research

https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/

https://www.theasa.org/downloads/ethics/asa_ethicsgl_2021.pdf and the principles of the declaration of Helsinki.

18 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

Research related events and incidents can encompass incidents that involve participants, staff or a carer/visitor during the course of the research study (e.g. a member of staff may be injured whilst administering an intervention, participants may not have been consented properly, collected data may be misplaced or stolen, data losses or breaches in confidentiality may occur, protocol violations or non-compliances with regulatory requirements or Sponsor conditions of approval, etc.).

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor (UCL) via UCL REDCAP incident reporting form and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor (UCL) will be responsible for investigating, reviewing, or escalating to a serious breach if required.

Although unlikely (given our experience and protocols), the following incidents may occur in this study

- Researcher injured or upset during interviews – report to sponsor (UCL)
- Participants not consented properly – reported to sponsor (UCL) and NHS Trust
- Loss or theft of interview data (on recording device) before transcription – report to sponsor and NHS Trust
- Breach in confidentiality - report to sponsor and NHS Trust

19 Personal Data Breaches

In some instances, despite risk management and mitigations, personal data breaches may occur throughout the duration of the study. GDPR broadly defines personal data breaches as a security incident that has affected the confidentiality, integrity or availability of personal data. In short, there will be a personal data breach whenever any personal data is lost, destroyed, corrupted or disclosed; if someone accesses the data or passes it on without proper authorisation; or if the data is made unavailable, for example, when it has been encrypted by ransomware, or accidentally lost or destroyed.

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer Spenser Crouch data-protection@ucl.ac.uk, (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Sponsor via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.

20 Incidental Findings in Research

There will be no incidental findings (defined as a finding that has potential health or reproductive importance, which is discovered in the course of conducting research, but is unrelated to the aims of the study)

21 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study

The CI and Sponsor will be notified immediately of any case where the above definition applies via UCL: research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form

22 NHS Serious Incidents and near misses

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

23 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor (UCL) via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

24 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor (UCL) should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

25 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

Specific training for the main researcher on this project will include UCL Data Safe Haven and UCL Data Protection training

26 INTELLECTUAL PROPERTY

The only intellectual property produced will be "scholarly works" (academic articles, research papers and other written works intended principally for the purpose of peer review and/or scholarly publication, papers summarising the results of research, conference papers and presentations). In line with UCL policy, where UCL agrees that copyright in scholarly materials and teaching materials shall belong to the UCL staff member who is the author/originator of such materials. The academic partners and NHS Trusts will not have copyright over scholarly work produced but these scholarly works will be made available through open access publications..

27 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office (UCL).

Hospitals selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity

28 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

29 PUBLICATION AND DISSEMINATION

We will publish academic papers, policy briefings and disseminate to lay audiences, acknowledging the funding body (NIHR) with their standard wording. We will feedback findings of the study to participants via a specifically designed briefing, plus links to any publications. The full study report will be submitted to funder in Feb 2026 and will be published after peer review and an embargo period. Describe any plans for publication and dissemination. We will email resulting publications to the JRO.

29.1 Associated Documents

There are no further associated documents

30 REFERENCES

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2. World Health Organization. Adverse Childhood Experiences International Questionnaire (ACE-IQ). 2018.
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4. Office for the Children's Commissioner. Estimating the prevalence of the 'toxic trio': evidence from the Adult Psychiatric Morbidity Survey. London; 2019.
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