Study Protocol

Title: A Mixed Methods Study Investigating the Health, Caring Activities, and Experiences of Informal Carers of Patients in Hospital at Home Services

Short Title: Informal Carers in Hospital at Home (HaH)

Protocol Version: 3.0a

Date: 5 March 2026

Funder: NIHR Research for Patient Benefit (RfPB) Programme (NIHR208749)

IRAS ID: 356332

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Project Duration: 18 months (Start date: 01 August 2025)

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Lay Summary

Title: *Understanding the Experiences and Needs of Carers Supporting Hospital at Home Patients*

Background:
Hospital at Home services (HaH), also known as Virtual Wards, provide hospital-level care to patients in their own homes. This model reduces the need for inpatient hospital stays and is often preferred by patients. These services rely heavily on informal (unpaid) carers, usually family members, who take on some responsibility of helping patients recover at home. Despite the vital role they play, we know little about the experiences and support needs of these carers.

What the study will do:
This research aims to understand what it's like to be a carer for someone receiving HaH care. It will look at carers' physical and mental wellbeing, the tasks they carry out, how much time they spend caring, and whether they face any financial or emotional strain. We also want to know whether carers feel supported by HaH services and what improvements could help them.

How will the study be done:
We will ask 158 carers to complete questionnaires at two points in time: during the patient's care (within 7 days of patients being taken on the HaH team) and in the fifth week after HaH care ends. In addition, 40 carers will be invited to take part in interviews to talk more about their experiences. The study will take place in two NHS areas; one in London and one in Hertfordshire, and carers will be offered support with translation or literacy needs if needed.

Why this matters:
By understanding what carers experience, we can make HaH services better and more supportive. Carers who are well supported are more likely to provide effective care, which can help patients recover safely at home. This study will offer practical recommendations to improve HaH services across the NHS.

Public involvement:
Members of the public, including people with experience as carers, helped shape the design of this study and will continue to advise the team throughout the project.

1. Background and Rationale

Hospital at Home (HaH) services provide hospital-level care to patients in their own homes, offering benefits such as reduced admissions and improved patient satisfaction. These models depend heavily on informal (unpaid) carers, who may face physical, emotional, and financial strain. Despite their central role, carers' experiences within HaH are under-researched. This study addresses that gap, exploring carer wellbeing, burden, and support needs to inform future service delivery and policy.

The research responds to NHS priorities by addressing the sustainability of HaH services, focusing on carer support as key to service delivery. Evidence shows carers' wellbeing can directly influence patient outcomes and their ability to remain at home safely. Identifying what carers need to sustain their role will inform recommendations to improve support and reduce hospital readmissions.

2. Aim and Objectives

Aim: To characterise the physical health and mental well-being, caring activities and experience of informal (unpaid) carers of patients receiving Hospital at Home service.

Objectives:

1. Identify themes arising from the reported experiences of carers before, during, and after HaH.
2. Explore relationships between carer characteristics and their wellbeing and perceived burden.
3. Document the demographic profile and contribution of unpaid carers involved in HaH.
4. Measure the type and amount of caregiving activities undertaken before, during, and after HaH.
5. Assess carers' wellbeing, perceived burden, and psychological and physical status at two timepoints.
6. Assess the economic impact on carers including out-of-pocket costs and health/social care use.
7. Develop evidence-informed recommendations to support carers and optimise HaH delivery.

3. Study Design

A mixed methods study gathering:

- Quantitative data collected from 158 carers via validated questionnaires at two time points (within 7 days of HaH care commencing and again in the fifth week following HaH discharge).
- Mixed quantitative and qualitative data from 40 carer semi-structured and carer activity interviews.

4. Study Setting

Two NHS services providing 7 days a week multi-professional care and treatment as an alternative to acute in-patient treatment. Services accept referrals as step-up (from community/primary care) **AND** step-down (from in-patient services). One team will be based in an urban setting (London) and one in a mixed suburban/rural area (Hertfordshire).

5. Participant Eligibility Criteria

Inclusion criteria:

- Informal carers
- Not receiving payment for their caring role, aside from any entitlement to Carer's Allowance
- Aged 18+ years
- Caring for someone receiving HaH care during the first 7 days of their treatment, and who:
    - is likely to have face-to-face or other contact with the patient
    - will be involved in organising or providing practical, emotional, or other support that assists the patient's care or daily life

- Able to give informed consent and participate via English or using translated questionnaires or with interpreter

Exclusion criteria:

- Unable to give informed consent
- Carers being paid to support the individual patient (excluding carer benefits or allowances)
- Carers under the age of 18 years

6. Recruitment Strategy

Recruitment Protocol for Study Participants

Step 1. Patient admission to HaH Service and Initial Identification of Carers

1.1: Patient entry to HaH service

Day 1: The patient is assessed and accepted for treatment by the Hospital at Home (HaH) service.

1.2: Identifying whether there are informal carers supporting the patient

Day 1: The HaH team will, in discussion with the patient, determine whether one or more informal carers are currently providing unpaid support. They will identify whether any of these carers are present during the first or second HaH visits. An informal carer is defined as: someone providing care without payment, excluding those receiving Carer's Allowance; who is likely to have face-to-face or other contact with the patient; will be involved in organising or providing practical, emotional, or other support that assists the patient's care or daily life, during the first 7 days of HaH treatment.

1.3. HaH discussion with the patient re: involving the carer in the study

Day 1: The HaH team will initially introduce the study to the patient, informing them they would like to discuss the research with the carer(s), and ask if the patient has any objections to the HaH team doing this. Following any discussion about this, if the patient has any objection, then the HaH team will notify the trust research practitioner who will anonymously record 'PATIENT DECLINES'. The carer(s) will not be asked to participate where there remains any objection by the patient after discussion.

1.4. HaH discussion with the carer re: the study

Day 1 or Day 2: If carer(s), meeting the criteria (above), are present at the first or second HaH visit, and if no objection has been raised by the patient, the HaH team will explain the purpose of the study to the carer(s) and provide the Participant Information Sheet (PIS) and Consent Form (CF, for information only). They will then ask if the carer(s) agrees for their telephone contact details to be shared with the research team, for the research team to make contact and provide further information. The carer(s) attention will be drawn to the specific telephone number(s) the research team will call from. The reason for this is to reassure carers that a phone call is coming from a known source. If the carer(s) does not agree to be contacted by the research team, the HaH team will subsequently notify the trust research practitioner who will anonymously record

this as 'DECLINED'. If more than one carer is present during either visit, the same process can be followed with all carers.

If the carer(s) is not present during the first or second home visit, they will not be invited into the study, and the HaH team will notify the trust research practitioner, who will record 'CARER NOT PRESENT'.

1.5. Process if carer(s) agrees to contact from the research team
The HaH team will pass the outcomes of the processes described above to the trust research practitioner who will allocate a unique PID (see 3.1 below) and transfer the contact details of the carer(s) who have agreed to this information being shared, to the research team. The HaH team will also inform the research practitioner as to the route of referral to HaH of the patient associated with the carer, i.e. either from non-inpatient services (including community, primary care and A and E) or from inpatient services. This service information will only be retained by the research team if the carer in question subsequently participates in the study.

Step 2. Contact from the Research Team and Obtaining Consent

2.1. Contact from the research team
Carer(s) will be contacted by phone using the number(s) provided by HaH. If there is no answer, the research team will leave a voicemail **and a text message**, informing the carer that they will attempt to call again. The research team will contact carers within **1 working day (and no later than 2 working days)** of receiving their contact details.

The team will make up to **three attempts** to contact the carer. If no contact is made, the carer will be considered lost to follow-up. **All contact attempts will be logged.**

Eligibility will be confirmed during the call (see above). If eligible, the research team will provide study information, as in the PIS, and answer any questions.

If the carer does not wish to take part in the study, the reason (if provided) will be recorded against an anonymous PID number.

2.2: Invitation to participate
The first 4 carers identified each calendar month will initially be invited to take part in interviews until four interviews are completed within that month. They will also be invited to take part in the survey but will be given a choice whether they wish to do both.

All other potential carer participants will be invited to take part in the survey only.

Scheduling of surveys/interviews will be flexible to respond to participants' family, work and caring commitments. Interview participants will be able to specify gender preference for the interviewer.

All participants will be offered a £10 voucher for each survey completed or interview activity (maximum £50) to recognise their contribution and time commitment to the study.

2.3: Targeted recruitment review

Initially, potential participants for interviews will be invited randomly from the total sample of carers, to lessen any reliance on self-selection which may disadvantage some groups. **After three months**, demographic characteristics of those already interviewed will be reviewed against characteristics of all patients using the HaH services in the area, and demographics of the entire local population controlled by age group and gender, to ensure representation of underrepresented groups. If required, targeted recruitment for interviews may be undertaken from that point onwards, and carers will be informed about the purpose of any demographic questions that may be asked by the research team to support targeted recruitment.

2.4: Consent process

The method of consent process will depend on the type of participation (survey or interview) and the means by which data will be gathered.

- **Telephone survey**: The survey can be completed immediately or scheduled. If taken immediately, remote consent will be taken verbally by the researcher, recorded on a consent form as 'REMOTE CONSENT TAKEN' and signed by the researcher. If scheduled, this consent process will take place at the time of the scheduled call.
- **Online survey**: Participants will need to complete electronic consent before accessing the survey. The means for recording electronic consent will be included in a secure Qualtrics link which will be sent via text/email.
- **Postal survey**: Consent form and survey will be mailed with a stamped addressed envelope. Only carers able to consent to participation within **5 days of the start of HaH care,** can be offered a postal survey due to data collection time constraints i.e. postal delivery times.
- **Telephone/online interview**: Verbal consent will be taken by the interviewer at the point of interview and recorded on a consent form as

'REMOTE CONSENT TAKEN' and signed by the researcher and sent to participants for their records.
- **Face-to-face interview**: Written consent will be taken and signed by the carer at the point of interview.

When giving consent, participants will be told the study is entirely voluntary and they can withdraw at any time without giving a reason.

Step 3. Allocating Participant IDs (PIDs)
Every HaH first contact will be assigned a unique anonymous PID by the trust research practitioner. This will be used to manage responses, match data collection timelines, and prevent duplication. The PID list will only record details (first name and contact number) for carers with their agreement and NO patient data.

Step 4. Sending surveys and Ensuring PID Matching

4.1: Pre-filling PIDs on surveys

- **Paper**: PID will be entered manually on the survey prior to mailing.
- **Online**: PID will be embedded in the survey link (e.g., https://qualtrics.com/survey?pid=P001).
- **Telephone**: PID will be entered into surveys during the call.

Step 5. Timelines for Completing Surveys and interviews

5.1: First survey/interview
To be completed (whenever possible) within **7 days of HaH start**. Late completions will be recorded as 'AFTER 7 days'.

Note. Up to 3 attempts to prompt completion of measures will be made, with no more than two prompts within 7 days of participants agreeing to complete measures.. Prompts will be via email or SMS text message. Participants will be notified of the prompting schedule in the covering email (for the online survey link) or letter (for the hard copy of the survey).

5.2: Post-discharge survey/interview
To be completed (whenever possible) within **the 5th week after discharge**. Late completions will be recorded as 'AFTER 5 weeks'.

Note. Up to 3 attempts to prompt completion of measures will be made, with no more than two prompts within 7 days of participants agreeing to complete

measures.. Prompts will be via email or SMS text message. Participants will be notified of the prompting schedule in the covering email (for the online survey link) or letter (for the hard copy of the survey).**Step 6. Post-discharge surveys/interviews and tracking**

6.1: Linking follow-up to PID
The trust research practitioner will receive patient discharge dates from the HaH team and link these to the assigned PID for the relevant carer/participant. **Master file (containing no patient data)** will be updated and accessed by the research team who will use this information to organise follow-up survey completion and interviews.

6.2: Updating the PID tracking document
Scheduled and completed surveys and interviews will be logged in the Master file, marked green to show completion.

Step 7. Translation services

Translations will be made of the PIS into the second most frequently spoken language after English in each of the two study areas.

Translators will be offered to:

- potential participants in considering the information included in the study PIS. The HaH team will ask if an interpreter is preferred to be present when the research team contact them. If this is preferred, the HaH research practitioner will inform the research team who will organise for an interpreter to be present when the research team contacts the carer.
- carer participants who are offered to participate in interviews will be offered translators, for example, where they state they do not feel fully confident in their spoken English in an interview situation.

Where available, surveys will be offered in languages other than English.

Participants will be offered the opportunity to have the survey in English read to them by the research team. Routinely offering this will facilitate the participation of people with visual impairment or those with limited literacy, whilst avoiding asking potentially embarrassing questions regarding literacy.

Security and Confidentiality

8. Sample Size Justification

In this study, we aim to examine the relationship between carer characteristics (predictors) and a continuous outcome (e.g., mental wellbeing) using multiple regression analysis.

To achieve reliable results, we took a conservative approach, calculating the sample size to detect a medium effect size (f2 = 0.15). The effect size is measuring the proportion of explained variance relative to unexplained variance. Given 10 carer characteristics, a significance level of 2.5%, and power of 80%, a sample size of 126 patients is required. The sample size is sufficient to detect an effect of moderate strength and therefore meaningful associations between carer characteristics and outcomes. The significance level was reduced to reflect the two timepoints and therefore the two main regression models. To allow for 20% attrition we will recruit a sample of 158 carers. Calculations were conducted using the pwr package in R.

An objective of the study is to describe the physical and mental health status of carers. With this sample size, we can estimate the prevalence of poor physical and mental health, based on validated thresholds, with a margin of error of ±8%, reflecting the width of the 95% confidence intervals (CI).

Feedback from the 2 participating HaH sites indicate approximately 50-60 patients are referred to HaH per site each month. Of these 90% will have an informal carer and we expect 30% of these carers will agree to participate. Over a nine-month period of recruitment that would potentially provide a minimum sample of 243 carers indicating our target sample size is attainable.

Quantitative

The proposed sample size of 40 informal carers for qualitative interviews is based on established guidelines for qualitative research, existing literature on informal caregiving, and the need to achieve data saturation. Research indicates that data saturation typically occurs within 20–40 interviews, depending on sample diversity and research focus (Guest, Bunce, & Johnson, 2006; Hennink, Kaiser, & Marconi, 2017). For thematic analysis, a range of 30–50 participants is often recommended to ensure comprehensive exploration of experiences (Braun & Clarke, 2019), particularly in studies involving diverse populations. Given the variability in HaH carers' experiences, spanning different demographics, caregiving activities, and support needs, this sample size is designed to capture a broad spectrum of perspectives while maintaining methodological rigor.
Previous research on informal carers in home settings supports this approach, with studies typically employing 15–30 participants to explore implementation,

stakeholder perspectives, and service adaptations (Federman et al., 2022; Levine et al., 2021; Langley et al., 2022). Our study will use an element of purposive sampling to ensure diverse representation, with an interim review of participant characteristics to address any potential underrepresentation. This approach aligns with best practices in qualitative research and will provide robust, transferable insights into the role, challenges, and support needs of informal carers within the HaH model.

9. Data Collection Methods

Quantitative: Six validated questionnaires administered at two time points: in the first week of HaH care and in the fifth week post-discharge. Available methods for completion include online, paper, phone, or face-to-face.

Qualitative: Semi-structured interviews and activity logs conducted at the same two timepoints. Available methods for completion include online, face-to-face, phone. Interviews will be recorded and transcribed with participant consent.

10. Outcome Measures

Questionnaires

The study will use six validated questionnaires that allow quick and simple completion and cover a wide range of experiences and health aspects, including physical, social, psychological, and economic domains. Additionally demographic data will be collected.

Demographic data will be gathered at the point of completing baseline questionnaires (first week of receiving HaH care) and will include gender, age, ethnicity, marital status, faith, dependents, education, disability, current and past employment status, whether receiving carers allowance, context of care (living together, relationship with patient), previous contact with HaH service, and if patient's are in receipt of social care.

- CO OP-WONCA. A validated tool which measures an individual's self-perceived functional ability over the previous two weeks, providing an indication of a person's overall well-being. It examines 6 domains, with 5 choices of response for each domain, each described by text and pictorial representations.
- Carer Experience Scale (CES). A validated tool developed to assess the quality of life and well-being of individuals providing unpaid care. It focuses on capturing the multidimensional aspects of the caregiving experience. It includes six domains: activities, support, social participation, control, fulfilment, and feelings. Respondents rate their

experiences in each domain using a three-point Likert scale, with higher scores indicating more positive experiences.

- Zarit Burden Interview (ZBI). A widely used tool designed to assess the level of burden experienced by carers of individuals with conditions that require significant caregiving. The interview focuses on the emotional, physical, and social strain that caregiving can impose. The short ZBI [19] consists of 12 items rated on a 5-point Likert scale ranging from 0 (never) to 4 (nearly always). Items assess emotional health, social relationships, physical health, financial impact and sense of personal freedom. Funding for use of the scale is included project costings.
- The Client Service Receipt Inventory (CSRI). A research data collection instrument used in health economic research designs to capture information from study participants in relation to their NHS and Social Care service utilization, participant accommodation and employment circumstances, their income, any benefits they are receiving and information about support for informal carers. CSRI is a flexible tool and the most suitable questions selected for use dependent on research context. It can be used face to face, via telephone or via post. CSRI data collected over time can be used to calculate changes in resource use patterns and ultimately costs associated with an intervention.
- Warwick-Edinburgh Mental Wellbeing scale (WEMWBS). A scale that enables the monitoring of mental wellbeing in the general population A short 7-item scale will be used in the study being less time consuming for participant and which is considered as robust and valid when applied to population, community and clinical settings. The scale has been shown to be responsive to change in clinical populations including health services and community wellbeing projects.
- EQ-HWB. A standardised measure of health and wellbeing. A short 9-item version will be used in this study. The scale comes with preference-weighted value sets from the EuroQol Group to facilitate its use in the economic evaluation of health and social care interventions. Participants are asked to rate any difficulties they have experienced for a range of day-to-day activities, including their mobility and any difficulties experienced around feelings of exhaustion, loneliness, anxiety, depression, pain and control over their lives. 5 potential responses ranging from ‘none’ to ‘most or all the time.’

Carer Activity Interview (CAI) - 1st and 2nd time point

In the absence of an established gold standard tool for measuring carer activity, this interview has been developed specifically for this study informed by existing literature. This interview will methodically gather information regarding the frequency and nature of caring activities carried out by the participants in the past week. It will record the delivery of practical care, and identify the time required for carer "presence" or "awareness", aspects of the carer's role often missing from activity measures. The CAI interview will take place at two time points, one during HaH care and the second in the fifth week following discharge from HaH care. The second CAI will take place at the same as the semi-structured interview.

Semi-Structured Interview - 2nd time point

The semi-structured interview schedule for this study builds on a previous schedule developed by the research team in 2023/24 (Wood et al., manuscript under review) which has subsequently undergone significant revisions. Changes were informed by the research team's experience conducting and analysing interviews using the original schedule and by engagement with PPIE representatives.

The original interview schedule developed using HaH and carer literature, incorporated feedback from a PPI representative. It addressed key topics, including general experiences, the pros and cons of HaH, perceived safety, comparisons with inpatient care, acceptability, impacts on other services, education, respect, areas for improvement, and independence.

In the earlier study, participants raised additional issues during interviews that were not part of the original schedule but appeared important to carers. These topics were noted for future exploration and have been incorporated into the current version of the interview schedule. For example, new questions address the impact of HaH visit timing and carers' understanding of the purpose of the HaH treatment. Additionally, some issues, such as how discharge decisions from the HaH service were made, emerged as significant but were not sufficiently explored during the interviews, highlighting the need for further investigation. Feedback from PPI representatives, via CLCH NHS trust, has been sought after the initial study and which recommended clarifying the wording of specific questions, and this has been addressed in the revised schedule.

11. Data Management

Data will be stored securely on encrypted university systems, anonymised and handled in accordance with GDPR. Only authorised researchers will have access. A Data Management Plan has been developed for the study.

Data analysis

12. Statistical Analysis Plan

Descriptive statistics for outcomes; regression analysis to explore predictors of carer wellbeing. Multiple regression using generalised linear models. Missing data will be handled via imputation. Extrapolation of costs and outcomes to the long-term horizon. Sensitivity analyses will be conducted to assess the impact of uncertainties on outcomes.

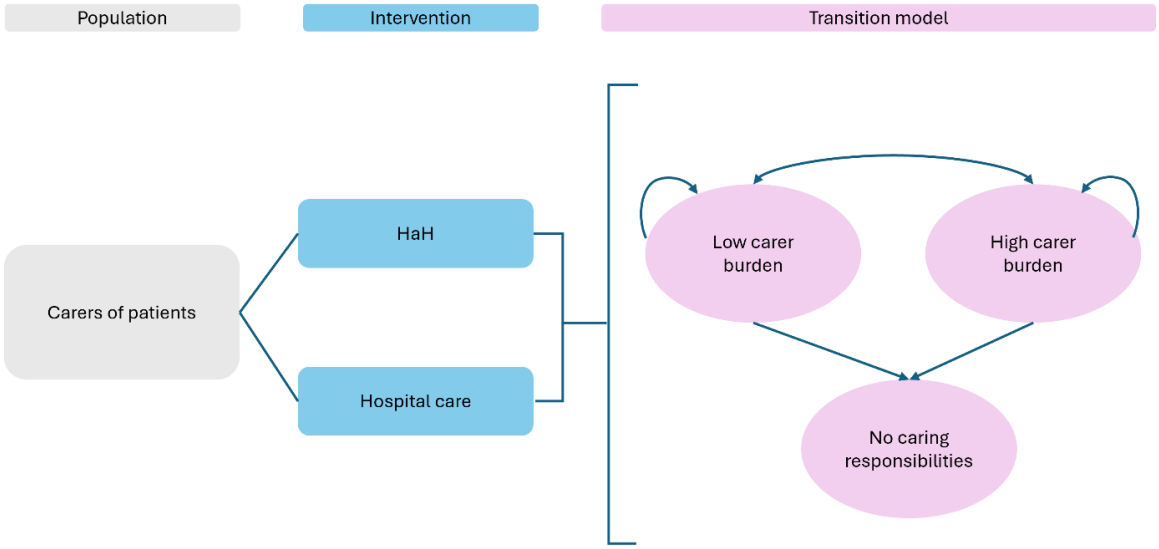
13. Qualitative Data Analysis

Thematic analysis using an essentialist, inductive approach. An inductive, essentialist approach to thematic analysis will be applied to the interview transcripts. Two researchers will independently code the first transcript from each carer and discuss these to identify preliminary themes. This will both inform an iterative process of data-collection to allow further exploration of topics raised in subsequent interviews in line with MRC key recommendations and make sure themes are closely grounded in the data. Subsequent analysis steps and interpretation will be discussed as a team to achieve a robust analysis.

14. Economic Evaluation/analysis

EQ-HWB scores sourced from the quantitative survey will be converted to utility values using a UK value set. HaH will be compared to hospital care in a state transition model, where outcomes will be extrapolated to the long-term using established extrapolation methods and validated by consulting published literature. The hospital care comparator arm will be constructed using statistical techniques and published literature. Utility values will be combined with CSRI cost data to calculate average carer costs and estimate cost-effectiveness compared to hospital care. Costs will include healthcare resource use, productivity costs, and costs of providing HaH services.

A schematic for the economic model is shown below. Outcomes of the model will include total costs, quality of life, clinical outcomes, and an incremental cost-effectiveness ratio (ICER) over the 1 year, 5 year, and lifetime horizon.



15. Triangulation

Qualitative findings will be triangulated with quantitative data collected through questionnaires to enhance the depth and validity of the overall analysis. This will involve comparing and integrating themes identified in interviews with patterns observed in the survey responses to identify areas of convergence, divergence, and complementarity. Triangulation will help contextualise the quantitative findings, provide richer insight into carers' experiences, and support a more comprehensive understanding of the research questions.

14a. Data Management

Maintaining participant confidentiality
Participant data will be stored securely in a password-protected or encrypted system. The PID will be the only link between a participant's identity and their data. Personal identifiers will be stored separately from survey data. All completed survey (including demographic) data collected in this study will be identified by a unique pseudonymised study identification code. All electronic data will be password protected and accessible only by delegated members of the research team during the active phase of the study and until the data have been analysed. Hard copies of paper surveys and consent forms will be stored in a locked cabinet, in a locked office, within LSBU/CLCH.

Hard copies of surveys, completed by carers, will be sent (using a SAE) to the NHS partner site, scanned and sent via secure NHS email to a Project Team member with NHS email access. They will save it in Teams in a password-

protected file. The NHS site will store hard copies securely as per NHS data storage guidelines.

Data privacy
All data will be handled in accordance with GDPR and LSBU and NHS data protection standards (see study Data Management Plan).

The sponsor data protection Officer is:

Caroline Law

Head of Information Governance and Data Protection Officer

Central London Community Healthcare NHS Trust

E-mail: caroline.law3@nhs.net or clchig@nhs.net

Tel: 020 8102 5297

Mobile: 07506 937 257

15. Ethical and Regulatory Considerations

Ethical approval will be sought from a UK REC, HRA and LSBU. Confidentiality, informed consent, and risk minimisation will be prioritised. Interpreters and accessible formats will be available.

The study will not commence until all relevant regulatory approvals (HRA/LSBU ethics), Confirmation of Capacity and Capability from the applicable participating site and Sponsor Green Light are in place. Before any site can enrol participants into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

The study will be conducted in accordance the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines. It will be conducted in compliance with the protocol, the General Data Protection Regulation (GDPR), the Data Protection Act 2018 and other regulatory requirements as appropriate.

Protocol Compliance

In the event of a protocol deviation or breach, this will be documented on the relevant sponsor governance form and reported to the Chief Investigator and Sponsor immediately.

16. Public and Patient Involvement Group (PPIG)

A PPIG will be established, chaired by the PPI co-applicant. They will offer ongoing guidance and structured support at all stages. They will meet at key points in the study to provide input and feedback:

- **Before the study begins**: To review the latest versions of study tools and procedures, and to agree priorities for future involvement.
- **Midway through the study** (approximately six months into data collection): To reflect on progress, raise any emerging issues, and provide advice on the direction of the study.
- **After data collection ends**: To review and help interpret the findings, and to ensure that outputs are understandable, relevant, and accessible to carers, patients, and the wider public.

PPIG meetings will be minuted and a summary shared with the Study Steering Committee.

17. Dissemination, Outputs, and Anticipated Impact

The results of this study will be actively communicated to academic, policy, practice, and public audiences with the aim of influencing practice and policy at both local and national levels. The Carer and Clinical Lead co-applicants will play a visible role in dissemination activities, alongside the wider research team. Planned dissemination routes include:

Academic Audiences:

- Publication in peer-reviewed journals such as *BMJ Open*, *BMC Health Services Research*, and the *Journal of Health Services Research & Policy*.
- Presentations at national and international academic conferences, including the Royal College of Nursing (RCN) International Research Conference, with a focus on engaging healthcare researchers and professionals.

Policy Stakeholders:

- Reports and presentations for NHS Hospital at Home (HaH) policy leads, including engagement with NHS Virtual Wards Programme Groups and Integrated Care System (ICS) leads.

Healthcare Practice:

- Articles in professional publications to support clinical implementation, such as *Nursing Times*, *Community Practitioner*, and the *British Journal of Community Nursing*.
- Workshops for NHS Trust staff, clinical managers, and partner organisations to facilitate real-world application of findings.
- Targeted dissemination to carer organisations and health charities, including Carers UK and The Patients Association.

Public and Participant Engagement:

- A co-produced, plain English summary of findings will be developed with the Carer co-applicant and PPI contributors and shared study participants who opt in to receive.
- Outreach activities, including summaries and knowledge-sharing events, will ensure the findings are accessible to patients, carers, and the wider public.

Anticipated Outputs and Impact

This study will generate a range of outputs with the potential for meaningful and lasting impact on carers, patients, service providers, and the broader healthcare system. Key contributions include:

Improving understanding of carer experiences in HaH settings
The study will explore the lived experiences of informal carers supporting patients in Hospital at Home services. Insights will inform practical recommendations to improve service acceptability and reduce stress for carers. By identifying factors contributing to carer burden, the findings aim to enhance resilience, reduce burnout, and support continuity of care. Improved carer well-being can lead to better patient outcomes and more sustainable HaH services.

Clarifying the nature and scope of carer activities
Understanding the range of tasks that informal carers undertake will help services better recognise and support the skills and resources carers bring. This knowledge will inform targeted training and support strategies and may also reveal gaps—highlighting where carers could take on additional roles with appropriate preparation and support.

Informing future research and policy
By exploring carers' health, well-being, and quality of life during and after HaH care, the study will build an evidence base that can inform future research and

policy development. It will provide insight into the longer-term implications of caring, including the risk of carer burnout and the potential for reducing hospital readmissions. These findings will help shape policies that better support carers during acute episodes and future patient deterioration.

Supporting the development of targeted interventions

The study will lay the groundwork for the design and testing of a future intervention aimed at supporting carers within the HaH model.

Given existing evidence, the study team expects that the results of this study will support the need for further research designed to better support informal carers of patients receiving HaH care and improve carer and patient outcomes. The anticipated research process will be to develop, deliver and test an intervention, by:

i. Engaging with carers, clinicians/providers and patients using nominal group techniques to:

a. Review the study's findings.

b. Prioritize areas for intervention.

c. Propose specific interventions, both general (for all carers) and individualised (for carers with defined characteristics).

ii. Developing a manualised intervention program, based on the identified priorities.

iii. Piloting the intervention program within an HaH service to:

a. Assess its acceptability and feasibility among carers, patients, and providers, ensuring inclusivity of underrepresented groups.

b. Evaluate the appropriateness of outcome measures.

c. Refine the interventions and outcome measures based on pilot feedback.

iv. Conducting a comparative study to evaluate outcomes in services implementing the refined interventions versus those in services providing standard care. Primary and secondary outcomes will focus on carer, patient and service use measures.

This research will play a crucial role in improving the quality and effectiveness of HaH services.

18. Estimated Study Timeline and Milestones

- Months -3 to 0: Approvals, staff recruitment, materials finalisation
- Months 1–14: Participant recruitment and data collection
- Months 9–16: Analysis
- Months 14–18: Reporting and dissemination

The research project will follow a structured timeline to ensure timely completion of milestones and deliverables. In the pre-study phase (months -3 to -1), permissions, ethics approvals, and protocol finalization will be completed. Recruitment of the Research Fellow will also occur during this time, alongside the setup of NHS processes.

In months 1 and 2, study setup activities will continue, including liaison with NHS services and staff training. Patient and Public Involvement and Engagement (PPIE) activities will also begin during this period.

Participant identification and recruitment will span months 2 to 13, during which baseline survey and baseline carer activity interviews will be conducted. Semi-structured interviews and carer activity interviews will take place in months 3 to 14, alongside the re-administration of survey.

The qualitative analysis phase will run concurrently with the qualitative interviewing to allow for an iterative approach. Quantitative analyses will take place at months 14-16, to allow sufficient time to process data and interpret findings.

Finally, months 14 to 18 will focus on synthesizing results into reports, publications, and presentations. Dissemination of findings will also commence during this period, ensuring that insights are shared with key stakeholders and inform future practice.

Months from commencing research study	**-3**	**-2**	**-1**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Complete permissions/ ethics/protocol finalisation																					
Recruitment of Research Fellow																					
Study set up – NHS																					
NHS Service liaison/training																					
Patient Public Involvement & Engagement																					

Participant identification & recruitment																					
Baseline questionnaires																					
Baseline Carer Activity Interview																					
Semi Structured interviews & Time 2 Carer Activity Interview																					
Time 2 questionnaires																					
Analysis - qualitative																					
Analysis - quantitative																					
Write up reports, publications, presentations																					
Commence dissemination of findings																					

19. Project Management and Oversight

Led by Prof. Brimblecombe. Project managed by Dr. Wood. PPI activities led by Nas Harrison.

Study Management Group (SMG)

The day-to-day management of the study is the responsibility of the Chief Investigator (CI). The SMG will meet weekly to assist with this function, attended by co-investigators and collaborators, representatives of the sponsor/participating NHS Trust, and others by invitation.

Study Steering Committee (SSC)

The Steering Committee will provide overall supervision for the project on behalf of the study's Sponsor and Funder and ensure that it is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care and the

Guidelines for Good Clinical Practice. The SSC comprise of an independent chair, 3 other independent expert members from an academic/clinical/PPI background. The SSC terms of reference and roles are in line with NIHR policy:

- To meet at least three times within the 18-month study period, with a minimum of three independent members (including the chair) present at each meeting.
- To provide advice, through its Chair, to the study's funder, sponsor, Chief Investigator, host institution, and contractor
- To concentrate on the study's progress, adherence to the protocol, and patient safety (where appropriate), and to consider new information of relevance to the research question
- To uphold the rights, safety and well-being of the participants
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the study

SSC meetings will be organised by the CI on behalf of the chair. SSC meetings will be minuted and disseminated to all attendees, the study sponsor and NIHR.

20. Risks and Mitigation Strategies

- Recruitment shortfalls: two sites, flexible methods
- Attrition: voucher incentives and adaptable formats
- Language barriers: translation and interpreter support

21. Success Criteria

- Target recruitment achieved
- High retention and data completeness
- Practical, co-produced recommendations disseminated to stakeholders

22. Insurance and Indemnity

The study is sponsored by Central London Community Healthcare NHS Trust and the NHS Indemnity scheme will cover the study's management, design and conduct.

23. Data Monitoring and Audits

Internal monitoring via host organisation; external audits if required by the funder. The study will be monitored in accordance with the sponsor's research governance procedures and the requirements of the UK Policy Framework for Health and Social Care Research. The study may be subject to audits or monitoring visits by the sponsor or the NIHR as funder, to ensure that it is being conducted in accordance with Good Clinical Practice (GCP), ethical approvals, and regulatory requirements.

24. Amendments

Substantial amendments will be submitted to NHS REC, LSBU ethics and sponsor for approval after agreement from the SSC. Non-substantial changes logged internally. The Chief investigator will ensure any amendment to the study is agreed with the sponsor will submit information to the appropriate regulatory body for them to issue approval for the amendment. The HRA UK Amendment process will be followed utilising the amendment submission tool (as updated from time to time).

Participating sites will be responsible for reviewing study amendments in line with the relevant amendment categorisation.

25. End of Study Definition and Reporting

The study ends after final data collection and analysis. End of study notification and final report will be submitted to the REC and HRA within 12 months.

26. Archiving

All essential documents will be retained for 5 years after study closure in accordance with NHS sponsor and LSBU policy.

27. Funding

Total cost: £202,479. This study is funded by the NIHR through its Research for Patient Benefit Programme (RfPB).

28. Conflicts of Interest

None declared by any member of the research team.