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Evaluating the organisation, delivery and impact of person-centred ‘neighbourhood-based, integrated health and care’ models of home care: a multi-method study

The Home Care Study

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This protocol has regard for the HRA guidance.

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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Co-Leads agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements.

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

I also confirm that I will make the findings of the study 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; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

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

Name (please print): ....

Position: ....

Co-Leads:

Signature: .... EM Graham ……….................... Date: 18/09/2025

Name (please print): ……..Liz Graham ....

Signature: .... Date: 18/09/2025

Name (please print): ……...Karen Spilsbury ....

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2. Abbreviations

ASSIA	Applied Social Sciences Index and Abstracts
BSL	British Sign Language
CINAHL	Cumulated Index in Nursing and Allied Health Literature
EMBASE	Excerpta Medica dataBASE
HMIC	Healthcare Management Information Consortium database
HRA	Health Research Authority
HSDR	Health and Social Care Delivery Research
ID	Identification
IMD	Index of Multiple Deprivation
NCF	National Care Forum
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PPIE	Patient and Public Involvement and Engagement
PRISMA ScR	Preferred Reporting Items for Systematic reviews and Meta-Analyse - for Scoping Reviews
REC	Research Ethics Committee
SMG	Study Management Group
SOP	Standard Operating Procedure
SSG	Study Steering Group

3. Study Summary

Study Title	Evaluating the organisation, delivery and impact of person-centred, neighbourhood-based, integrated health and care models of home care: a multi-method study
Short Title	The Home Care Study
Research Aim	This study aims to: a) explore and describe current provision of integrated models of home care across the UK, b) evaluate the delivery of these new models of home care through in-depth case studies, c) make recommendations for future implementation and evaluation of integrated models of home care.
Study Design	Underpinned by national stakeholder engagement and consultation, this is a multi-method study using participatory and case-study approaches with 3 phases: 1) An evidence synthesis of literature on integrated models of home care, supplemented with descriptions of innovative models of home care. 2) Case studies in two diverse areas to explore integrated home care models' core components and impact. 3) Consultation with stakeholder and methodologist panels to establish the feasibility and acceptability of wider implementation of these models, and development of a methodological framework for future evaluation.
Study Participants	We will recruit a) commissioners and regulators, b) providers, c) home care staff and d) those in receipt of home care and their family members to join our four stakeholder panels. We will recruit academic experts to join our methodologists' panel. For our case studies (phase 2) we will recruit approximately 80 participants (commissioners, providers, home care staff, care users, family members) to take part in interviews.
Planned size of sample	Stakeholder panels: up to 55 participants across the four panels. Methodologist panel: approximately 10 members. Case studies (phase 2): approximately 80 participants across two sites.
Follow-up duration	N/A
Planned Study Period	30 months
Research question / aims	<u>Research questions</u> • What do person-centred 'neighbourhood-based, integrated health and care' models of home care look like, nationally? • How do they work in practice? • How can we optimise practice? • How can they be implemented and evaluated in future?

4. Roles and Responsibilities

4.1 Study Sponsor and Funder

The Sponsor (University of Leeds) is the organisation that takes responsibility for arrangements to initiate, manage, monitor and finance the study. The Sponsor will ensure responsibility and accountability for study conduct and procedures associated with the protocol.

The funder (NIHR) provides sole funding for this project. The funder will not have a direct role in study design, conduct, data analysis, interpretation and manuscript writing, but will require annual reports on study progress in line with plans outlined in the application for funding.

4.2 Individuals' roles and responsibilities

Team member	Role in project
Liz Graham	Project Co-Lead. PPIE oversight. Leading phases 1 and 3, and academic lead for stakeholder panels (staff and public)
Karen Spilsbury	Project Co-Lead. PPIE oversight. Leading phase 2 and academic lead for stakeholder panels (commissioners and providers)
Karen Bloor	Chair methodologists' panel. Support dissemination activity (policy perspective).
Theresa Bradley-Comstive	Co-chair staff stakeholder panel.
Sarah Brownlow	Support case study 1.
Pam Essler	Support Kate Smyth in the running of the PPI group. Promote study engagement via voluntary and community groups.
Barbara Hanratty	Advice on routine data use in home care. Primary care expertise.
Liz Jones	Co-chair public stakeholder panel. Support recruitment to commissioner, provider and public panels. Support dissemination activity.
Natalie King	Development of literature searches for phase 1.
Gretl McHugh	Methodological advice and researcher supervision.
Paul Phillips	Chair providers' stakeholder panel.
Cath Roff	Chair commissioners' stakeholder panel. Support recruitment to commissioner and provider panels. Support case study 1.
Carla Smith	Support case study 2.
Kate Smyth	Chair study-specific PPI group. Co-chair public stakeholder panel. Support recruitment to public panel.
Jacqui Turner	Support recruitment to commissioner and provider panels. Support case study 2.

Finn Turner-Berry	Co-chair staff stakeholder panel. Support methodologist panel. Support recruitment to commissioner, provider and public panels. Support dissemination activity.
Research Fellow 1 / Project Manager	Await appointment
Research Fellow 2	Await appointment

4.3 Study Oversight

Study Management Group

The Study Management Group (SMG) will comprise the co-leads and co-researchers detailed above. The group will meet once every two months (or more frequently, if required) to plan and implement the project; and to review project progress and protocol compliance (see section 15.4).

Study Steering Group

The Study Steering Group (SSG), including independent methodological and subject area experts will provide support and guidance. An independent Chair will be appointed, and the group will provide overall supervision of the study to ensure it is conducted in accordance with the HRA approved version of this protocol. The SSG will meet once at the start of the project and at regular intervals (approximately six-monthly) thereafter, as agreed by the SSG at their first meeting, for the duration of the project, unless further meetings are called by the Co-Leads when additional advice is required. Members of the SMG (a sub-set, as relevant to meeting content) will attend SSG meetings to present and report study progress and compliance.

The role of the SSG members will be made explicit in a ‘terms of reference’ document which will be agreed and signed by all members at the first meeting of this group.

Patient and Public Involvement and Engagement

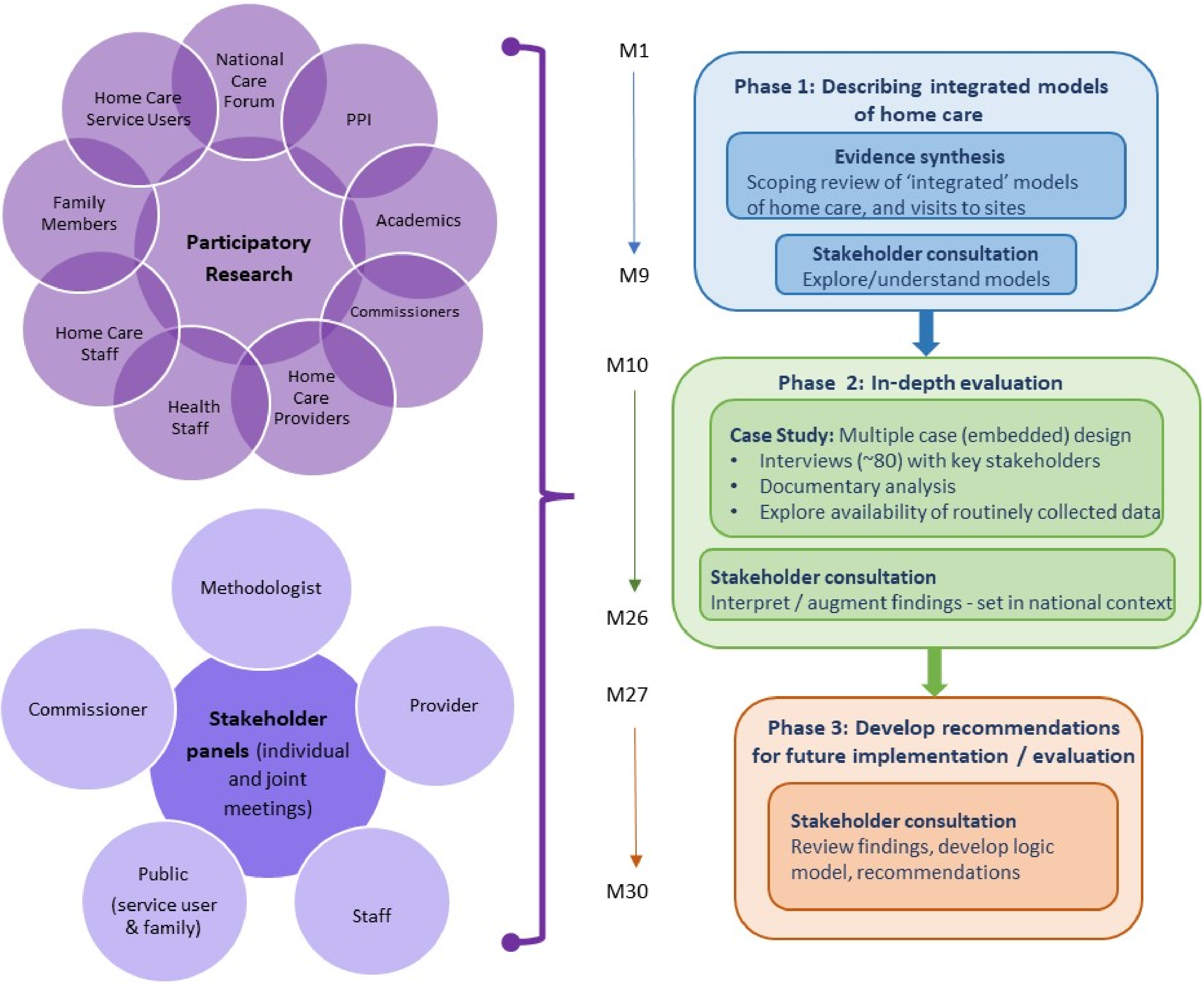
The project leads (LG, KSp), PPIE members of the team (KSm, PE), and National Care Forum co-researchers (LJ, FT-B) will work together to consolidate PPIE group membership and processes, arranging regular meetings, as well as other forms of contact for consultation - e.g. telephone calls, attendance at community groups. Responsibility for PPIE work will be shared across these applicants. PPIE group work will feed into SMG discussions, and vice versa.

PPIE group members will be recruited from existing care user panels (e.g. within Leeds’ NIHR School for Social Care Research), from diverse groups that advocate for people with long-term conditions, and those receiving home care. We will consult with our PPIE group regularly to discuss the project plan, and to obtain their opinions on and suggestions for information materials, methods of approaching participants and conducting stakeholder groups, interview topic guides and interpretation of findings (not an exhaustive list).

We will also consult with community groups in diverse settings across our region, attending a wide variety of groups to obtain their views on key aspects of the project, and to inform our recruitment and engagement approaches.

Further information about our PPIE approach and how we will ensure inclusion, and diversity of representation is laid out in a PPIE Plan, agreed by the SMG.

5. Study Overview Diagram



6. Background

The number of people with complex health conditions requiring local authority funded home care is rising,[1] with many requiring health as well as personal care at home. At the same time staffing and financial pressures are affecting quality of and access to care.[2] There are policy [1, 3, 4] and population [5] drivers to integrate health and social care and support services to better meet people's needs, to enable them to remain independent and in their own homes, and to increase efficiencies. There is considerable evidence that having more 'joined up care' and improving home-based services is seen as a priority by the general population.[6, 7]

To date, a significant proportion of home care staff have zero-hours contracts, and are paid, as commissioned, according to 'time and task' (for time spent with care users only, not for extended travel or down time between visits) [8] and have been limited to providing personal care only. People often have multiple disconnected visits from different teams of health staff and care staff which can be disruptive to their daily routine, inefficient and unsatisfactory. It is also well-known amongst home care stakeholders that strict time-based approaches can limit the quality of care provided.[9] Commissioners and providers also recognise the limitations of current approaches, such as market instability and a lack of focus on longer-term outcomes.[10] Poor pay and conditions for staff has a significant impact on continuity of care workers, with a staff turnover rate of 30.6% in 2022/23.[8]

New models of commissioning and delivery of home care are emerging in the UK to address these issues.[11] These models present a welcome paradigm shift: from offering home care and health care separately to the provision of place-based, person-centred, holistic care. The aim is to provide integrated health, social care and community support to care users, putting their needs first, promoting continuity of care (reducing unnecessary duplication), and enhancing neighbourhood connection. Some models also include new approaches to staff training and contracting (moving away from zero-hours contracts) which have the potential to improve workforce satisfaction, autonomy, stability and quality. However, innovation in the provision of home care occurs at a local level, dependent on culture, leadership and funding; there is no consistency across regions, nor national attempts to scale up approaches that work well.[10] A new policy and regulatory approach is required to support this objective. Commissioners and providers report that there is little formal evidence to draw upon to support model development (an observation borne out by the literature[12]). In addition, there is varied implementation by local authorities of provider contracts, service offer, staff contracting, and the way in which models are described. As a result, there are likely unwarranted variations in service provision, staff pay/reward and experience for care users. There are challenges when new models are introduced, e.g. optimisation of implementation, clinical governance/accountability when some elements of health care are delivered by home care staff, and staff recognition/reward for additional responsibilities.[13] It is important to explore the most efficient way to deliver a neighbourhood-based integrated model (hereon referred to as an 'integrated' model) in order to retain critical elements that benefit and improve outcomes for care users, whilst maintaining affordability.

In developing new service models, commissioners have considered case scenarios in which holistic care improves outcomes for care users - for example, a person living with Alzheimer's and diabetes would currently be visited by care workers and a district nurse, but within the new model it will be possible for carers to support insulin administration (with appropriate training, assessment of competence, oversight from a registered clinician and reward for the extra responsibility) to minimise disruption to the individual and provide greater efficiency. A key component of new models of care is a drive to be more place-based which will benefit a) care users through care workers' accumulated knowledge of available local support (to which care users can be signposted), and b) care workers themselves through reduced transport burden and associated time and cost (so also reducing the carbon footprint of providing home care).

New models are in their infancy, being designed and piloted in a number of areas across the UK, some supported by an evidence-based implementation approach.[14] However, research evidence is lacking, so detailed exploration to support future implementation, scalability and evaluation is required.

7. Project Rationale

Evidence explaining why the research is needed now

Review of the literature
At the time of grant submission (May 2024), a search of published evidence was undertaken using a focused version of the draft strategy that will be used for Phase 1 of this study. Co-applicants also provided detailed service specifications and local reports of pilot work to inform our understanding of emerging models of home care.

We found that evaluation of newer approaches is limited; we identified no large-scale evaluation findings directly relevant to our research proposal. A review of innovation in UK independent home care services concluded that “research has focussed on the positive effects of innovation, neglecting to define the concept or explore its complexities”[15]; and that an understanding of “the organisational practices and processes through which innovation is generated, achieved and sustained is largely missing.”[15] Work is needed to understand the organisation of interprofessional collaboration and analyse its effectiveness.[16] There is some reporting of small-scale studies [17] or local initiatives to foster place-based support,[18] but no larger scale evaluation of commissioned integrated models.

Innovation in the development and piloting of new home care approaches is progressing at pace in the UK with implementation and pilot work undertaken or ongoing in Bradford, Leeds, East Ayrshire and Gwynedd [14]; new models are also being piloted by Sheffield and Northumberland commissioning teams. The commissioners, providers, national care groups, and members of the public we spoke to whilst developing this project had much *anecdotal* evidence that these new models are well-received by staff and clients. Qualitative evaluation of the first phase of the pilot work to develop the ‘community health and wellbeing service’ in Leeds [19] found that staff had greater flexibility and autonomy to make decisions about client care, which in turn saved time as decisions did not have to be escalated elsewhere; staff also felt more supported and respected in their roles, and were able to get to know their clients better. Individual care user case studies [19] suggested cost savings for those supported during the pilot, through consistency of care team and adaptation of care provision to care user needs (which sometimes meant fewer hours were required due to more focussed and appropriate provision of support). Other similar pilots (e.g. for adults in Gwynedd, Wales [14]) have been positively received by home care staff who report feeling empowered. Providers report improvements in client experience - for example, a carer empowered to make the decision to adjust their visit times to provide personal care to fit with the client’s needs and wishes, rather than an inflexible schedule; and reductions in staff turnover (one provider involved in the Leeds pilot [19] began to pay staff for their whole shift rather than ‘time and task’ and observed a reduction in turnover from ~30% to 18%).

Consultation
During development of this project we consulted with commissioners, providers, and the public who told us that integrated models of care should improve the quality of care and experiences of care users - ‘telling their story once’ - and encourage personalised, place-

based care which is efficient and less disruptive to their daily routine, enhancing their quality of life. This approach also aligns with the policy direction of DHSC in nurturing place-based plans for service integration.[4]

Commissioners/providers told us that the current ‘time and task’ model is not satisfactory for staff: greater recognition, trust, autonomy, training and pay for home care work is needed, and new models would support these requirements. They described the importance of outcomes-based commissioning, paying staff for their whole shift (not by-the-minute), looking at the importance of social connection as well as practical support for care users, delegated healthcare activities, staff autonomy and better role satisfaction - all of which would contribute to attracting people to work in the sector, increase staff retention, and thereby care user satisfaction.

Provision of joined-up care closer to home to enable and sustain independence is a key policy of the NHS / DHSC,[7, 21] further endorsed by the government’s proposed 10 year health plan which includes as two of its strategic areas the shift from treatment to prevention, and from hospital to community care. In piloting integrated models, local authorities are aligning with this policy, and there is an appetite for long-term investment in this approach to improve experience and efficiency within a climate of considerable financial constraint.[8, 22] Commissioners anticipate that integrated models of home care have potential “to make better use of what we have” by improving outcomes for care users and staff within the same budgetary constraints. New models are proceeding at pace - e.g. Sheffield have recently launched their Care and Wellbeing Service for home care which, similarly, includes neighbourhood networking, signposting to community assets and having ‘small footprint’ providers to establish closer carer-care user relationships. Models are in development in Bradford, Leeds, East Ayrshire and Gwynedd,[14] whilst other local authorities across the UK are exploring this approach. There are some guiding principles [23] to support development of integrated care provision, but there are regional differences in how it is defined and implemented. There is no comprehensive understanding of these models at a national level and no existing methodological framework to support evaluation at scale..

This research will undertake essential work to provide an overarching understanding of the similarities and differences in approaches to providing integrated home care, at a time when this approach is in its infancy but gaining national traction. We will evaluate integrated home care provision, providing a much-needed ‘language’ to describe the components of care and support delivered across regions, and identify key components that contribute to the success of such models. It will also identify outcomes and costs of importance to all stakeholders, and how these are, or could be, measured, contributing to standardisation of practice, and the development of a methodological framework. Such a framework does not exist, limiting research and service evaluation. Our findings will inform commissioning of integrated models of home care and provide the foundations for future evaluation.

8. Research Question / Aims

The overall **aim** is to evaluate the organisation, delivery and impact of person-centred, neighbourhood-based, integrated health and care models (integrated models) of home care from multiple perspectives to inform future implementation and evaluation.

Throughout our study we will consult with stakeholders to enhance the national value of our work.

Definition of ‘integrated models of home care’

For this study, ‘integrated home care’ is defined as a person-centred, neighbourhood-based contracted model to promote the seamless provision of care to people at home, and to meet their needs (personal care and health care) as these change. This model is either jointly commissioned between a local authority and an NHS body, or is commissioned on a neighbourhood footprint with the intention of collaborative working between the local authority, NHS bodies and care providers. As individual funding arrangements change (for example a shift to continuing health care funding), the individual continues to be supported by the same contracted provider organisation, with staff upskilled to meet individual needs.

Key components of this model therefore include one or more of:

- Co-ordinated delivery between social care and health to minimise disruption for people receiving services and to reduce inefficiency in service delivery
- increased health prevention activities provided by social care to reduce future demand on health
- holistic care delivered to meet individual needs as these change, and to improve individual outcomes
- care staff training and development provided to upskill staff to meet individual needs
- employment contract methods to pay per shift (rather than by task) to enhance workforce satisfaction and stability.

These integrated home care models therefore aim to promote continuity of care, reduce unnecessary duplication, and strengthen neighbourhood connections, ultimately improving the quality of life for care users and quality of work for staff, whilst maintaining affordability.

We consider it important to define the remit of this study, recognising the diversity of home care provision and funding arrangements; however, the exploratory nature of our study means we will seek to refine this definition through our work.

8.1 Objectives

Project objectives are to:

1. *Explore and describe* the current provision of ‘integrated models of home care’ - to generate a cohesive understanding of current approaches across the UK, and to develop a common language (or taxonomy) describing these new models.
2. *Evaluate* the delivery of these new models of home care through in-depth case studies of model components and functioning associated with outcomes of importance for people using, delivering, providing and commissioning integrated models of home care; including perceived benefits, disadvantages and unintended consequences of integrated models.
3. *Plan* for the future: to make recommendations for future implementation and evaluation of integrated home care models.

8.2 Outcomes

Our outputs will include:

- A comprehensive description of new models of home care provided across the UK - providing a taxonomy to support national understanding of the components of integrated models of home care.
- Identification of factors that may explain how, when and why integrated home care models work. Our study design will ensure that findings are generalisable, and that conclusions drawn have UK-wide applicability.
- Illustrated ‘personas’ to concisely demonstrate the impact of new models of home care on different ‘types’ of care users (i.e. those with different needs and support systems). These personas can provide powerful visualisations of the impact of particular approaches to care.

- Identification of outcomes of importance to each stakeholder group, describing convergent and divergent priorities.
- A logic model to describe the key ingredients of the successful elements of integrated models of home care and outcomes of importance, to inform commissioning and delivery.
- Recommendations (based on our logic model) for national commissioning of integrated home care - we will have identified drivers of efficiency and barriers to implementation (from our case study work and our national stakeholder consultation) which will inform changes in the way home care is specified and commissioned.
- A methodological framework (including opportunities and challenges) for large scale evaluation, including outcomes-based and cost effectiveness studies of home care.
- Establishment of enduring stakeholder partnerships to inform and guide future work.

9. Design and Theoretical Framework

This is a multi-method study using participatory and case study approaches, across three phases to gain depth (service level) and breadth (national level) of understanding about integrated health and social care and support models of home care, and to establish a framework for future evaluation. A multi-method design [24] enables varied research approaches and findings to be triangulated. The participatory approach [25] will facilitate our collaborative endeavour with key stakeholders (commissioners, providers, care staff, care users/families) who have direct involvement with integrated models of home care. The case study approach [26] will allow an in-depth exploration and evaluation of how integrated home care is organised and delivered, and the impact it has on care users, family members, home care staff, and the health and social care system. The case studies (described in Phase 2), augmented by national stakeholder consultation, provide opportunities to develop new knowledge and understanding of national relevance.

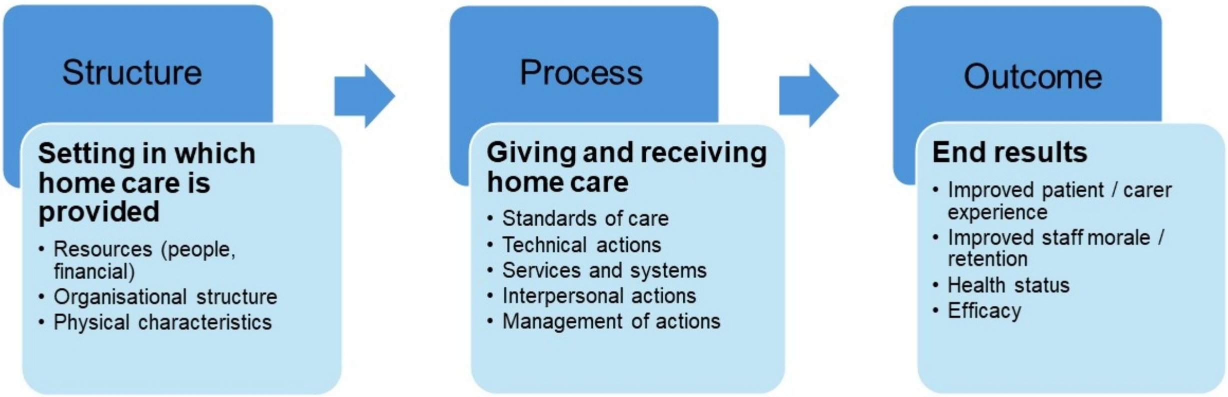
The study is underpinned by our participatory approach, with UK-wide stakeholder consultation taking place throughout the study (Phases 1 to 3). Stakeholder panels will comprise commissioners/regulators, providers, home care staff, members of the public, and methodologists.

The study has three phases:

1) Phase 1: Evidence synthesis, including visits to sites implementing new models of integrated home care to understand and describe the national landscape.
2) Phase 2: Case studies for in-depth evaluation of integrated home care models' core components and impact (how, when and why they work) and unintended consequences
3) Phase 3: Develop recommendations on a) the feasibility and acceptability of wider implementation of these models, and b) a methodological framework for future evaluation.

We will use Donabedian's approach to quality [27] as our organising framework: considering during each phase how organisational structures (such as the commissioning, funding and provision of home care) influence processes (including activities/actions undertaken by care staff) and affect outcomes (e.g. care user experience or staff satisfaction). Figure 1 below illustrates Donabedian's model for quality of care and our focus on the key domains within home care. Whilst represented linearly, we recognise that the three domains can influence and interact with each other and that other factors (e.g. socio-demographic and political) can be important precursors to evaluating quality care. Our approach enables us to address this in our study.

Figure 1: Donabedian's Quality of Care Model within a home care context



10. Stakeholder Engagement (Phases 1-3)

From study commencement we will engage relevant stakeholders (commissioners and regulators, providers, care staff, care users and their families) to establish partnerships that we plan to sustain throughout the study period in the form of stakeholder panels. Embedding our engagement activity from the outset is important to ensure stakeholders: inform our scoping review, support identification of innovative integrated home care models nationally, help us to contextualise the findings of the review, guide our planning for data collection, support us to make sense of and elaborate our case study findings, and consider pathways to (and how best to maximise opportunities for) impact and knowledge mobilisation. We acknowledge difference across the four nations and will seek representation on the stakeholder panels so that a more nuanced understanding will be developed through this work.

We will establish four stakeholder panels - (i) commissioners and regulators, (ii) providers, (iii) home care staff, and (iv) public (care users/families) - each chaired by a member of our team with the relevant expertise and credibility. We will establish separate stakeholder panels, rather than one panel with diverse stakeholder representation, to enable people to have a voice within their area of expertise and interest. This will ensure equality of engagement by people in each stakeholder panel and promote environments that provide opportunity for expression of views and experiences. Separate stakeholder panel meetings will enable more in-depth and focussed discussion on specific elements of integrated home care relevant to each panel. As shown in Table 1 (below) the focus of each panel varies by stakeholder group; however, we plan to invite representatives from each panel to meet later in the study once trust and confidence are established between stakeholders and the research team. These mixed group discussions will help facilitate interpretation of emerging findings from varied stakeholder perspectives.

As each phase is completed, we will share our findings with our stakeholder panels, conducting consultation events to challenge our assumptions, reasoning and thinking.

Table 1: Stakeholder panels - areas of focus and membership

Stakeholder panel	Areas of focus	Included members
Commissioner panel	• Identification of existing integrated models of home care, nationally • Background to development and funding • Commissioning of home care services • Component parts of each regional model • Changes in the commissioning of these models since inception • Diversity and inclusion policies and processes which inform equity of access • Costs across localities • Challenges to commissioning of services • Measures of satisfaction/success (system, provider, staff, care user) • Review of emerging findings from evidence synthesis and case studies to provide national context and insight	12 commissioners (social care and community health) and regulators of home care (we will include at least one member from Wales, Scotland and Northern Ireland) *Chaired by co-applicant Cath Roff (Leeds City Council)*
Provider panel	• Identification of existing integrated models of home care, nationally • Provision of home care services, including assessment process • Changes in provision of these models since inception • Component parts of each regional model • Types and frequency of provision • Diversity and inclusion policies and processes which inform equity of access • Costs of provision • Case mix • Challenges to providing home care within localities. • Staff recruitment/retention • Measures of satisfaction/success (system, provider, staff, care user) • Review of emerging findings from evidence synthesis and case studies to provide national context and insight	12 providers of home care, including community health staff involved in integrated models (we will include members from Wales, Scotland, and Northern Ireland) *Chaired by co-applicant Paul Phillips (Springfield Healthcare Group Ltd)*
Staff panel	• Identification of existing integrated models of home care, nationally • Delivering and supporting home care services • Challenges to delivery of services • Staff satisfaction and morale • Existing measures of satisfaction/success (staff, care user) Review of emerging findings from evidence synthesis and case studies to provide national context and insight	12 staff who deliver/support home care (including community health staff, as appropriate, and representation from the four nations) *Co-chaired by co-applicants: Finn Turner-Berry (National Care Forum) & Teresa Bradley-Comstive (Springfield Healthcare)*
Public panel (care users & family)	• Identification of existing integrated models of home care, nationally • Referral, assessment and delivery of home care • Challenges and benefits to receiving care at home • Changes to provision over time • Care user and family satisfaction • Measures of satisfaction	Up to 15 people receiving care at home, including family members who support someone receiving care at home *Co-chaired by co-applicants: Liz Jones (National Care Forum) & Kate Smyth (PPIE)*

	• Review of emerging findings from evidence synthesis and case studies to provide national context and insight	

10.1 Setting

Each panel will meet on five occasions, virtually where possible, with discussions recorded; however, we will be mindful of maximising inclusion, offering members the option to meet in person, or to be consulted by telephone.

10.2 Sample and Recruitment

10.2.1 Eligibility

Those involved in 'integrated models' of home care in the UK (see definition provided in Section 8, page 15) are eligible to take part in the Stakeholder Panels.

a) Commissioners Panel

Inclusion criteria
- Involved in the commissioning (social care or health) or regulation of a new integrated model of home care in the UK

Exclusion criteria
- Will be included in a Phase 2 case study as a participant

b) Providers Panel

Inclusion criteria
- Part of a Provider organisation (social care or community health) that is involved in the provision of a new integrated model of home care in the UK

Exclusion criteria
- Will be included in a Phase 2 case study as a participant

c) Home Care Staff Panel

Inclusion criteria
- Involved in delivering home care to care users (including community health, where appropriate) as part of a new integrated model of home care in the UK

Exclusion criteria
- Will be included in a Phase 2 case study as a participant

d) Public Panel

Inclusion criteria
- Receiving home care that is part of a new integrated model of home care in the UK, OR
- Is a family member of a person receiving home care that is part of a new integrated model of home care in the UK
- Aged 18 years or over

Exclusion criteria
- Lacks capacity to consent*
- Will be included in a Phase 2 case study as a participant

* it would be difficult for those without capacity to engage in panel discussions; however, a family member with capacity could choose to join the public panel to represent their views and experiences,

10.2.2 Sampling technique

Sampling will be opportunistic but extensive in its reach: panel members will be identified via a wide range of national networks and groups known to our co-applicants and collaborators. We will ensure that the organisations we work with to support recruitment enable the sampling and selection of a diverse population, including under-served populations.

Sampling will be purposive in nature to ensure a) representation from the four devolved nations (at least one member from Wales, Scotland, and Northern Ireland on each panel) and b) diversity.

10.2.3 Sample size

Commissioner, provider and staff panels will each comprise approximately 12 members; whilst the public panel (care users and family members) will comprise up to 15 people.

10.2.4 Identification and recruitment

We will identify panel members through existing networks and care groups (e.g. Care Providers Alliance, Home Care Association, Skills for Care), organisations that represent care workers (e.g. the Care Workers Charity, National Association of Care and Support Workers, Home Care Workers Group), Local Authorities and Health and Care Partnerships across the UK. In addition, we will work with the IMPACT team at the University of Birmingham [14] - who have supported the implementation of new models of home care in Leeds, Gwynedd and East Ayrshire - to identify a range of stakeholders with experience of different models.

The above networks, care groups and organisations will be provided with a study flyer advertising the opportunity to become a panel member and describing briefly what it would involve. We will ask them to use this flyer (‘as is’ or using the content in their newsletters / communications) to inform their members or individuals about the study. It will signpost interested individuals to email or telephone the research team to find out more and to obtain an information sheet (i.e. the relevant stakeholder group participant information sheet).

Recruitment of commissioner and provider panel members

Commissioner (CR, JT), NHS (CS, SB) and National Care Forum (LJ, FT-B) members of our research team will be responsible for the identification and engagement of ‘commissioner’ and ‘provider’ panel members.

Recruitment of staff panel members

The opportunity to join the staff stakeholder panel will be advertised to home care workers via engaged provider organisations, and via organisations and groups that represent care workers (e.g. Care Workers Charity, National Association of Care and Support Workers, Home Care Workers Group). This dual approach to staff recruitment allows for the involvement of those whose provider organisations are supportive of research involvement, as well as those without provider organisation engagement in the research or who would prefer to take part as an individual voice rather than that of their employer.

Where we ask organisations to advertise directly the opportunity to their staff, and we will obtain appropriate managerial approvals to do so.

Recruitment of public panel members

The opportunity to join the public (care users and family) stakeholder panel will be advertised via national provider organisations, who will act as brokers for the research team, introducing the concept of the research early (ahead of required recruitment timelines) to facilitate trust and engagement. It will also be advertised via the Care Provider Alliance (to providers and the people they support), Think Local Act Personal and Learning Disability England, as well as other appropriate organisations that represent a diverse range of care users (e.g. younger people with a learning disability, older people living with dementia). NCF members of our team have well-established links with many of these organisations, and our PPIE team members have diverse and active links with charitable and voluntary sector organisations regionally and nationally. These members of the research team will support engagement of our public members.

The study-specific Research Fellow will support those members of the team outlined above as having responsibility for participant identification and engagement.

10.2.5 Consent

Those responding to the advertised opportunity to join a stakeholder panel will discuss what involvement would entail with a member of the research team (they will be signposted to contact a study researcher). Those who are eligible and remain interested will be provided with a study information sheet (specific to each group), which will include a summary of the study plan and the expectations of stakeholder panel members to enable them to make an informed decision about their involvement. There will be opportunities for interested parties to discuss involvement further with the research team once they have read the information sheet. We will ask those who remain interested to briefly tell us (verbally or in writing) why they would be suitable for the role, to enable the research team to make an informed decision about their eligibility and ability to meaningfully contribute to panel discussions. We will make it clear that we may not be able to include everyone if we have many volunteers.

The Research Fellow will be responsible for ensuring written informed consent is received from all panel members prior to the first panel meetings. Consent forms will include a prompt to identify any conflicts of interest and contact details to enable future contact (with preference for contact method specified by the participant). Signed consent forms may be posted or emailed to the researcher. Signed and scanned, or typed signatures on emailed consent forms will be accepted.

10.3 Data collection

At the initial meeting, we will explain the study’s purpose and scope, gather evidence on panel members’ views of integrated home care models, and gain insight into integrated home care approaches from their diverse perspectives. This will enable members to introduce themselves and learn about each other’s experience of integrated home care. It will support the identification of grey literature and reports for our evidence synthesis, as well as the identification of sites implementing integrated models of home care (where reports might not yet be available) that we will seek to visit to develop an understanding of integrated home care models. Panels will meet again at the end of phase one: at this meeting we will present findings of our evidence synthesis and visits to innovative sites (see Phase 1 below). We will seek to clarify with them the specific details of identified integrated models, as well as obtain new information about regional models not described by our Phase 1 work. In later meetings, they will be integral to shaping our approach to and interpreting findings from our case studies. Further details about our four panels and the areas of focus for their meetings are provided in Table 1 (above).

10.4 Data Management and Analysis

Data will be managed in accordance with the study's Data Management Plan agreed by the research team, and with the Sponsor and Information Governance team at the University of Leeds.

We will audio record each stakeholder panel meeting and transcribe them verbatim. Transcription will be undertaken either by the study researcher, or by an external transcription service approved and contracted by the University of Leeds. The accuracy of these transcriptions will be checked (and amended where necessary) by a researcher. In the written transcripts, participants will be given pseudonyms and any identifiable information will be removed. All audio files and transcripts will be stored in a secure location at the University of Leeds, where access will be restricted to the researchers undertaking the data collection and analysis. Audio files will be retained in their secure location until analysis of transcripts is complete; they will then be securely deleted. Original audio files held in Microsoft Teams or on a Dictaphone will be deleted as soon as they have been saved in the secure location.

See also Section 16.5: "data protection and participant confidentiality".

We will undertake content analysis[28]: coding and organising data from the literature and from our stakeholder panel discussions to identify model components, processes and structures within and across local authorities to produce a taxonomy [29] of integrated home care models, and identify similarities and differences between models.

11. Methodologist Engagement (Phases 1-3)

In addition to the stakeholder panels, we will establish a panel of methodologists with diverse expertise. Methodologists will provide independent expert advice based upon emergent findings from all phases of the study, which will direct data collection and analytic decisions to maximise the opportunities offered, so optimally informing processes for current and future evaluation.

It is not possible at this stage to undertake robust outcomes-based studies of home care, nor a cost-benefit or cost-effectiveness study. However, through our work we will determine whether more granular data is available, what is needed for any future studies, the feasibility of organisations being able to generate or collect improved costing data required for any future evaluation studies, and the processes required to share these data for this purpose. It is these exploratory areas that will be presented to and discussed with our expert panel to support the direction of our work.

11.1 Setting

The panel, chaired by a policy-focused economist with extensive experience of interdisciplinary and mixed-methods research (KB), will meet three times during the study, virtually where possible, with discussions recorded; however, as for the stakeholder panels, we will be mindful of maximising inclusion, offering members the option to meet in person or to be consulted by telephone.

11.2 Sample and recruitment

11.2.1 Eligibility

We will invite to participate in the panel, methodologists who have:

- expertise representing areas such as labour economics, human resource management, modelling, trials, qualitative approaches, and implementation science, and
- expertise in evaluations of home care.

11.2.2 Identification and recruitment

The research team will identify and recruit up to 10 members with diverse methodological expertise, ensuring geographical and institutional variation of members.

The IMPACT team at the University of Birmingham (the UK centre for IMProving Adult Care Together) - who have worked closely with commissioning teams across the UK to implement new ways of delivering integrated home care - will support our work and will be represented on our panel; they will also support the identification of suitable panel members.

Potential members will be provided with a short information sheet summarising the study and the expectations of their role in the study. REC approval is not required for this work as methodologists (academic members of staff) will be recruited by virtue of their professional role to provide their expert views and advice (i.e. no personal information will be requested). We will establish an agreement with members of this group and our intention to publish an output focusing on opportunities and challenges for research on home care.

11.3 Data collection

We will consult the methodologist panel for their views on data and processes to be explored during phase 2 case studies based on findings from phase 1. We will consult them again towards the end of phase 2 to review preliminary findings and inform analysis, and finally during phase 3 for their expert input to study recommendations and a future methodological framework.

11.4 Data Management and analysis

We will audio record each meeting, narratively summarising panel members' opinions and decisions to support the undertaking of later work and transparency of reporting.

12. Phase 1 - Evidence Synthesis

12.1 Scoping review of the literature

A scoping review of the literature will be undertaken to identify evidence describing or evaluating integrated models of home care for adults in the UK, with the aim of identifying and describing the characteristics (similarities and differences) of UK integrated models, and producing a working definition (or definitions) of 'integrated home care' in this context. The goal of a scoping review is to determine and summarise the range of available evidence,[30] so providing an overview of existing reports.

The scoping review will provide:

- Systematic identification of 'integrated models of home care' across the UK.
- A comprehensive understanding of the variety of existing approaches to providing integrated models of home care in the UK.
- Rich descriptions of models of home care to be able to specify their format, content and delivery approaches.
- Findings to inform our interview schedules and data collection requirements for phase 2 (case studies).

12.1.1 Search strategy

We will work with an information specialist, local authority and NHS colleagues to identify appropriate literature published in the most recent 5-year period to capture recent models. Published literature will be sought from health and social care databases including Medline, PsycInfo, EMBASE, CINAHL, Web of Science, Scopus, Sociological Abstracts, ASSIA and HMIC. Grey literature will be an important source of information, identified in

Gov.uk and local government websites, Care Quality Commission, King's Fund, Google, Google Scholar, and conference abstracts; and importantly identified via consultation with our research team and stakeholder panel members who will be aware of new models of home care in development but that are not necessarily widely reported or readily available in the public domain.

Searches will be developed by our Information Specialist and peer reviewed. Search terms will be included which cover the concepts: ‘Home care’, ‘Models’ of service delivery, limited to ‘Adults’, the ‘UK’ and published ‘from 2020’ onwards. Example search terms include: homecare, domiciliary care, home carers, social care, and models, services, organisation, integration, councils, local authorities, long-term care. Further relevant studies will be sought from reference lists of included studies, contacting experts and forward citation searches (if appropriate).

12.1.2 Review strategy and strategy for reviewing the literature

Search results will be reviewed in accordance with Joanna Briggs Institute evidence synthesis guidance specific to scoping reviews.[31] All records will be independently screened by two members of the research team, using software such as Rayyan. Any disagreements will be resolved by a third reviewer. A data extraction form will be designed to support structured review of eligible full text articles and reports, including all grey literature. This form will record study / report characteristics (e.g. author, year, geographical location) and key information about the identified integrated home care models - e.g. component parts the model - what and how it is delivered, commissioning model, provider(s), costs, service location, reach, population, any findings relating to effectiveness or acceptability. Extracted data will be tabulated and narratively summarised to describe the variation and similarities between services, providing an initial framework to present for stakeholder consultation. Methods and findings will be reported to PRISMA ScR standards.[32]

The review protocol will be published on Open Science Framework (https://osf.io).

12.2 ‘Fact-finding’ visits to sites

New models of integrated home care are in their infancy, so we expect published evaluations or descriptive reports to be limited. We will thus augment our literature review with fact-finding visits to a diverse selection of (up to five) sites implementing new models of home care. These visits will support rapid assessment of the components and functioning of other innovative models to augment our understanding (from the literature) of the national landscape of integrated models of home care. They will provide national context for our case study sites (phase 2) and provide valuable insights to inform our methods for recruitment and data collection in our subsequent phase 2 work.

12.2.1 Site identification

Members of the research team are already aware of several sites involved in innovative new approaches to the provision of home care (e.g. Gwynedd, Tameside, Wigan, Islington, Sheffield, Northumberland), and other sites may be identified during the grey literature search and via consultation with our stakeholder panels. We will approach a selection (up to five) of sites to represent diversity of population, geographical location, home care model type and length of time in operation.

12.2.2 Recruitment

Members of the research team will identify and engage local authority commissioning team members and home care providers from the selected sites, and invite them to have a short discussion with a researcher. A study information sheet will be provided to explain the purpose of the research and what their involvement would entail, and verbal agreement will be obtained and documented by the researcher. We will obtain appropriate management approvals to ensure transparency and organisation-level agreement to their contribution to our research. REC approval is not required for this work as staff will be recruited by virtue of their professional role to provide only information about the service their organisation offers (i.e. no personal information will be requested).

12.2.3 Data collection

Site visits will be undertaken by study researchers. We expect to need one in-person visit to each site, augmented by further remote contact as required. We will structure our discussions around the following topics (similar to those that will be explored in much greater depth during our phase 2 case studies):

Structure: Setting in which home care is provided

- Resources (people, human resources, financial)
- Organisational structure
- Physical characteristics
- Benefits and disadvantages of integrated home care.

Process: Giving and receiving home care

- Standards of care
- What services/care are being provided and received (technical, support, medical)
- How the service/care is organised/managed
- How the service is being delivered/received
- Perceived benefits/disadvantages
- Challenges of providing, delivering and receiving home care.

Outcomes of importance: End results

- Views on care user/carer experiences and satisfaction
- Views on staff perceptions of working in integrated home care, and their morale / retention.
- Unintended consequences (positive and negative)

12.2.4 Data management and analysis

Discussions will be audio-recorded, and narratively summarised by a member of the research team.

These summaries of innovative models will be used to locate the in-depth case studies (Phase 2) within the national landscape. Understanding gained from these visits and from the literature of the variety of models and their component parts will provide a framework for discussion with stakeholders.

13. Phase 2: Case Studies

13.1 Design

We will undertake an in-depth exploration of integrated models of home care, using case study methodology. Case studies provide insights into complex ‘real world’ developments that emerge through day-to-day practices [26, 33] and generate depth of explanation using theory.[34, 35] They are appropriate for researching issues of social action and will provide detailed insights into how commissioning and provision influence the integrated model of home care delivery and the experiences of care users.[34, 36] A key characteristic of case study design is using a number of data sources that can be triangulated to provide a holistic understanding of integrated home care.

A multiple (two) case (embedded) design [34] will be used to enable theoretical replication. Each case study consists of a ‘whole’ study and will generate insights into the development and impact of integrated models of home care located within physical, social, temporal, organisational and economic contexts. The case study sites have been selected to enable exploration and evaluation to understand and explain similarities and differences both within and across each case study. We will use theory to support analytic generalisation from our case studies.[34]

13.2 Setting

Each ‘case’ will be a commissioning group introducing a new integrated home care model which is either jointly commissioned between a local authority and an NHS body, or is commissioned by the local authority on a neighbourhood footprint with the intention of collaborative working between the local authority, NHS bodies and care providers. We will thus work across several settings: 1) community-based - people’s homes (to engage those receiving home care) and other community locations (to engage health and care staff, and providers) and 2) local authority - to engage commissioners of integrated home care.

13.3 Selection of case study sites

Our two case study sites have been selected to ensure variation in models of integrated home care provision and population, so enabling comparisons to be drawn.[37] Our case studies represent diverse regions including rural and urban, affluent and deprived areas.

13.4 Participant selection and recruitment

13.4.1 Care users and family members/friends

Care user eligibility

Care users will be included if they:

- are aged 18+,
- are receiving home care that is part of a new model of integrated home care in one of our case study sites,
- have capacity to consent or, if they lack capacity,[38] have a personal consultee who is available and willing to agree to their involvement, and is willing to support their participation in the form of dyad-based interviews

Care users will be excluded if they:

- lack capacity to consent, and do not have a personal consultee who is available and willing to agree to their involvement, or
- are a member of the public stakeholder panel for this project

Care users without family members will not be excluded if they are able to consent for themselves, or if a personal consultee (e.g. a relative or friend) can be identified to support their participation where they lack capacity.

Family member/friend eligibility

Family members or friends will be included if they:

- are aged 18+,
- have a relative / friend receiving a new model of integrated home care in one of our case study sites,

- have regular contact with and provide support to their relative / friend (i.e. understand their needs and care received), and
- have capacity to consent to their own involvement (and to agree to the involvement of their family member who is receiving home care, if necessary)

Family members or friends will be excluded if they:
- do not have capacity to consent to their own involvement, or
- are a member of the public stakeholder panel for this project

Sampling
Our sampling strategy will facilitate inclusion of people who represent diverse backgrounds and those with protected characteristics. Purposive sampling [39] will ensure inclusion of participants with a range of personal characteristics such as ethnicity, gender, age (including younger people with a disability and older people living with a disability / frailty / multi-morbidity), relationship to care user (e.g. spouse or child) and geographical location (including rural and urban, and a range of Index of Multiple Deprivation (IMD) [40] scores from least to most deprived). We will target neighbourhoods of high socioeconomic deprivation (20% most deprived).

Recruitment
Prior to approaching individuals to take part we will engage with providers and diverse community groups (via our PPIE team members), providing introductory information (e.g. flyers, a study summary, personal attendance at groups to discuss the study) to introduce the research concept with the aim of facilitating trust and engagement.

Thereafter we will work closely with providers of integrated home care to identify potential care user participants and facilitate recruitment. We will obtain appropriate management approvals to ensure transparency and organisation-level agreement to their contribution to our research. We will ask them to identify eligible clients and target the sending of REC-approved study information sheets to them - targeted in accordance with our sampling approach to ensure diversity. Information sheets will be sent directly to those assessed by the provider as having capacity, or to a family member where there are concerns regarding a care user's mental capacity. Different information sheets will be available for a) care users with capacity, and b) family members who are taking on the role of personal consultee and also participating in the research. We will also produce a short easy-read information sheet that may be suitable for participants lacking capacity, so that they have information to support decision making with their consultee.

When recruiting care users with capacity, we will ask whether there is a family member or friend whom we could also (or instead, if they don't wish to participate) approach to take part. Care users may find it helpful to have a family member or friend present to support them during the interview. Preferences for individual or dyad interviews will be guided by participants. There will be a further information sheet available for family members/friends who wish to consider participating in the research (where taking on a personal consultee role is not required). This information sheet will be given to care users to pass on to their relative/friend.

To address barriers to participation, we will ensure our recruitment materials and approaches are accessible by working with the PPIE members of our research team and PPIE groups, the National Care Forum, and our public stakeholder panel. Easy read, large print, video and audio materials will all be considered; as will engagement with interpreters (language and BSL).

Information sheets will invite care users / family members to contact the researcher to discuss participation if they are interested, and before deciding whether they wish to take part. Those who are willing to take part after such discussions will be asked by the researcher to provide written informed consent (or consultee agreement, where appropriate) prior to undertaking any research procedures. Signed consent forms may be provided in person, posted or emailed to the researcher. Signed and scanned, or typed signatures on emailed consent forms will be accepted. This will be the case for all participant groups described hereafter.

The researcher will always make it clear that potential participants can have more time to decide if they wish, contacting them around a week later to discuss further.

13.4.2 Commissioners and providers of home care

Commissioner eligibility

Commissioners will be included if they are:

- actively involved in the commissioning and implementation of new models of home care in our case study sites, and

Commissioners will be excluded if they are:

- a member of the commissioner stakeholder panel for this project, or
- a member of the research team for this project

Provider eligibility

Individuals from home care provider organisations will be included if:

- their organisation holds a provider contract to deliver new models of home care in our case study sites,
- they are directly involved in the service organisation and planning the delivery of this model of home care

Individuals from home care provider organisations will be excluded if they are:

- a member of the provider stakeholder panel for this project, or
- a member of the research team for this project.

Sampling and recruitment

We will aim to interview commissioners from our two case study sites, and a representative from all the providers of integrated home care: we anticipate there will be approximately eight to nine providers across the two sites. We will obtain appropriate management approvals from commissioner and provider organisations to ensure transparency and organisation-level agreement to their contribution to our research.

Members of our research team who work in commissioning and provider roles will facilitate recruitment by endorsing research credibility and introducing the research team. We will write to the providers (expect N=8-9) in our two case study sites, inviting one representative of each to take part.

Potential participants will be provided with a role-specific study information sheet and those interested in taking part will have the opportunity to discuss study participation with a researcher before deciding whether to take part. Thereafter the researcher will ask them to provide written informed consent prior to undertaking any research procedures.

13.4.3 Home Care Staff

Eligibility

Home care staff will be included if:

- their employing organisation holds a provider contract to deliver new models of integrated home care in our case study sites, and
- they are directly involved in the delivery to care users of this model of home care

Home care staff will be excluded if:

- they are a member of a stakeholder panel for this project.

Sampling and recruitment

Our purposive sampling strategy will facilitate inclusion of staff participants across a range of home care providers, and with a range of personal characteristics including: ethnicity, gender, age, and level of experience (time in role / home care). If a model of home care involves NHS community health care staff, then we will also consider recruitment of these staff members to enhance our understanding of the approach to home care delivery. NHS staff would be asked to participate in an interview in their own time.

The research team will work closely with home care providers within our case study sites to encourage engagement with the research. We will obtain appropriate management approvals to ensure transparency and organisation-level agreement to their contribution to our research. We will ask them to promote the study within their organisations to facilitate staff recruitment. We will provide a flyer or summary information to enable this approach. We will also present the research at their local meetings to inform them about the study and arrange study-specific meetings to optimise engagement and ensure participant (provider and staff) diversity.

We will ask providers to distribute staff-specific information sheets to potential participants (including any NHS community health care colleagues, as mentioned above), or the research team will hand these out in person if they meet staff at research-focussed meetings. There will be opportunity for staff to discuss study participation with a researcher before deciding whether they wish to take part. They will be given time to consider their involvement, with the researcher contacting them around a week later to discuss further if they so wish. Those who are willing to take part will be asked by the researcher to provide written informed consent prior to undertaking any research procedures.

13.4.4 Overall sample size

Up to 80 interviews (approximately 40 per case study site) will be conducted with the stakeholders described above: care users (N~25) and their family members/friends (N~20), commissioners (N~4), providers of home care (N~8-9), staff providing home care (N~20-25).

13.5 Data collection methods

There will be two main approaches to data collection:

1) collection of documentary evidence, and
2) interviews with key stakeholders.

13.5.1 Documentary evidence

The collection of documents from each case study site will be undertaken by researchers. We expect to collect anonymised data in the form of specifications, reports or summaries, not individual participant data. These will include (subject to availability by case study):

- service delivery model(s), service specification and populations,
- role descriptors - of staff involved in delivering home care,
- routinely collected audit, survey, satisfaction, outcome data (available reports/summaries),

- available cost data - reports detailing the average unit cost for home care per care user in the two case studies,
- care user outcomes reports - determining the availability and quality of data collected by involved services to measure quality of life, well-being, independence, empowerment, safety, social connections, and continuity and quality of care,
- relevant staff outcomes data (e.g. absence from work, retention, well-being) and comparing with data from the adult social care workforce dataset (*https://www.skillsforcare.org.uk/Adult-Social-Care-Workforce-Data/Adult-Social-Care-Workforce-Data-Set/Adult-Social-Care-Workforce-Data-Set.aspx*) to contextualise case study data.

Documents relevant to each case study will be examined in detail to understand the structure (e.g. how integrated home care is organised); processes (e.g. data about the receipt and provision of integrated home care - what the offer 'looks like' and how it varies); and outcomes data available for integrated home care (e.g. staff retention figures, care user engagement and satisfaction).

We will explore and summarise the availability of routinely collected data to inform our understanding of measures available for future outcome and cost-effectiveness evaluation. We will work closely with the methodologist panel to help guide this work, identifying what more is needed for future studies, and then exploring the feasibility of organisations (including commissioners) being able to (i) generate or collect improved outcome data and (ii) processes required to share these data for any future evaluation studies.

13.5.2 Interviews with stakeholders

Interviews with stakeholders (see section 13.4) will be undertaken to understand core components ('active ingredients') of these models, resources required, perceived benefits, challenges and unintended consequences. Topic guides will be developed and structured around Donabedian's quality of care model.[27] A separate topic guide will be developed for each stakeholder group. Broad areas of questioning will include:

Structure: Setting in which home care is provided
- Resources (people, human resources, financial)
- Organisational structure
- Physical characteristics
- Benefits and disadvantages of integrated home care.

Process: Giving and receiving home care
- Standards of care
- What services/care are being provided and received (technical, support, medical), including those provided as part of the home care package and those provided separately.
- How the service/care is organised/managed
- How the service is being delivered/received
- Perceived benefits/disadvantages
- Challenges of providing, delivering and receiving home care.

Outcomes of importance: End results
- Views on care user/carer experiences
- Care user/family satisfaction
- Unintended consequences (positive and negative)
- Staff views and perceptions of working in integrated home care
- Views on staff morale/retention.

We will collect minimal data on personal characteristics to describe our study population and to aid interpretation of data. This will include, for example, ethnicity, gender, age, partial or converted (e.g. to LSOA or IMD decile) postcode.

Interviews will be conducted by a researcher to ensure neutrality and a confidential forum in which to explore the new models of home care. The interviews will be either face-to-face, by telephone or using video-call, depending on the preference of the participants, in order to optimise involvement. Care users will be given the opportunity to have a supporter or family member present to support their interview if this would put them at ease, or where they may struggle with one-to-one discussions (e.g. due to speech or hearing difficulties). Home care staff will be offered the opportunity for an individual or group interview. This will be determined by personal preferences of staff who consent to participate. Translators will also be available to support interviews with those whose first language is not English. The interviews will be recorded using either an encrypted digital recording device or the secure recording feature on the video conferencing tool.

13.6 Data management

Data will be managed in accordance with the study's Data Management Plan agreed by the research team, and with the Sponsor and Information Governance team at the University of Leeds.

Interview audio recordings will be transcribed for analysis by an external transcription service approved and contracted by the University of Leeds. The accuracy of the transcriptions will be checked by a researcher. In the written transcripts, participants will be given pseudonyms and any identifiable information will be removed.

All audio files and transcripts will be stored in a secure location at the University of Leeds, where access will be restricted to the researchers undertaking the data collection and analysis. Audio files will be retained in their secure location until analysis of transcripts is complete; they will then be securely deleted. Original audio files made in Microsoft Teams or on a Dictaphone will be deleted as soon as they have been saved in the secure location.

Documentary data will be stored in a similarly secure manner on University of Leeds servers, accessible only to the research team.

See also Section 16.5: “data protection and participant confidentiality”.

13.7 Data analysis

We will use parallel mixed data analysis. Interview and documentary data will be thematically analysed:[41] data familiarisation, followed by open coding of each transcript and document to describe units of meaning. Units of meaning will be compared and contrasted to produce thematic categories. Where data has been generated through group discussion, we will also analyse process to determine similarities or differences by participant. This will provide analytical depth. To enhance rigour, data will be coded by two experienced qualitative researchers. The findings from each case study will be compared to determine convergent findings (regardless of context) and divergent issues (dependent on context). The case studies will have more than one unit of analysis because of the multiple levels of analysis - commissioners, providers, home care staff, care users and family - and the use of more than one method: embedded units of analysis.

We will develop propositions to enable a cross-case synthesis to compare findings between our case studies. By way of example, such propositions may include:

- What actions have been put in place to improve care user outcomes?

- For successful delivery of integrated home care, what processes need to be in place?

Routine measures of social care outcomes and costs are currently underdeveloped; however, we may be able to summarise some outcomes collected routinely by individual providers - e.g. regarding user satisfaction, onward referrals - but we do not expect to be able to analyse these types of data due to heterogeneity across the sector. We will describe available sources and their future potential, highlighting information gaps and primary data collection needs for any future outcome and cost-effectiveness evaluation. Our study will seek to advance understanding for future research.

14. Phase 3: Develop recommendations for future implementation and evaluation

14.1 Stakeholder consultation

Our final phase of stakeholder consultation work, with our existing panels, will support planning for future implementation and evaluation.

We will host two in-person consultations (each lasting up to two hours), with up to 3 people from each of our stakeholder panels. The timing and locations (hosted in geographically accessible locations for our panel members) will be planned in advance to increase inclusivity and to enhance attendance. The consultations will promote wide engagement and participation by stakeholders from across the four nations and from our different stakeholder groups (as suggested by PPI when designing the study). The consultations will be co-designed with PPI members. They will include a sense-check of the findings, and exploration to aid their interpretation and locate our research in the wider context of policy and practice.

Building on the consultations, we will develop a logic model to visually present the key ‘ingredients’ for integrated home care models, structured to reflect our theoretical framework [27]. This will enable our findings to be used to support future implementation of integrated models, and to support the wider evaluation of home care models.

14.2 Methodologist consultation

Our multidisciplinary panel of methodologists will meet for a final time to identify future research challenges and opportunities, and consider appropriate study designs, theoretical frameworks and methodological approaches, providing a platform for future research. We anticipate designing a general mixed methods framework which could evaluate the wider rollout of integrated health and care models. We will determine how existing data sources can best be used, how these sources could be refined and improved to aid their use for evaluative research, and what primary data collection will be required, as well as an appropriate quasi-experimental design and areas for future in-depth qualitative exploration.

15. Definition of End of the Study

The end of the study is defined as the date of the final phase 3 stakeholder or methodologist consultation meeting (whichever occurs at the latest time point).

16. Ethical and Regulatory Considerations

16.1 Assessment and management of risk

<u>Researcher safety and support</u>

Researchers undertaking home visits to conduct interviews with participants will consult University of Leeds lone working policy guidelines to ensure they work safely.

Researchers may witness upsetting events or circumstances, or participants may disclose information which is upsetting - this could cause distress for the researcher. To support researchers, the following will be made available to them:
a) Regular check-ins: researchers will be instructed to have regular check-ins with one another and the wider team to discuss any concerns.
b) Debriefs: following data collection, researchers will attend regular debriefs with the co-leads (LG/KS) to discuss, reflect and get advice.
c) Promotion of resources: researchers will be made aware of the University of Leeds' resources e.g. staff counselling.

Safeguarding
There is the possibility that safeguarding issues may be identified by researchers. Consent will be obtained from participants on the understanding that all information will be kept confidential unless the researcher witnesses or receives information that cause them to be concerned for a participant's or other person's safety. Our researchers will be aware of and trained in safeguarding. They will understand relevant Local Authority safeguarding policies and definitions of harm, abuse and neglect, as well as their own responsibilities within reporting guidance and procedures.

If the researcher witnesses something which they feel presents a potential or actual harm to the participant or others, or if a participant discloses information which the researcher feels has, or may result in harm, the researcher will encourage the participant to raise this with a relevant professional or seek their consent to raise it on their behalf. If the researcher feels that the participant is at risk, then the researcher will disclose the issue without consent but in the interests of the participant. Details will be discussed with one or both of the co-leads and other appropriate members of the SMG. All details discussed will be kept strictly confidential. The co-leads will then agree a strategy to minimise harm whilst maintaining privacy. This strategy is likely to involve discussing the anonymised details of the disclosure with a local health / care professional and / or reporting the concern to the local authority safeguarding hub.

16.2 Research Ethics Committee (REC) and other regulatory review & reports

Before the start of the study, Health Research Authority (HRA) approval will be sought, including a favourable opinion from an NHS REC for the study protocol, participant information documents, informed consent forms and other relevant documents.

- Substantial amendments that require review by HRA / NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement the changes.
- All correspondence with the HRA / REC will be retained.
- The chief investigator will be responsible for the production of reports, as required.
- The chief investigator will notify the HRA / REC / Sponsor of the end of the study.
- If the study is ended prematurely, the chief investigator will notify the HRA / 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 describing study findings, including any publications/abstracts, to the REC.

16.2.1 Regulatory Review & Compliance

- Before commencing participant activities, the chief investigator or designee will ensure that appropriate approvals from participating organisations are in place, where required.
- The Sponsor will arrange for the conduct of face-to-face interviews and stakeholder meetings at the Sponsor location (University of Leeds) or off-site in participants' homes or community venues, as appropriate.
- For any amendment to the study, the chief investigator or designee, in agreement with the Sponsor will submit information to the appropriate body, in order that they may issue approval for the amendment. The chief investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

16.2.2 Amendments

Should substantial amendments to the REC application or the supporting documents be required during the conduct of the research, the sponsor will submit a valid notice of amendment to the HRA for consideration. The study team will discuss required amendments with the sponsor: the sponsor will be responsible for deciding whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Approved amendments to the protocol or other documentation will be communicated to participating sites by the study team, as appropriate. Amendments that do not affect NHS, Local Authority or community partners will be managed and implemented directly by the study team.

Strict version control will be maintained, identifying finalised documents by a whole number - 1.0, 2.0, etc. - and date. A record of amendment history and each version of study documents will be held in electronic study master files on cloud servers at the University of Leeds; these will be made available for any audit of our research to regulatory authorities.

16.3 Peer review

This study was peer reviewed as part of the grant application process. Independent experts reviewed the study as part of the NIHR peer review process.

16.4 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

Accidental protocol deviations can happen at any time. Deviations from procedures outlined in this protocol will be documented and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable and will require immediate action; they could potentially be classified as a serious breach.

The study team will monitor protocol deviations at each study management group meeting, escalating any issues of concern to the study steering group, and subsequently the sponsor, if required.

All deviations and suspected serious breaches of the protocol will need to be reported to the sponsor within one working day to governance-ethics@leeds.ac.uk, and serious breaches of protocol will be reported by the Chief Investigator in conjunction with the sponsor within seven days to the NHS Research Ethics Committee.

16.5 Data protection and participant confidentiality

Data will be managed in accordance with the study's Data Management Plan agreed by the research team, and with the Sponsor and Information Governance team at the University of Leeds. The research team will also work to the University of Leeds' SOPs that relate to the protection and confidentiality of data.

All investigators, researchers and study site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing, and disclosure of personal information, and will uphold the Act's core principles.

All information collected during the research will be kept strictly confidential. Hard copy documents (such as consent forms) will be stored within a secure (controlled access) room in the Faculty of Medicine and Health, University of Leeds.

Stakeholder panels and interviews will be recorded using an encrypted audio recorder or using a University of Leeds' Microsoft Teams account. Recorded data will be uploaded as soon as possible to a secure area at the University of Leeds, accessible only to the study researchers at the University of Leeds, and then deleted from the recording device (or Teams storage location). These audio recordings will be transcribed for analysis by an external transcription service approved and contracted by the University of Leeds. Returned transcripts will again be stored in the limited access secure area and checked for accuracy by a study researcher. Audio recordings will be retained in the secure area, then deleted once analysis is complete. Transcripts will be pseudonymised: researchers will give all participants study IDs and pseudonyms throughout the transcripts wherever names are used, so they will not be identifiable from transcripts. It is these pseudonymised transcripts that will be used by study researchers at the University of Leeds' for the purposes of analysis.

Any field notes made during interviews or stakeholder / methodologist panel meetings will be anonymous (participants identified only by study ID). They will be transcribed by the researcher for secure storage at the University of Leeds and paper notes then securely destroyed.

In all cases, data access will be limited to those members of the SMG and study researchers who need access for data management and analysis.

In compliance with the Data Protection Act 2018, researchers will ensure that:

- Consent (or agreement) for all participants taking part in the research is obtained to record personal details including name, address, email address and telephone number. This will be part of the consent process. Personal details will not be recorded or stored alongside any data collected for the study.
- Appropriate storage, restricted access and disposal arrangements for participant personal details (consent forms) and study data is maintained.
- All transcripts from stakeholder discussions and interviews are pseudonymised and include only a study ID number.

At the end of the research, consent forms, including personal data, will be retained for 12 months and then confidentially destroyed. Deidentified data collected for the purposes of the study will be archived securely at the University of Leeds for five years. Arrangements for confidential destruction will then be made.

16.6 Indemnity

The University of Leeds has insurance cover in force, which meets claims arising from death or injury which are brought against the University and where those claims arise from the

University's own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy).

Where activities (e.g. interviews, stakeholder group meetings, PPIE meetings) take place at other non-NHS sites then their public indemnity would apply.

16.7 Access to the final study dataset

Members of the SMG and study researchers who are directly involved in data management and analysis, including the Co-Leads, will have access to the full dataset.

Data arising from the study is owned by the Sponsor organisation, the University of Leeds.

Participants may optionally consent to the use of their anonymised data by other research teams in the UK. A log of those providing such consent will be held securely by the research team. Requests for these data would be reviewed and agreed by the SMG. These data will be available for the duration of the archiving period (5 years) and will then be confidentially destroyed.

17. Equality, Diversity and Inclusion

We will anonymously monitor diversity and inclusion, developing and embedding an equality impact assessment [42] to ensure that our study helps to address health inequities. We will also use the Thermometer and Screening Tool 'for equity' (forequity.uk) to ensure we consider equity at the start of and throughout our study, and we will follow NIHR guidance on making research inclusive. This consideration and monitoring approach will be applied throughout and for each phase of the study. We will develop and agree an EDI policy and plan with our co-applicants, oversight groups and through PPIE at study commencement.

18. Dissemination

18.1 Dissemination plan

We will ensure knowledge generated through our research has societal benefits and influence. Our pathway to impact will be based on the widely used W.K. Kellogg Foundation Logic Model.[43] This recognises what researchers need (INPUTS), what researchers do (ACTIVITIES), the products of research (OUTPUTS), wider awareness and use of products of research in the short-to medium-term (OUTCOMES), and wider changes in society from outputs and outcomes in the longer term (IMPACTS).

Impact will be achieved through wide dissemination to multiple stakeholders (academics, commissioners, providers, lay audiences) of the above outputs which will inform efficient targeting and monitoring of service delivery. Our approach to dissemination is framed by the Knowledge-to-Action framework's [44] multifaceted, multi-dimensional and targeted approach: with the right messages delivered to and by the right people, meeting needs at the right time and in the right place.

We will achieve effective reach through usual publication routes (academic and lay), but also via in-person and online regional and national events. In designing our activities, we will consider the context and best methods of communicating our findings to tailor knowledge exchange to our varied audiences, so maximising impact and subsequent uptake or influence of our findings on practice and user experience. Our varied co-applicant team will be attuned to pathways to impact throughout the study because of their vested interest in the delivery of policy and practice change. We have a wide range of non-academic co-applicants - commissioners, providers, PPIE and National Care Forum - all of whom are engaged in this study primarily because they want to see change. They exist within separate but interconnected national networks (including regional ICBs), so providing comprehensive pathways for dissemination activities to maximise knowledge exchange.

Dissemination activities will include, but are not limited to:

a) a lay summary and infographic for dissemination to care users, families and the wider community (co-produced with our PPIE colleagues and groups);
b) a short video explaining study findings which will be made available via co-applicants' websites, and more widely - for example, via Social Care Institute for Excellence, Skills for Care, Queens Nursing Institute - to maximise dissemination;
c) presentations at conferences such as the National Children and Adult Social Care Conference (NCASC), Care England events, National Care Forum and the Home Care Association events, Integrated Care conferences;
d) publications in academic, policy and professional journals including, for integrated models of home care: our evidence synthesis (published as soon as this is complete); evaluation of their organisation and delivery; a discussion paper on our approach, including methodological insights for future larger scale evaluations.

Importantly, we will develop a national network of stakeholders (commissioners, provider organisations, home care workers, care users and methodologists) who will each bring varied networks for knowledge exchange activities. The establishment of these stakeholder panels (or groups) confers important impact by providing a novel and enduring platform for ongoing expert consultation, idea generation, and dissemination.

Dissemination to participants

We will set up a study website, which will be regularly updated to include study information, progress updates and findings. The website will be publicised to study participants at the beginning of their participation (as part of the information giving process) and throughout via regular communications from the research team to enable them to keep abreast of progress.

At the end of the study we will produce an accessible written and illustrated summary of our findings which will be distributed to all study participants - those involved in the panels and participants in the case studies. This will be available online, with paper or email copies also sent to participants (in line with their communication preferences, provided at the start of their involvement in the study). We will also make the video of our study findings (see previous section) available to participants via our website.

18.2 Authorship eligibility guidelines

Authorship and acknowledgement

The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the study, through authorship and by contribution. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on:

- substantial contributions to the conception and design of the work; or acquisition, analysis or interpretation of data for the work; AND
- drafting the article or revising it critically for important intellectual content; AND
- final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Full details of authorship and contributorship requirements which will be upheld for this study can be found at: http://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship.

Study publications

In line with these recommendations the Co-Leads, Co-applicants and research staff involved in implementing project procedures will be named as authors in publications arising directly from the protocol (subject to their meeting the above criteria), and an appropriate first author agreed through discussion amongst the Study Management Group. In addition, all collaborators will be listed as contributors for the main publication, giving details of their roles in planning, conducting and reporting the findings of the study.

Publications arising from the study but not part of the study

In normal circumstances other members of the study team would not be named as contributors. The study team must agree all proposals for publications using data arising from the study. A writing team will be established with a designated first author. To ensure that all major contributors to the study have the opportunity to become named authors on publications arising from the study, lead writers should circulate the first complete draft electronically to all of them.

Acknowledgement

The study team should be acknowledged in all publications, as should the NIHR. Other key individuals will be included as authors or contributors as appropriate and at the discretion of the study team. Contributors will be designated as such in line with ICMJE guidance. Any disputes relating to authorship will be resolved by the Study Steering Group (SSG).

The Chair and Independent members of the SSG will be acknowledged but will not qualify for full authorship in order to maintain their independence.

Relevant NIHR Research Delivery Networks' support should be acknowledged appropriately in study publications.

Publication Plan

The SMG will draft and the SSG will agree a publication plan. This plan will be monitored by both groups throughout the lifetime of the study.

Processes for the drafting, review and submission of abstracts and manuscripts

The agreed first author of abstracts is responsible for circulating these to the other members of the study team (and any other agreed authors) for review at least 15 days prior to the deadline for submission.

The agreed first author of manuscripts is responsible for ensuring:

- timely circulation of all drafts to all co-authors during manuscript development and prior to submission,
- timely (and appropriate) circulation of reviewers' comments to all co-authors,
- incorporation of comments into subsequent drafts.

The first author is responsible for submission of the publication and must keep the project team and all authors informed of the abstract's or manuscript's status. The SSG will be kept informed of rejections and publications at the SSG meetings. After the end of the project the first author will keep the study team, co-authors, SSG members and Sponsor informed of successful publications.

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