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Safety and autonomy for everyone at Home. Understanding safety, risks and harm-benefit balances arising from home-based care.

Submission date
01/09/2025

Recruitment status
Recruiting

Registration date
04/09/2025

Overall study status
Ongoing

Last Edited
02/09/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at how to make care provided in people's homes safer. While home-based care is important, we don't yet fully understand what "good" care looks like or how to make sure it's safe. The research team wants to learn more about the risks and benefits of care at home, and how to improve it. They'll do this by reviewing existing research, looking at safety reports, and speaking with both professionals and people who receive care.

Who can participate?
The study is inviting two main groups to take part:
-Professionals involved in planning, managing, or delivering home-based care (such as care workers, managers, and organisations).
-People who receive care at home, their family members, and unpaid or paid carers. This includes people who used to receive care at home but now live in care homes.

What does the study involve?
Participants will be asked to take part in either a focus group or an interview:
-Professionals may join a one-hour focus group or a one-on-one interview.
-People receiving care, their families, or carers will be invited to take part in an interview to share their experiences and views.

What are the possible benefits and risks of participating?
Taking part could help improve the safety of home-based care for others in the future. There are no expected risks, but some conversations may touch on sensitive or emotional topics. The research team will handle these discussions with care and respect.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
March 2025 to February 2027.

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Joy McFadzean, SAFEATHOME@Cardiff.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
358127

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR 161525

Study information

Scientific Title
SAFE@HOME: Safety and Autonomy For Everyone At home. Understanding safety, risks and harm-benefit balances arising from home-based care

Acronym
SAFE@HOME

Study objectives
To understand safety, risks and harm-benefit balances arising from home-based care

Ethics approval required
Ethics approval required

Ethics approval(s)
1. submitted 11/08/2025, Wales REC Research Ethics Committee (REC) 7 (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922941107; Wales.REC7@wales.nhs.uk), ref: 25/WA/0256

2. approved 08/08/2025, Cardiff University School of Medicine Research Ethics Committee (Cardiff University, Heath Park, Cardiff, CF14 4YS, United Kingdom; -; Medic_REC@Cardiff.ac.uk), ref: 25/38

Study design
Mixed- methods including observational (focus groups and interviews) a Realist synthesis of the literature and a descriptive analysis of safety notifications

Primary study design
Observational

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Care received at home, focusing on older adults (>60 years old).

Interventions
This is an observational study, which will carry out a realist synthesis of the existing literature to understand safety within a home-based care context, analyse up to 6000 safety notifications from social care, and carry out focus groups and interviews with participants.

Intervention Type
Mixed

Primary outcome(s)
1. Concepts and constructs used to define safe home-based care are measured using realist synthesis of published literature
2. Characteristics of safety incidents in home-based care are measured using analysis of up to 6000 safety notifications from social care data sources
3. Professional stakeholder views on enablers and constraints to safe home-based care are measured using qualitative focus groups and interviews
4. Organisational factors influencing safe outcomes in home-based care are measured using qualitative focus groups and interviews with care providers and related organisations
5. Experiences and safety concerns of care recipients and their families/informal caregivers are measured using qualitative interviews
6. Multivoiced conceptualisation of safety in home-based care is developed using realist methodology combining synthesis of literature, quantitative summaries of safety notifications, and qualitative data from interviews and focus groups
7. Additional stakeholder perspectives on what matters to people receiving care will be collected at three stakeholder events

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
28/02/2027

Eligibility

Key inclusion criteria
Work Package 2b (focus groups and interviews with professional stakeholders):
1. Adults (over the age of 18 years)
2. Stakeholders responsible for the planning, management or delivery of home-based care from across the four UK nation, plus perspectives from community teams and leaders.
3. Participant is willing and able to give informed consent

Work Package 3 (interviews with people who receive care, carers, theirs families and personal consultees):
1. Participant is willing and able to give informed consent
2. Servicer users over the age of 60 years old, who currently receives home-based care, or used to receive home-based care and now resides within a care home or paid/unpaid carers. This group will also include family members or a 'personal consultee' who can discuss home-based care in lieu of people who receive home-based care but do not have the capacity to consent to participate.
3. Reside within Wales

Participant type(s)
Health professional, Carer, Employee, Service user, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
Work Package 2b (professional stakeholders and interviews)
1. If participants already sit within our oversight groups (e.g., Steering committee or Research Management group)
2. If they cannot give informed consent to participate

Work Package 3 (interviews with service users/families/personal consultees or unpaid/paid carers):
1. If they cannot give informed consent to participate within the study

Date of first enrolment
01/10/2025

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Cardiff University
Park PLACE
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CF10 3AT

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised interview transcripts generated during the current study will be stored within a non-publicly available repository via Cardiff University. Details to be shared at a later date and subject to participant consent.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes